

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

**PHILIP MORRIS PRODUCTS S.A., PHILIP MOR-
RIS USA, INC., ALTRIA CLIENT SERVICES LLC,**
Appellants

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

**RAI STRATEGIC HOLDINGS, INC., R.J. REYN-
OLDS VAPOR COMPANY, R.J. REYNOLDS TO-
BACCO COMPANY,**
Intervenors

2022-1227

Appeal from the United States International Trade
Commission in Investigation No. 337-TA-1199.

Decided: March 31, 2023

GREGORY G. GARRE, Latham & Watkins LLP, Washing-
ton, DC, argued for appellants. Also represented by GA-
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LYNDE FAUN HERZBACH, Office of the General Counsel,
United States International Trade Commission,

Washington, DC, argued for appellee. Also represented by WAYNE W. HERRINGTON, SIDNEY A. ROSENZWEIG.

GREGORY A. CASTANIAS, Jones Day, Washington, DC, argued for intervenors. Also represented by AMELIA A. DEGORY; SUSAN M. GERBER, DAVID MICHAEL MAIORANA, RYAN BOYD MCCRUM, Cleveland, OH; ANTHONY INSOGNA, San Diego, CA.

Before PROST, REYNA, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company (collectively “Reynolds”) filed a complaint at the International Trade Commission alleging that respondents Philip Morris Products S.A., Philip Morris USA, Inc., and Altria Client Services LLC (collectively “Philip Morris”) violated Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, through the importation and sale of tobacco products that infringed certain claims of U.S. Patent Nos. 9,901,123 and 9,930,915. After conducting a Section 337 investigation, the Commission barred Philip Morris and its affiliates from importing products infringing the asserted patents. Philip Morris appeals, contending that the Commission failed to “consult with, and seek advice and information from” the Department of Health and Human Services (HHS) as required by Section 337. In addition, Philip Morris challenges the Commission’s determinations on public interest, domestic industry, patent validity, and infringement. For the reasons set forth below, we affirm the Commission’s decision in full.

BACKGROUND

Philip Morris and Reynolds are competing manufacturers of tobacco products including heat-not-burn tobacco products. Their dispute in this case began in April 2020,

when Reynolds filed a complaint with the Commission alleging that the IQOS line of electronic nicotine delivery system products imported and sold by Philip Morris infringed claims 27–30 of the '123 patent and claims 1–3 and 5 of the '915 patent. J.A. 1019, 3658; *see also In the Matter of Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, Final Initial Determination, 2021 WL 2333742, at *13 (May 14, 2021) (*FID*) (identifying Philip Morris's "IQOS 2.4, IQOS 3, and IQOS 3.1 Duo systems" and "HeatSticks" as the accused products).

The patents-in-suit are directed to electrically powered "smoking articles" that heat tobacco instead of burning it, providing an inhalable substance in vapor or aerosol form. '123 patent col. 4 ll. 42–65; '915 patent col. 2 ll. 12–22.

Claim 27 is representative of the asserted claims of the '123 patent:

27. An electrically-powered, aerosol-generating smoking article comprising:

an electrical power source in the form of a battery within a tubular outer housing having a mouth-end and an end distal to the mouth-end;

at least one electrical resistance heater powered by said electrical power source, wherein at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the elongated portion of the resistance heating element positioned proximal to the center of the outer housing;

a controller within the tubular outer housing and adapted for regulating current flow through the electrical resistance heater; and

a cigarette-type device removably engaged with the mouth-end of the tubular outer housing and comprising a tobacco segment circumscribed by a

wrapping material and comprising a tobacco material and an aerosol-forming material, wherein the elongated portion of the resistance heating element extends into the tobacco segment when the cigarette-type device is engaged with the mouth-end of the outer housing, such that during draw, aerosol-forming material can be volatilized to produce a visible mainstream aerosol incorporating tobacco components or tobacco-derived components that can be drawn into the mouth of the user of the smoking article.

'123 patent col. 34 ll. 31–58.

Claim 1 is representative of the asserted claims of the '915 patent:

1. A reusable control unit for use with a disposable smoking article, the reusable control unit comprising a control housing including:

a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source that includes a projection extending outwardly therefrom and that includes a component that forms an electrical connection with electrical contacts on a separate electrical heating member; and

a control unit section that houses a power source, a switching component that actuates flow of electrical current from the electrical energy source to the electrical heating member, and a flow regulating component that regulates a previously initiated current flow from the electrical energy source to the electrical heating member, wherein the component that forms an electrical connection with the electrical contacts is located on the projection.

'915 patent col. 42 ll. 22–39.

Reynolds also asserted in the complaint that its VUSE line of vapor nicotine products established both the economic and technical prongs of domestic industry. J.A. 1047–48; *see also FID*, 2021 WL 2333742, at *13 (noting Reynolds’ assertion that “VUSE Solo G1 and G2 devices are articles protected by the ’915 patent . . . and that the VUSE Vibe devices are articles [] protected by [the] ’123 patent.”).

In response to Reynolds’ complaint, the Commission instituted an investigation and ordered the presiding administrative law judge (ALJ) to “provide the Commission with findings of fact and a recommended determination on [the] issue” of public interest. J.A. 3432–33 (85 Fed. Reg. 29,482–83 (May 15, 2020)).

The ALJ conducted the investigation over the course of the next year. After reviewing briefing from both parties and holding a claim construction hearing, the ALJ issued an order construing certain disputed claim terms. J.A. 10904–36. In view of the construed claims, the ALJ granted summary determination that there existed an economic domestic industry for the ’915 patent.¹ J.A. 12761–62. And, following a six-day evidentiary hearing, Philip Morris stipulated that Reynolds had also established economic domestic industry for the ’123 patent. *FID*, 2021 WL 2333742, at *53. The ALJ issued a final initial determination (FID) concluding that: (1) Reynolds had shown that Philip Morris infringed the asserted claims, and that Philip Morris had not shown the asserted claims to be invalid, *id.* at *58; (2) Reynolds had established the existence of a domestic industry with respect to both of the asserted patents, *id.*; and (3) “the public interest evidence of record [did] not weigh against entry of a

¹ It is undisputed that Reynolds satisfied the technical prong of the domestic industry requirement with respect to the asserted patents.

remedy,” *id.* at *73. The ALJ also recommended that the Commission issue a limited exclusion order, *id.* at *74, but not cease and desist orders, *id.* at *76. Philip Morris petitioned the full Commission for review of the FID.

The Commission decided to review the FID in part. *In the Matter of Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, Commission Opinion, 2021 WL 4947427 (Oct. 19, 2021) (*Commission Op.*). Among other things, it affirmed the ALJ’s determination of nonobviousness of the asserted claims of the ’123 patent and the ALJ’s determination that Reynolds satisfied the domestic industry requirement. The Commission concluded that Philip Morris had violated Section 337 and issued cease and desist orders directed to Altria Client Services LLC and Philip Morris USA, Inc., and issued a limited exclusion order banning the importation of infringing products by Philip Morris and its affiliates.

Philip Morris appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(6).

DISCUSSION

Philip Morris raises numerous issues on appeal. First, it asserts that the Commission legally erred by failing to comply with its statutory duty to “consult with[] and seek advice and information from” HHS. Appellants’ Br. 27–28. More specifically, Philip Morris complains that the Commission failed to consult with the Food and Drug Administration (FDA), the HHS agency that exclusively oversees the regulation of tobacco products in the United States. *Id.* Second, Philip Morris argues that the Commission abused its discretion in holding that the public interest does not preclude issuance of remedial orders. *Id.* at 64. Third, Philip Morris challenges the Commission’s finding that a domestic industry exists as being legally erroneous because the products on which Reynolds relies for its assertion of domestic industry had not received FDA approval at the time the complaint was filed. *Id.* at 35.

Philip Morris also raises several patent-specific issues. Philip Morris's fourth argument is that the Commission's conclusion that Philip Morris did not show that the asserted claims of the '123 patent would have been obvious is unsupported by substantial evidence. *Id.* at 38–39. Fifth, Philip Morris asserts that the Commission's conclusion that the accused products infringed the asserted claims of the '915 patent rests on an erroneous claim construction. *Id.* at 48. Sixth and finally, Philip Morris challenges the Commission's finding—that Philip Morris failed to show that the asserted claims of the '915 patent are invalid because the allegedly invalidating product does not qualify as prior art—as unsupported by substantial evidence. *Id.* at 55. We address each issue in turn.

Our court reviews the Commission's decisions under the standards of the Administrative Procedure Act (APA). 19 U.S.C. § 1337(c); 5 U.S.C. § 706(2). We review the Commission's legal determinations, including statutory interpretation, de novo and its factual findings for substantial evidence. *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1343–44 (Fed. Cir. 2010).

Duty to Consult Under Section 337

We begin with Philip Morris's argument that the Commission erred by failing to meet its statutory duty as set forth in Section 337. That statutory duty requires that:

During the course of each investigation under this section, the Commission shall consult with, and seek advice and information from, the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and such other departments and agencies as it considers appropriate.

19 U.S.C. § 1337(b)(2).

According to Philip Morris, the FDA determined that the accused products “help protect, promote, and benefit

public health” when it granted the accused products’ pre-market tobacco product applications (PMTAs) and, later, the modified risk tobacco product applications (MRTPAs). Appellants’ Br. 4–5. Philip Morris argues specifically that the FDA determined (1) in granting the PMTAs, that authorizing the accused products for the U.S. market “is appropriate for the protection of the public health,” J.A. 41199, and (2) in granting the MRTPAs, that the science-based evidence “demonstrates” that the accused products are “appropriate to promote the public health” and “expected to benefit the health of the population as a whole,” J.A. 41391. Therefore, in Philip Morris’s view, the FDA’s grant of the PMTAs and MRTPAs demonstrates that the accused products provide “enormous public health benefits,” Appellants’ Br. 7, and that “[t]he Commission’s decision” to stop importation of those products “deprived consumers of an unparalleled tool to curtail [traditional combustible cigarette] smoking,” *id.* at 12. Thus, Philip Morris argues, had the Commission consulted the FDA, as was its duty, the FDA may have provided “significant information, as well as sound advice,” *id.* at 32, that would have dissuaded the Commission from ultimately issuing cease and desist and limited exclusion orders. Because Philip Morris forfeited this argument, and because in any event the Commission satisfied its duty to “consult with” HHS, we conclude that the Commission committed no error.

A

The Commission found that Philip Morris had forfeited this argument in its opinion denying Philip Morris’s motion to stay the Commission’s limited enforcement and cease and desist orders. J.A. 15054. In particular, the Commission noted that “Philip Morris’s motion to stay” before the Commission “[wa]s the first time that Philip Morris made such an argument before the Commission” or the ALJ. *Id.* The Commission posited that, if Philip Morris had

sought participation from HHS at the ALJ stage, and objected if no such participation occurred—and then again sought participation at the Commission stage—the Commission would have been in a position to determine whether [Philip Morris] had demonstrated the need for further outreach beyond what the Commission provides for in its rules, and exactly what further outreach, if any, might have been conducted.

Appellee’s Br. 34–35; *see also* J.A. 15055 (“[Q]uestions concerning the relationship between coordinate government entities must be raised and preserved” in order for the agency to “address these concerns adequately and in a timely manner.”). The Commission cited 19 C.F.R. § 210.43(b)(2), which provides: “Any issue not raised in a petition for review will be deemed to have been abandoned by the petitioning party and may be disregarded by the Commission in reviewing the initial determination . . . , and any argument not relied on in a petition for review will be deemed to have been abandoned and may be disregarded by the Commission.” J.A. 15056 (quoting 19 C.F.R. § 210.43(b)(2)). On appeal, the Commission argues that it had no opportunity to address Philip Morris’s concerns due to Philip Morris’s own failure to raise the issue. Appellee’s Br. 34–35.

We agree with the Commission. As demonstrated by the procedural history of this case, Philip Morris had numerous opportunities to raise and preserve this issue but failed to do so.

“[F]orfeiture is the failure to make the timely assertion of a right.” *Pavo Sols. LLC v. Kingston Tech. Co.*, 35 F.4th 1367, 1380 (Fed. Cir. 2022) (quoting *United States v. Olano*, 507 U.S. 725, 733 (1993)). We have “regularly stated and applied the important principle that a position not presented in the tribunal under review will not be considered on appeal.” *Id.* (quoting *In re Google Tech.*

Holdings LLC, 980 F.3d 858, 863 (Fed. Cir. 2020)); *see also Singleton v. Wulff*, 428 U.S. 106, 120 (1976) (“It is the general rule . . . that a federal appellate court does not consider an issue not passed upon below.”).

Philip Morris failed to raise this issue before the ALJ. None of Philip Morris’s briefing before the ALJ addressed, or even mentioned, the Commission’s statutory duty to “consult with” HHS or the FDA. In fact, the ALJ directly asked the parties for their “views about [his] authority under 19 U.S.C. [§] 1337(b)(2), which instructs that the Commission may consult with [HHS], and, by implication, the [FDA],” J.A. 21372 (Hearing Tr. 1524:17–1524:21). But counsel for Philip Morris responded that he had “absolutely no objection whatsoever,” J.A. 21383 (Hearing Tr. 1571:03–1571:08), to the ALJ’s authority to “consult with any publicly-available information on the FDA’s web site regarding any of the products that have been discussed during [the] investigation.” J.A. 21372 (Hearing Tr. 1524:22–1524:25). He then stated that he had “nothing [further] to share on that.” J.A. 21384 (Hearing Tr. 1574:18–1574:20). At no point during the hearing did counsel for Philip Morris ask the ALJ to reach out to the FDA or suggest that the ALJ had not properly “consulted with” the FDA.

Philip Morris does not meaningfully dispute that it failed to raise the issue of the Commission’s statutory duty before the ALJ. As evidence of its efforts to “fairly alert” the ALJ to the issue, Philip Morris points only to its counsel’s statement that he had “nothing to share” regarding the Commission’s duty at the evidentiary hearing before the ALJ. Appellants’ Reply Br. 4–5; *see also* J.A. 21384 (Hearing Tr. 1574:18–1574:20). Instead, Philip Morris asserts that “notice to the Commission regarding the ‘consult with’ issue was unnecessary prior to the” Commission’s final determination. Appellants’ Reply Br. 4. We disagree.

This court recognizes that failure to raise an issue before an ALJ during an investigation constitutes forfeiture of that issue. *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1352 (Fed. Cir. 2008) (determining that an argument not set forth “until after the [ALJ] had made an initial determination” was “untimely and could properly be rejected on that ground alone”). We have also recognized that a party’s failure to make a specific argument in its petition for review of the FID before the Commission constitutes forfeiture. *Guangdong Alison Hi-Tech Co. v. Int’l Trade Comm’n*, 936 F.3d 1353, 1362 (Fed. Cir. 2019) (citing 19 C.F.R. § 210.43(b)(2) and *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d 1354, 1362–63 (Fed. Cir. 1999)). Here, not only did Philip Morris fail to raise this issue before the ALJ, but it also failed to raise it before the Commission.² Two weeks after the ALJ issued the FID, Philip Morris filed its petition for review. The petition made no mention of the Commission’s alleged failure to “consult with” the FDA.

Throughout August 2021, both Philip Morris and Reynolds filed several rounds of briefing on the public interest issue. In its reply brief, Philip Morris stated, for the first time in the course of the investigation, that “[t]he Commission *may find it enlightening* to discuss these matters directly with various party and third-party experts in this field and *perhaps even representatives of FDA itself*.” J.A. 14780–81 (emphases added). The Commission argues

² Philip Morris argues that it was not required to raise the issue before the ALJ because the statutory duty to consult lies ultimately with the Commission, not the ALJ. See Appellants’ Reply Br. 3. Here, we need not decide whether Philip Morris needed to raise its duty-to-consult argument before the ALJ in order to avoid forfeiture because its failure to raise the argument before the Commission suffices to conclude that Philip Morris forfeited it.

on appeal, and we agree, that this “vague suggestion is nowhere near a specific request for additional Commission action, nor an assertion of legal error.” Appellee’s Br. 33. Phillip Morris did not assert that the FDA’s participation was mandatory nor that the FDA’s lack of participation was erroneous.

Philip Morris finally raised the issue in its motion to stay the Commission’s remedial orders, which it filed on December 3, 2021, two days after filing its notice of appeal before this court. There, relying on dictionary definitions for the ordinary meaning of “consult,” J.A. 14939–48, Philip Morris argued that it was entitled to a stay because “the Commission failed to ‘consult with’ [HHS] as required under [S]ection 337,” J.A. 15053.

Until its motion to stay the Commission’s final exclusion order, Philip Morris failed to do more than suggest that the Commission “may find” value in discussing the public interest issue with the FDA. J.A. 14780. Philip Morris certainly did not raise, develop, or preserve the issue in any of its briefing prior to the motion to stay. We agree with the Commission that Philip Morris’s argument about the Commission’s duty to consult came far too late and, thus, we conclude that Philip Morris forfeited the argument.

B

Even in the absence of forfeiture, we conclude that, in this case, the Commission satisfied its duty to “consult with” HHS and the FDA.

When the Commission instituted the investigation in May 2020, it published a Notice of Investigation in the Federal Register, J.A. 3432–33, and individually served letters enclosing the Notice of Investigation to representatives of the Department of Justice, the U.S. Bureau of Customs and Border Protection, the Federal Trade Commission, and HHS. J.A. 43501. The letter served on HHS was delivered

to the employee designated by HHS to monitor Section 337 investigations. J.A. 43515. The letter stated that non-confidential pleadings could be obtained upon request and that any questions should be directed to the specific Commission Investigative Attorney assigned to the case. *Id.* The appended notice of investigation in turn stated that: (1) the Commission had ordered an investigation concerning whether certain imported “electric tobacco heating device systems and the associated tobacco sticks sold for use with the device systems” infringed certain claims of particular patents; (2) the complainant requested that the Commission “issue a limited exclusion order and cease and desist orders”; and (3) the presiding ALJ would “take evidence or other information and hear arguments from the parties or other interested persons with respect to the public interest in this investigation.” J.A. 3432–33.

Although the FDA did not respond to the initial letter with evidence or other information, the Commission had input from the FDA on the public interest issue. Indeed, the ALJ explained that he reached his conclusion on public interest “based on scientifically reliable information from expert and independent government authorities, *including the FDA and the U.S. Surgeon General.*” *FID*, 2021 WL 2333742, at *60 (emphasis added). The ALJ identified the exhibits of record bearing on the public interest issue, including over 30 FDA documents, such as the PMTA and MRPTA documents. *Id.* at *59.

In August 2021, after the ALJ issued the FID, the Commission published an additional notice in the Federal Register soliciting input from interested government agencies. J.A. 13973–75 (86 Fed. Reg. 41,509–11 (Aug. 2, 2021)). The notice identified the specific parties and patent issues under consideration, indicated that the Commission was considering an exclusion order, and encouraged “interested government agencies . . . to file written submissions on the issues of remedy, the public interest, and bonding.” J.A. 13974. The notice emphasized that “such submissions

should address the recommended determination by the ALJ on remedy.” *Id.*

Philip Morris argues that even if the notice in the Federal Register “could be deemed adequate *notice*, there is a difference between *notice* and actual consultation.” Appellants’ Br. 28. Philip Morris argues that the Commission was required to take “*joint* action” and participate in “an exchange of information” with HHS. *Id.* To this end, Philip Morris urges us to adopt the Ninth Circuit’s view that the statutory language “consult with” requires something more than providing interested government agencies with notice and an opportunity to respond. *Id.* In particular, Philip Morris stresses that consultation, as recited in the statute, requires “hav[ing] discussions or confer[ring] with (someone), typically *before* undertaking a course of action.” *Id.* at 29–30 (quoting *New Oxford Am. Dictionary* (3d ed. 2010) and citing *Cal. Wilderness Coal. v. U.S. Dep’t of Energy*, 631 F.3d 1072, 1087 (9th Cir. 2011)).

We need not resolve whether the directive to “consult with” HHS within this particular statutory framework requires more than notice in the Federal Register and an opportunity to comment. Even if we were to adopt Philip Morris’s statutory construction, we conclude that, in this case, the record demonstrates that the Commission satisfied its duty.

Particularly persuasive is the fact that the Commission asked interested government agencies, including the FDA, to provide written submissions on the public interest factor and address the ALJ’s FID well before the Commission issued its exclusion order. J.A. 13974. This invitation allowed agencies to respond directly to the ALJ’s public interest analysis for the Commission’s consideration and also comment on the appropriate remedy. We do not conclude that the Commission failed to perform its duty simply because the FDA chose not to submit any additional information. The Commission cannot force the FDA to engage.

We are also persuaded by the fact that Philip Morris never articulated what, in its view, the Commission had to do to comply with § 1337(b)(2). Throughout the course of this investigation, the Commission followed its longstanding typical process for complying with § 1337(b)(2)'s mandate to “consult with” other federal agencies.³ Only afterward, in its motion to stay the Commission's remedial orders, did Philip Morris complain that the Commission did not properly “consult with” the FDA. Philip Morris never asked the ALJ or the Commission to depart from its usual process during the investigation. For example, Philip Morris never asked the Commission to invite briefing from the FDA or seek other submissions from the FDA through a different procedure. Nor did Philip Morris specify what it expected the FDA to provide beyond the upwards of 30 FDA documents that the ALJ already considered in analyzing the public interest factor. *See FID*, 2021 WL 2333742, at *59. Even on appeal, Philip Morris does not articulate exactly what the Commission should have done to comply with § 1337(b)(2). As the Commission noted, the APA “generally limits the ALJ's and the Commission's authority to engage in *ex parte* communications relevant to the merits of the investigation,” and Philip Morris never “identified a specific consultation with [HHS] that was required . . . or what form that coordination must take.” J.A. 15055 (citing 5 U.S.C. § 557(d)(1)). Because Philip Morris has neither developed nor supported its

³ The Commission's process for complying with § 1337(b)(2) had been in place for nearly 30 years. It was developed in 1994, when the Commission's Inspector General investigated the Commission's practices as part of an audit to “increase the economy and efficiency of the process for conducting Section 337 investigations.” J.A. 43516 (cleaned up); *see also* J.A. 43523–24.

argument, we reject its view that the Commission did not comply with § 1337(b)(2) in this case.

Public Interest

Next, we address Philip Morris's assertion that the Commission abused its discretion by granting injunctive relief notwithstanding the evidence Philip Morris provided on public interest. According to Philip Morris, the FDA is the only agency competent to oversee tobacco product regulation, and the Commission should have deferred to its expert findings. Specifically, Philip Morris contends that because the FDA granted the IQO products' PMTAs—issuing marketing orders available for products “appropriate for the protection of public health”—and MRTPAs—issuing modified risk orders allowing a product to be marketed as “reduced risk” or “reduced exposure”—the Commission should have denied injunctive relief. Appellants' Br. 9, 65.

“Congress intended injunctive relief to be the normal remedy for a Section 337 violation” *Spansion*, 629 F.3d at 1358. Indeed, § 1337(d)(1) provides that if the Commission determines “that there is violation of this section, it *shall* direct that the articles concerned . . . be excluded . . . unless, after considering [public interest,] it finds that such articles should not be excluded” (emphasis added). In deciding this issue, the Commission must consider the effect of the remedy on four statutory public interest factors: (1) public health and welfare, (2) competitive conditions in the U.S. economy, (3) the production of like articles in the United States, and (4) U.S. consumers. 19 U.S.C. § 1337(d)(1), (f)(1). “[T]he Commission has broad discretion in selecting the form, scope and extent of the remedy, and judicial review of its choice of remedy necessarily is limited.” *Viscofan, S.A. v. Int'l Trade Comm'n*, 787 F.2d 544, 548 (Fed. Cir. 1986). Stated another way, because the Commission is “the expert body to determine what remedy is necessary,” it has “wide latitude for judgment and the courts will not interfere except where

the remedy selected has no reasonable relation to the unlawful practices found to exist.” *Id.* (quoting *Jacob Siegel Co. v. Fed. Trade Comm’n*, 327 U.S. 608, 611–13 (1946)). This court therefore must affirm the Commission’s choice of remedy unless the action is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Spansion*, 629 F.3d at 1358.

For its part, the Commission asserts that record evidence, including “numerous FDA statements and documents regarding [the] IQOS” products, support the conclusion that “excluding [the] IQOS [products] will not adversely impact the public health and welfare,” and thus the Commission has acted within its “wide discretion to evaluate the public health and welfare . . . and to grant appropriate relief.” Appellee’s Br. 51–53. Reynolds notes that the Commission has determined that the public interest outweighed the need for injunctive relief in protecting intellectual property rights in only three prior investigations. In each case, the Commission determined that an exclusion order would have deprived the public of “products necessary for some important health or welfare need: energy efficient automobiles, basic scientific research, or hospital equipment.” *Spansion*, 629 F.3d at 1359–60. Reynolds asserts that this is not such a case.

We hold that the Commission provided a sufficient basis for issuance of an exclusion order and that its actions were not arbitrary, capricious, an abuse of its discretion, or otherwise not in accordance with law. The ALJ and the Commission properly considered and weighed the public interest evidence put forth by the parties, including expert testimony, scientific evidence, and, importantly, over 30 FDA documents regarding the IQOS products, including the PMTA and MRTPA documents on which Philip Morris relies. The Commission reasonably agreed with the ALJ that, notwithstanding the granted PMTAs and MRTPAs, numerous FDA documents in the record demonstrate that exclusion of the IQOS products will not adversely impact

the public health and welfare, particularly given the existence of other non-tobacco therapies that reduce tobacco use and consideration of the population as a whole. For example, the FDA stated that “[w]hile [the grant of the PMTA] permits the tobacco products to be sold in the U.S., it does not mean these products are safe or ‘FDA approved.’” *Commission Op.*, 2021 WL 4947427, at *40 (quoting J.A. 41199). The FDA also stated: “All tobacco products are potentially harmful and addictive and those who do not use tobacco products should continue not to.” *Id.* (quoting J.A. 41199). It further stated that “the use of the IQOS system clearly still exposes users to HPHCs [(harmful and potentially harmful constituents)] and would be expected to cause harm.” *Id.* at *41 (quoting J.A. 41422). The FDA also stated that:

[Philip Morris] **has not demonstrated** that, as actually used by consumers, the products sold or distributed with the proposed modified risk information will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as whole.

Id. at *40 (quoting J.A. 41386) (emphasis in original).

Because the Commission’s decision rests on a reasonable review of the public interest evidence, we conclude that the Commission did not abuse its discretion in its selection of the form, scope, and extent of the remedy.

Domestic Industry

We turn next to Philip Morris’s assertion that the Commission legally erred in finding a domestic industry based on Reynolds’ investments in activities relating to its VUSE Vibe and Solo products, which had not yet received FDA authorization at the time of the complaint. According to Philip Morris, because Reynolds’ products had not received

FDA authorization, they were illegal and could not form the basis for a domestic industry. Appellants' Br. 5.

The domestic industry requirement of Section 337, 19 U.S.C. § 1337(a)(2) and (a)(3), includes an economic prong, which “requires that there be an industry in the United States,” and a technical prong, which “requires that the industry relate to articles protected by the patent,” both of which must be met. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 707 F.3d 1295, 1298 (Fed. Cir. 2013). Philip Morris does not dispute that Reynolds satisfied the technical prong. We are instead presented with the singular question of whether the economic prong of the domestic industry analysis excludes products that have not received regulatory authorization as of the filing of the complaint.⁴

To resolve this issue, we must interpret the statute. Statutory interpretation presents a question of law, which we review de novo. 5 U.S.C. § 706. We start with the language of the statute. Section 1337(a)(2)–(3) outlines the domestic industry requirement:

(2) Subparagraphs (B), (C), (D), and (E) of paragraph (1) apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, mask work, or design concerned, exists or is in the process of being established.

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the

⁴ We note that although the FDA granted Reynolds' PMTAs after the Commission issued its opinion, the filing date of the complaint is the “relevant date at which to determine if the domestic industry requirement” is satisfied. *Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013).

articles protected by the patent, copyright, trademark, mask work, or design concerned—

(A) significant investment in plant and equipment;

(B) significant employment of labor or capital; or

(C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(2)–(3).

Nothing in the plain language of the statute requires that the protected articles have regulatory approval. As the Commission aptly explained, “Philip Morris points to no authority that FDA approval is a condition precedent to the establishment of a domestic industry, nor is the Commission aware of any such authority.” J.A. 15061. Even if the articles could not be sold commercially in the United States, the parties do not dispute that sufficient investment in labor and capital had been expended. In addition, the record demonstrates that, at the time of the complaint, Reynolds’ VUSE products were being sold in the United States with knowledge of the FDA.

Philip Morris responds that the FDA’s so-called Deeming Rule, enacted on August 8, 2016, applied the Family Smoking Prevention and Tobacco Control Act (TCA) to “new tobacco products,” including Electronic Nicotine Delivery Systems, rendering non-approved products illegal and unusable in a domestic industry analysis. *See* Appellants’ Reply Br. 7; *Deeming Tobacco Products to be Subject to the Federal Food, Drug and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, 81 Fed. Reg. 28,974, 29,975–76 (May 10, 2016) (“Deeming Rule”); *see also* 21 U.S.C. § 387j. The Deeming Rule required electronic nicotine products to receive premarket tobacco authorization, and retroactively applied to products already on the market. Due to the new requirement that manufacturers comply with the TCA by filing for

PMTA for products already being sold in the United States, the Deeming Rule included staggered compliance periods, essentially grace periods, for existing products to comply with certain provisions of the TCA. 81 Fed. Reg. at 29,010 (May 10, 2016). During these periods, which were extended multiple times, the FDA announced that it did not “intend to take enforcement action against products remaining on the market for failure to have a premarket authorization order.” *Id.*

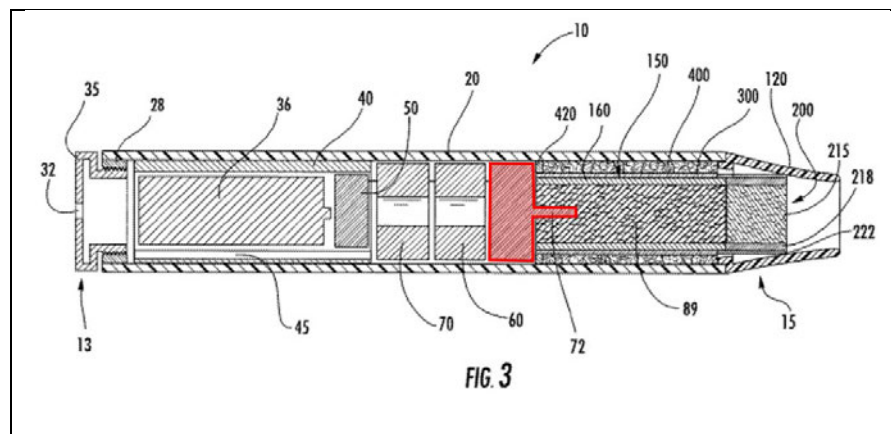
At the time it filed the complaint on April 9, 2020, Reynolds’ VUSE products had been on the market for some time, and the FDA’s “May 12, 2020 deadline for PMTA[s]” for electronic nicotine products had not yet passed. *See* J.A. 43278. Thus, Reynolds’ VUSE products still fell within the grace period during which a granted PMTA was not required for the products to remain on the market. Additionally, Reynolds had already applied for, and was awaiting, approval of a PMTA for its VUSE Solo product, and less than a week after filing the complaint filed a PMTA for its VUSE Vibe product. J.A. 43278–79. That the regulatory process, for which there was an explicit grace period, was not complete at the time that Reynolds filed the complaint does not mean the domestic industry products were “illegal,” as Philip Morris insists.

On this record, we conclude that Philip Morris’s argument—that Reynolds’ products that had not received FDA authorization are precluded from consideration by Section 337 for purposes of its domestic industry requirement—has no merit. We therefore affirm the Commission’s final determination that Reynolds established the existence of a domestic industry.

Obviousness of the ’123 Patent Claims

Turning to the patent-specific issues, we begin with Philip Morris’s challenge to the Commission’s conclusion that Philip Morris failed to show that claims 27–30 of the ’123 patent would have been obvious.

The asserted claims cover an electrically powered smoking article having a “tubular outer housing,” an electrical power source, “at least one electrical resistance heater” with a portion “positioned proximal to the center of the outer housing” of the smoking article, a controller for regulating current flow through the heater, and a disposable tobacco stick that can be inserted into the outer housing. ’123 patent col. 34 ll. 31–58. An exemplary smoking article (10) having an electrical resistance heating element with an elongated portion (72) positioned central to the housing is shown in Figure 3 of the ’123 patent and depicted below.

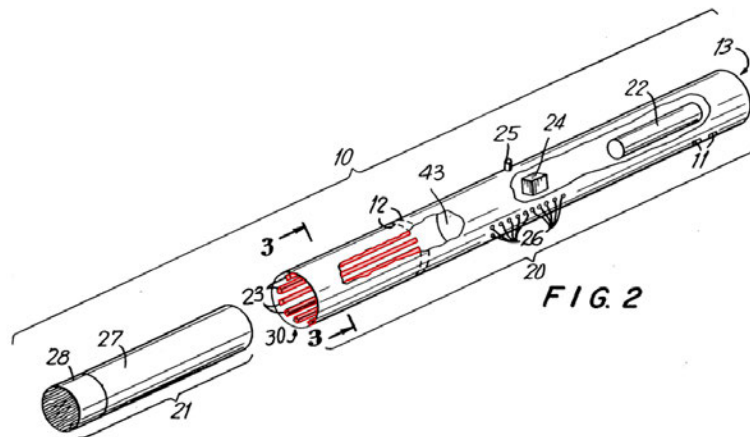


Id. Fig. 3 (electrical resistance heating element indicated in red).

The ultimate question of obviousness is a legal question that we review *de novo* with underlying factual findings that we review for substantial evidence. *Fleming v. Cirrus Design Corp.*, 28 F.4th 1214, 1221 (Fed. Cir. 2022). Under the substantial evidence standard, this court “must affirm a Commission determination if it is reasonable and supported by the record as a whole, even if some evidence detracts from the Commission’s conclusion.” *Spansion*, 629 F.3d at 1344 (quoting *Nippon Steel Corp. v. United States*, 458 F.3d 1345, 1352 (Fed. Cir. 2006)); see also 5 U.S.C. § 706(2). “[T]he possibility of drawing two

inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence." *Consolo v. Fed. Mar. Comm'n*, 383 U.S. 607, 620 (1966).

Before the ALJ, Philip Morris argued that claims 27–30 of the '123 patent would have been obvious over U.S. Patent No. 5,249,586 ("Morgan") in view of the general knowledge and creativity of a person having ordinary skill in the art. *FID*, 2021 WL 2333742, at *27. Morgan describes a tobacco heating system, shown below, having multiple heating elements (23) "preferably distributed substantially uniformly around the circumference of [a] cavity" within the smoking article that houses a disposable tobacco stick. Morgan col. 5 ll. 18–25.



Id. Fig. 2 (heating elements indicated in red).

Morgan discloses two embodiments in which the heating elements heat the outside of the disposable tobacco stick and one embodiment in which the heating elements "actually pierce and extend into [the] disposable" tobacco stick "to provide the desired intimate thermal contact." *Id.* at col. 6 ll. 46–62. In all of the embodiments, the heating elements are arranged circumferentially and "spaced apart sufficiently" to heat non-overlapping regions of the

disposable tobacco stick. *Id.* at col. 5 ll. 18–25. Morgan explains that this arrangement advantageously allows the heating elements to heat discrete regions of a disposable tobacco stick in sequence. *Id.* at col. 5 ll. 61–65; *see also id.* at col. 3 ll. 9–21. In particular, Morgan emphasizes that this sequential heating provided by the circumferentially located heaters avoids reheating portions of tobacco stick, which can lead to “the production of undesired compounds and off tastes.” *Id.* at col. 5 ll. 18–25.

Morgan also recognizes that placing the heating elements around the circumference of the cavity can result in an “inefficient use of tobacco” when using disposable tobacco sticks filled with tobacco product because that filling “provides bulk and compressibility but is never heated to deliver flavor to the smoker.” *Id.* at col. 6 l. 63–col. 7 l. 10. To address this inefficiency, Morgan proposes using an alternative disposable tobacco stick that does not contain tobacco filling and instead is a non-tobacco “fiber bundle” wrapped in foil and coated in a tobacco-flavored “slurry.” *Id.*

The parties agreed that only one limitation of representative claim 27 is missing from Morgan. *FID*, 2021 WL 2333742, at *27. That limitation recites:

at least one electrical resistance heater powered by said electrical power source, wherein at least a portion of the resistance heating element is elongated and extending downstream toward the mouth-end of the outer housing, the *elongated portion of the resistance heating element positioned proximal to the center of the outer housing*

’123 patent col. 34 ll. 36–42 (emphasis added).

Philip Morris argued before the ALJ that the claimed central heating element would have been obvious in view of Morgan—which discloses only multiple circumferentially placed heaters, not central heaters—in combination

with the skilled artisan's knowledge that central heating elements existed at the time of the invention.

Specifically, Philip Morris asserted that the state of the prior art as of the earliest priority date of the '123 patent "taught not just centered heaters, but also their advantages, including simplicity, reliability, reduced cost, and thermal efficiency." *FID*, 2021 WL 2333742, at *27. Relying on the testimony of its technical expert, Stewart Fox, Philip Morris asserted that "it is undisputed that centered heaters were well known before the priority date of the '123 patent." *Id.*; *see also* J.A. 21199 (Hearing Tr. 1075:03–1076:01) (testifying that centered heaters were "not new . . . at the time of Morgan, centered heaters were disclosed"). According to Mr. Fox, one of ordinary skill would have known that central tobacco heaters provided various advantages over "a number of smaller individual heaters positioned inside . . . the cigarette." J.A. 21199 (Hearing Tr. 1074:06–1074:19). For example, Mr. Fox testified that a single centered heater uses fewer electrical connections than multiple individual heaters and, thus, would likely be more reliable. J.A. 21199 (Hearing Tr. 1074:02–1074:21). Additionally, he opined that a single centered heater conducts heat "in a symmetrical manner," which is the "most efficient" method for heating tobacco in certain applications. *Id.* Mr. Fox further agreed that a skilled artisan would readily understand how to modify Morgan to implement a single centered heater instead of using the multiple circumferential heaters: "[A]ll you do is take out this array of heaters and put in one central heater in the same place." J.A. 21200 (Hearing Tr. 1078:07–1078:21).

In addition to this testimony, Philip Morris pointed to the '123 patent specification's statement that "[s]election of the power source and resistance heating elements can be a matter of design choice." '123 patent col. 29 ll. 32–50; *see also FID*, 2021 WL 2333742, at *29. In Philip Morris's view, this statement established that there was a narrow

list of design choices that were known and available to the skilled artisan. *FID*, 2021 WL 2333742, at *29. Philip Morris thus argued that the known advantages of a single centered heater, combined with the general knowledge that centered heaters were available in the art, would have motivated one of ordinary skill “to implement Morgan using a centered heater as the predictable solution from the narrow list of known and available design choices.” *Id.*

After weighing the evidence, the ALJ found that Morgan’s emphasis on placing heating elements circumferentially around the outside of the housing—and its lack of discussion of such elements being centrally placed—was evidence that “Morgan itself shows that it would not have been obvious to modify Morgan to include a centered heater.” *Id.* Furthermore, the ALJ noted that Philip Morris had not actually cited any evidence to show that there was a narrow list of known and available design choices. The ALJ thus concluded that “Philip Morris has failed to show by clear and convincing evidence that Morgan in view of the general knowledge of a person of ordinary skill in the art renders obvious claims 27–30 of the ’123 patent.” *Id.* at *30.

Philip Morris petitioned for review to the full Commission, arguing that the ALJ erred in “requiring an express ‘motivation’ to modify Morgan with a centered heater” and by ignoring evidence that one of ordinary skill “would have been aware of numerous benefits of centered heating elements . . . and therefore would have had additional good reason to design the Morgan smoking article with one.” *Commission Op.*, 2021 WL 4947427, at *24. The Commission affirmed the ALJ’s findings and provided supplemental reasoning. *Id.*

In particular, the Commission explained that Philip Morris’s obviousness theory before the ALJ was premised on the “assumption that there were only three options for placement of the heater in the Morgan device.” *Id.* But,

explained the Commission, Philip Morris failed to support this assumption. According to the Commission, Philip Morris failed to “cite any evidence demonstrating there were a limited number of design choices for the heating element.” *Id.* at *25. Additionally, due to the “multitude of design considerations beyond just the heater location,” the Commission found that “heater design in an electronic cigarette was anything but a ‘simple design choice,’” as Philip Morris asserted. *Id.* This, the Commission reasoned, was therefore not a case in which there were only a few known, predictable solutions available such that a skilled artisan would have “faced a simple design choice between” them. *Id.* (quoting *Uber Techs., Inc. v. X One, Inc.*, 957 F.3d 1334, 1341 (Fed. Cir. 2020)).

Additionally, the Commission found that Philip Morris’s reliance on the ’123 patent specification’s statement that “[s]election of the power source and resistance heating elements can be a matter of design choice” was misplaced. ’123 patent col. 29 ll. 32–50. In so finding, the Commission pointed out that “[t]he ’123 patent does not state . . . that the arrangement and positioning of those resistance heating elements are matters of design choice.” *Commission Op.*, 2021 WL 4947427, at *24. Instead, the Commission agreed with the ALJ’s explanation that the design choices described in the ’123 patent “actually refer[] to the amount of resistance in the resistance hea[t]ing elements and the voltage and current provided by the power sources,” not the location or placement of the heating elements. *Id.* at *23–24 (citing *FID*, 2021 WL 2333742, at *29). In other words, the Commission explained that the ’123 patent’s disclosure did not support Philip Morris’s assertions that choosing heating element placements was a simple design choice or that there was a finite number of known solutions for such placements.

The Commission also agreed with the ALJ that Morgan itself suggests not using a central heater. The Commission noted that Morgan already recognized inefficiencies with

its circumferential arrangement of heaters, because the heating elements would only heat the tobacco on the outside of a disposable tobacco stick. *Id.* at *24, 26. To address this problem, the Commission noted, Morgan did not, for example, disclose modifying its device to implement the allegedly “known” solution of a single centered heater to heat the tobacco on the inside of the disposable tobacco stick. Instead, Morgan describes “removing the tobacco from the center of the disposable portion and putting in its place a non-tobacco ‘fiber bundle’ surrounded by a layer of metallic foil with a slurry of tobacco coated onto it.” *Id.* at *26 (citing Morgan col. 6 l. 63–col. 7 l. 10). Thus, the Commission determined that the evidence of record weighed against one of ordinary skill implementing a single centered heater in Morgan.

On appeal, Philip Morris repeats the arguments that it made before the ALJ and the Commission. Philip Morris argues there was “no need to show any additional ‘reason for why’ [one of ordinary skill] would be motivated to modify” Morgan to implement a centered heating element. Appellants’ Br. 42–43 (citing *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1347 (Fed. Cir. 2017)). This is so, Philip Morris argues, because our court’s precedent dictates that when a feature is “a simple design choice,” to be selected from among “a finite number of identified, predictable solutions,” it “would have been obvious” to pursue one of the known, predictable solutions. *Id.* at 42–43. Philip Morris also reiterates its position that the ’123 “patent itself confirms” heating element placement is a “*matter of design choice*.” *Id.* at 38–39 (citing ’123 patent col. 29 ll. 32–50).

While the issue of obviousness in view of Morgan is a close one, we are not convinced that the Commission erred in its fact findings or its ultimate conclusion. The Commission did not err in finding that the ’123 patent specification’s statement that “[s]election of the power source and resistance heating elements can be a matter of design choice” merely contemplates that the amount of resistance

in the resistance heating elements—not their placement—was a simple matter of design choice. Read in context with the remainder of the specification, the Commission’s understanding is not unreasonable.

The Commission also did not err in finding that Philip Morris’s expert testimony did not establish that only a limited number of design choices were available to the skilled artisan. Philip Morris argues that the Commission erred in ignoring the “[u]ncontested” testimony “establish[ing] that there were just three locations for the placement of a heater in an electronic heat-not-burn device:” (1) outside the cigarette, (2) inside the cigarette but not centered, or (3) inside and centered. Appellants’ Br. 39 (citing J.A. 21198 (Hearing Tr. 1072:05–1073:14)). Philip Morris does not accurately represent this testimony. This testimony actually states that there are “a limited category of—limited number of categories of heater design,” and that “some of them,” the “main ones,” included “an internal heater, internal to the tobacco rod,” or “external” heater designs in the form of “either a shell around the tobacco stick or a plate at the end of the tobacco stick.” J.A. 21198 (Hearing Tr. 1072:05–1073:14). As the Commission points out, Mr. Fox “never actually opined that there were only *three* locations for placement of the heater.” Appellee’s Br. 59. The Commission found instead that “there are numerous locations that are ‘inside the cigarette but not centered,’ instead of only one, as [Philip Morris] argues.” *Id.* We agree with the Commission that Mr. Fox’s testimony does not support Philip Morris’s assertion.

Finally, substantial evidence also supports the Commission’s finding that Morgan itself provides strong evidence against a conclusion that it would have been obvious to replace the circumferential heaters with a centered heater. Indeed, Morgan explains that its circumferential placement is advantageous and goes so far as to modify the tobacco sticks instead of resorting to a central heater. Testimony from Reynolds’ technical expert, Charles Clemens,

also supports the Commission’s finding. Mr. Clemens explained that it was Morgan’s arrangement of “separate heaters around the periphery of the tobacco stick” that provided the advantages of Morgan’s purported invention: allowing “fresh tobacco [to] be heated with each sequential puff” to avoid “the reheating of the tobacco[, which] produces undesired compounds and off-taste.” J.A. 21367 (Hearing Tr. 1505:01–1507:17); *see also* J.A. 21367–68 (Hearing Tr. 1507:23–1508:21). In other words, as Mr. Clemens explained, “Morgan teaches the opposite of a centered heater.” J.A. 21367 (Hearing Tr. 1505:01–1507:17).

Philip Morris argues that the Commission improperly treated Morgan’s disclosure as teaching away from centered heaters. Appellants’ Br. 46. But the Commission never made a teaching away finding, instead focusing on Morgan’s teachings as a whole as they related to motivation to modify Morgan to include central heater. *Commission Op.*, 2021 WL 4947427, at *26 (citing Morgan col. 5 ll. 18–25, col. 5 ll. 61–65 and *FID*, 2021 WL 2333742, at *29–30). We decline Philip Morris’s invitation to address whether Morgan teaches away from central heaters, an issue that the Commission never reached. *Singleton*, 428 U.S. at 120 (“It is the general rule . . . that a federal appellate court does not consider an issue not passed on below.”).

In sum, we are not convinced by Philip Morris’s arguments on appeal. Importantly, Philip Morris still has not cited to any evidence supporting its argument that there were only three design choices, let alone that it is undisputed that there are only three such choices. The question before us is “not whether we agree with the Commission’s decision, nor whether we would have reached the same result as the Commission had the matter come before us for decision in the first instance,” *U.S. Steel Grp. v. United States*, 96 F.3d 1352, 1357 (Fed. Cir. 1996), but whether the Commission’s findings are supported by substantial

evidence, *see Norgren Inc. v. Int'l Trade Comm'n*, 699 F.3d 1317, 1326 (Fed. Cir. 2012) (“The responsibility of this court is not to re-weigh de novo the evidence on close factual questions; it is to review the decision of the Commission for substantial evidence.”). Based on the record before us, we cannot say that the Commission’s fact finding—based on the disclosure of Morgan itself, the lack of evidence showing that there were only three possible heater locations, and expert testimony that one of ordinary skill would not have been motivated to modify Morgan to include a central heater—was unsupported by substantial evidence.

Thus, we affirm the Commission’s final determination with respect to the validity of the ’123 patent.

Infringement of the ’915 Patent

We turn next to the issue of infringement. Philip Morris argues that the Commission erred in finding that the accused IQOS products infringe claims 1–3 and 5 of the ’915 patent. Specifically, Philip Morris contends that (1) the Commission’s decision is grounded in an erroneous claim construction; and (2) under the correct claim construction, the accused products do not infringe. Appellants’ Br. 48.

The infringement analysis “entails two steps,” the first of which is construing the claims, and the second of which “is comparing the properly construed claims to the” accused products. *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1360 (Fed. Cir. 2019) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995)). Whether a product infringes an asserted claim is a question of fact. *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1202 (Fed. Cir. 2010).

Philip Morris’s accused IQOS products include a holder and a disposable tobacco stick. *Commission Op.*, 2021 WL 4947427, at *8–9. The tobacco stick is inserted into the

holder, which heats, without burning, the tobacco stick to generate a visible nicotine-containing aerosol for inhalation. *Id.* A representative example of an accused product with a disposable tobacco stick inserted into the holder is shown below:



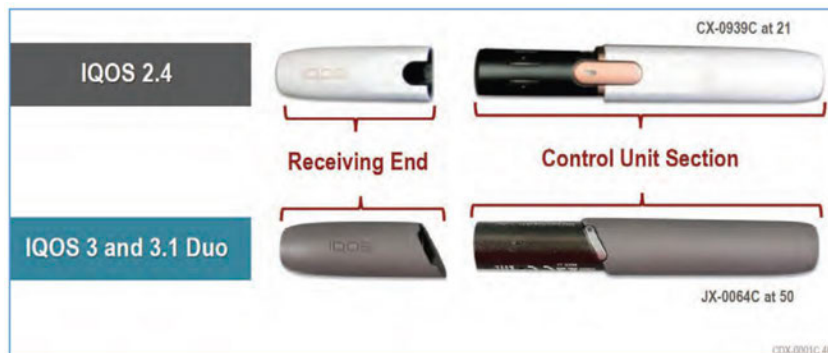
FID, 2021 WL 2333742, at *31.

The only limitation of representative claim 1 in dispute for purposes of infringement recites: “a receiving end for receiving an engaging end of the disposable smoking article and having an electrical energy source.” ’915 patent col. 42 ll. 25–27. Before the ALJ, Philip Morris asserted that this “receiving end” limitation should be interpreted as “a portion of the control housing for receiving an engaging end of the disposable smoking article and containing an electrical energy source” such that the “electrical energy source” is “wholly contained” within the “receiving end.” J.A. 10916–17. Reynolds countered that the “receiving end” simply means “a portion of the control housing for receiving an engaging end of the disposable smoking article and having an electrical energy source” such that the electrical energy source may be “only partially located within the ‘receiving end.’” *Id.*

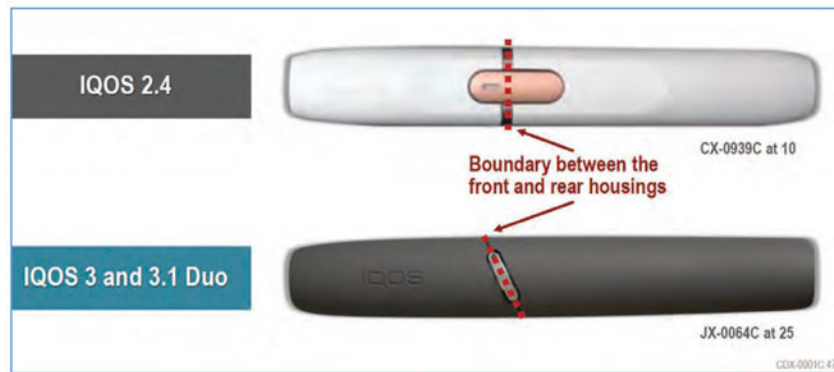
The ALJ agreed with the parties that the “receiving end” must receive an engaging end of the disposable

smoking article and have an electrical energy source. Based on the claim language and the intrinsic evidence, however, the ALJ agreed with Reynolds that the limitation required only that “a portion of the electrical energy source be present within the receiving end of the control housing, but another portion of the electrical energy source may be contained elsewhere.” J.A. 10920. Philip Morris did not challenge this claim construction before the Commission and, thus, it cannot do so on appeal.

To prove infringement, Reynolds relied on the testimony of its technical expert, Ramon Alarcon. He explained that the accused products each include a “cap” corresponding to the claimed “receiving end” that receives a disposable tobacco stick, as depicted below. *FID*, 2021 WL 2333742, at *30–33 (citing J.A. 20897 (Hearing Tr. 195:11–196:18)).

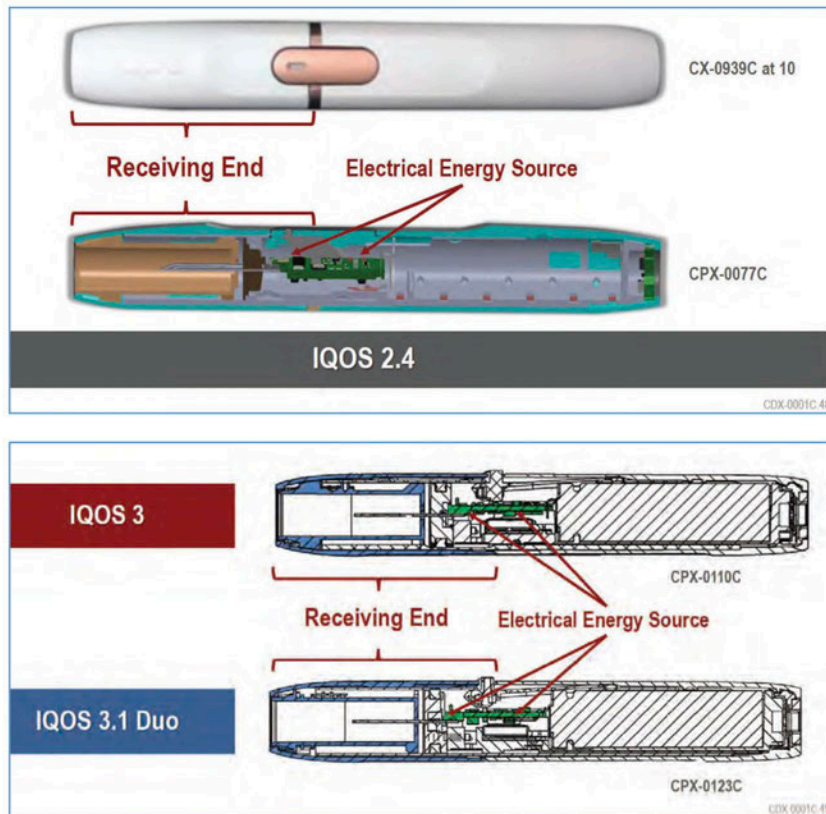


Id. at *30. Reynolds also cited to several of Philip Morris’s own internal documents that characterized the IQOS product cap as the end of the device that receives the disposable tobacco stick. *Id.* at *32. Reynolds asserted that although the claim language did not specify a boundary between the “receiving end” and any other claimed structure, this description of the IQOS product cap confirmed that the “receiving end” in the accused products extends at least to the boundary between the front and rear housings, as depicted below.



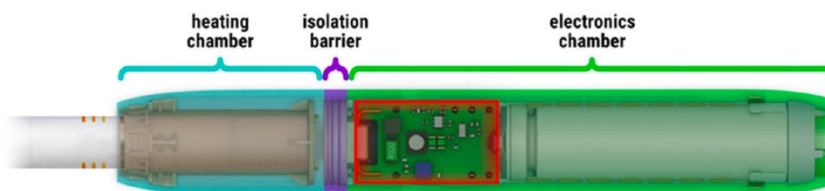
Id. at *31.

Mr. Alarcon also testified that the accused IQOS products include an electrical energy source in the form of a printed circuit board (PCB) that is at least partially located within the portion of the housing corresponding to the cap and thus the “receiving end.” *Id.* (citing J.A. 20898–99 (Hearing Tr. 200:14–201:02)). The PCBs that Reynolds allege correspond to the electrical energy sources are shown below:



Id.; see also Appellants’ Br. 49 (citing J.A. 4205). Thus, Reynolds contended, the accused IQOS products met the disputed limitation and infringed the asserted claims.

Philip Morris argued, to the contrary, that the boundary between the “receiving end” and the control unit section is physically defined by an isolation barrier within the IQOS products, indicated in purple below:



Appellants’ Br. 49 (citing J.A. 42057).

The ALJ considered Philip Morris’s arguments and its expert testimony, but ultimately gave Reynolds’ arguments—supported by Mr. Alarcon’s testimony and Philip Morris’s own internal documents—more weight. The ALJ thus found that the accused IQOS products met the “receiving end” limitation regardless of the existence of the isolation barrier within the “receiving end.” *FID*, 2021 WL 2333742, at *31–32.

Before the Commission and now on appeal, Philip Morris essentially asserts that the ALJ and the Commission erred in their interpretation of the ALJ’s claim construction. Specifically, Philip Morris argues that the ALJ and the Commission misconstrued the claim construction by interpreting it to define the boundaries of the “receiving end” based on the external structure of the smoking article or to include portions that extend beyond an internal isolation barrier. Appellants’ Br. 48–53.

At the outset, we note that Philip Morris’s alleged “claim construction” argument sounds more like a challenge to the factual question of whether the claims as construed read on the accused devices. In any event, we reject Philip Morris’s attempt to reconstrue the claims. We see no error in the ALJ and Commission’s analysis and understanding of the claim construction. The claim language expressly defines “the receiving end” as (1) “receiving . . . the disposable smoking article” and (2) “having an electrical energy source.” ’915 patent col. 42 ll. 25–27. As the ALJ aptly stated, “[t]he term ‘receiving end’ is a term of

orientation; it is the end of the device that receives a disposable smoking article and has an electrical energy source.” *FID*, 2021 WL 2333742, at *31. In other words, any portion of an accused device that receives a disposable smoking article and has an electrical energy source is a “receiving end”; the term “receiving end” is not a name for a specific component. Furthermore, we agree that “[t]he presence of additional structures neither required nor prohibited by the claims, such as an ‘isolation barrier,’” is allowed by the claim language. *Id.* Nothing in the claim language or specification indicates that the “receiving end” cannot include additional elements. *See Mannesmann Demag Corp. v. Engineered Metal Prods.*, 793 F.2d 1279, 1282–83 (Fed. Cir. 1986).

Because we reject Philip Morris’s legal argument, we affirm the Commission’s determination that Philip Morris’s accused IQOS products infringe the ’915 patent.

Corroboration

Finally, we turn to the issue of corroboration. Philip Morris challenges the ALJ’s conclusion that Philip Morris “failed to demonstrate, by clear and convincing evidence,” that the ’915 patent was invalidated by public use of a device alleged to be prior art.⁵ *FID*, 2021 WL 2333742, at *40. Specifically, Philip Morris relied on testimony from a former employee to establish prior public use of the allegedly anticipatory device, but the ALJ found that this testimony was insufficiently corroborated. *Id.*

Courts impose a corroboration requirement when a witness’s “testimony alone is asserted to invalidate a patent,” *Finnigan*, 180 F.3d at 1369, because such testimony “can be ‘unsatisfactory’ due to ‘the forgetfulness of witnesses, their liability to mistakes, [and] their proneness to

⁵ The Commission declined to review the ALJ’s determination.

recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury.” *Id.* at 1366 (quoting *Washburn & Moen Mfg. Co. v. Beat 'Em All Barbed-Wire Co.*, 143 U.S. 275, 284 (1892)). The Supreme Court has long cautioned that “[w]itnesses whose memories are prodded by the eagerness of interested parties to elicit testimony favorable to themselves are not usually to be depended upon for accurate information.” *Washburn*, 143 U.S. at 284. Requiring independent confirmation of the truth of the matter asserted through a threshold level of corroboration thus “provides an additional safeguard against courts being deceived.” *Medi-chem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1170 (Fed. Cir. 2006).

The “Accord K” was an “electronic heat-not-burn tobacco device developed by Philip Morris.” *FID*, 2021 WL 2333742, at *39. Before the ALJ, Philip Morris asserted that the “Accord K” met every limitation of the asserted claims of the ’915 patent and that it had been publicly used more than one year prior to the earliest possible priority date of the ’915 patent—August 9, 2011—thus anticipating the asserted claims. To establish the prior public use, Philip Morris relied heavily on the testimony of Doug Burton, a former employee. Mr. Burton was the “leader of the product management team,” and testified that he helped design, manufacture, and test the “Accord K.” J.A. 21095 (Hearing Tr. 774:03–775:06). He recalled that Philip Morris held a “series of consumer research events in Miami,” Florida, to demonstrate and distribute the “Accord K” to attendees in the late-2005 to early-2006 timeframe. J.A. 21099 (Hearing Tr. 788:19–789:10).

To support Mr. Burton’s testimony, Philip Morris introduced various documents that it alleged described the “Accord K” and its use in Miami. For example, Mr. Burton referenced a “presentation from June of 2006” that provided a “rundown of the events in Miami.” J.A. 21099 (Hearing Tr. 789:11–789:22). The 2006 presentation,

however, discusses a device known as the “EHCSS Series K.” J.A. 41477. Mr. Burton claimed “EHCSS Series K” was an “internal designation for Accord K.” J.A. 21099 (Hearing Tr. 789:11–789:22); *see also* J.A. 40774 (other documentation in the record referring to a “Series K Lighter”). The same presentation referenced an “NXT Smoking System™,” J.A. 41482, a brand that Mr. Burton asserts was also “a temporary branding . . . applied to Accord K for these events.” J.A. 21099 (Hearing Tr. 789:11–789:22). In support of this assertion, Mr. Burton pointed to a “marketing analysis report,” dated March 2006, for a device having yet another different name—the “Parliament NXT Smoking System”—that was introduced and tested in Miami. J.A. 21099 (Hearing Tr. 790:02–790:25); *see also* J.A. 41125. The 2006 presentation makes no mention of any device named “Accord K.”

With respect to the features of the “Accord K” device, Mr. Burton referenced a separate document: a “June 2004 technical file that [he] compiled for CE marking.”⁶ J.A. 21100–01 (Hearing Tr. 795:05–797:01). Mr. Burton contended that this technical file “describe[s] the Accord K that was given out at the Miami events.” *Id.* The only product designations appearing in the document, however, reference either a “Version NHA-PL7” or an “EHCSS Lighter.” J.A. 40791–824.

At the hearing, Mr. Burton also testified regarding a physical device that he claimed was “the same” as the “Accord K” device “that was given out at the Miami events.” J.A. 21100 (Hearing Tr. 794:01–795:04). Mr. Burton described an “Accord K” he had that “was turned into a

⁶ On commercial products, the CE mark, stylized as **CE**, means that the manufacturer or importer affirms the good’s conformity with European health, safety, and environmental protection standard. CE marking is required for goods sold in the European Economic Area.

demonstrator for display to upper management” and included modifications such as (1) “removing the outer shell from the heater cartridge and cutting away part of the holder body” and (2) adding two push buttons, one that allowed the device to “start without a cigarette in it,” and one that served as a “manual replacement for the puff activated switch.” J.A. 21100 (Hearing Tr. 794:01–795:04). Aside from these structural changes to the device, Mr. Burton contended that it represented the “Accord K” exactly as it existed when it was distributed in Miami. *Id.* Philip Morris asserted that this physical device definitively linked the “Accord K” that Mr. Burton testified was publicly used in Miami to the contemporaneous documentation of record. For example, Mr. Burton identified a photo of a “battery assembly” that he testified was removed from his modified “Accord K” as including a “commercialization production serial number sticker” indicating that the battery assembly was “ONLY for NHA-PL7,” and “NHA-PL7” was one of the product names appearing in the June 2004 technical file that Mr. Burton testified described the “Accord K.” J.A. 21100 (Hearing Tr. 794:01–794:25); *see also* J.A. 40073.

Regarding the link between the “Accord K” device that Mr. Burton testified was in public use in Miami and the documentation that allegedly describes the features of the “Accord K,” Mr. Burton acknowledged that “if you look at those documents, you will not see written anywhere this is the one [device] that you’re going to take to Miami.” J.A. 21103 (Hearing Tr. 807:03–807:24). Instead, Mr. Burton asserted that “there was only one Accord K,” and that Philip Morris “didn’t build a special [model] for [the] Miami” conference. *Id.* Therefore, Mr. Burton asserted that although the contemporaneous documents do not “say anything about whether that device [described in the document] with that structure was given out in Miami,” the documentation necessarily describes the “Accord K” that was displayed in Miami and corroborates his testimony

because every device referred to as the “Accord K” had the same characteristics. J.A. 21103 (Hearing Tr. 807:07–807:12).

On appeal, Philip Morris argues that Mr. Burton’s testimony was sufficiently corroborated and challenges the ALJ’s contrary finding. Appellants’ Br. 55–56. The sufficiency of corroboration is evaluated under the “rule of reason,” which involves “an assessment of the totality of the circumstances including an evaluation of all pertinent evidence.” *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1372 (Fed. Cir. 2007). We treat the determination of whether oral testimony is sufficiently corroborated as a question of fact, which we review for substantial evidence. *TransWeb, LLC v. 3M Innovative Prods. Co.*, 812 F.3d 1295, 1302 (Fed. Cir. 2016).

Substantial evidence supports the ALJ’s determination that Mr. Burton’s testimony was not sufficiently corroborated. As the ALJ explained, while Mr. Burton’s testimony “might establish that devices known as Accord K were in public use in Miami by no later than 2006, Philip Morris has failed to show that the Accord K devices used in Miami are the same . . . devices described in the technical documents that Philip Morris uses to support its invalidity arguments.” *FID*, 2021 WL 2333742, at *39. In other words, the ALJ found a critical gap in corroborating evidence linking the devices that were in public use with the devices that Philip Morris asserts invalidate the asserted claims of the ’915 patent.

The ALJ’s finding is supported by both the documents and Mr. Burton’s testimony. Indeed, the ALJ noted inconsistencies between Mr. Burton’s memory of the existence of a single device structure associated with the “Accord K” and the documentary evidence. For example, although Mr. Burton emphasized that there was “only one Accord K,” his testimony muddled the distinction between different Philip Morris devices, such as the “Accord JLI” and

“Accord K.” J.A. 21103 (Hearing Tr. 807:07–807:12). Without documentary support, Mr. Burton testified that the Accord JLI, and the Accord K “are very much alike because the configuration is essentially the same.” J.A. 21102 (Hearing Tr. 800:23–801:02). Mr. Burton further testified as to the existence of an “upgrade program” in “late 2002” for consumers to trade in products that they previously purchased, known as “old Accord K kits,” or the “E4 version,” for “the new one[s,] . . . the JLI version.” J.A. 21096 (Hearing Tr. 777:13–778:01). The ALJ reasonably explained that these statements made it unclear whether there were indeed various Philip Morris devices, any one of which could have been in public use in Miami. Furthermore, the allegedly contemporaneous documents include products with multiple different names, some of which include: “Series K,” “EHCSS Series K,” “NXT Smoking System,” and “Version NHA-PL7,” among other designations. Not a single document referred to the device it described as the “Accord K.” Additionally, the ALJ reasonably found Mr. Burton’s testimony internally inconsistent. For example, contrary to his testimony about the “old Accord K kits” being traded in for the new versions, Mr. Burton later agreed that the “Accord K was never launched or sold in the United States.” J.A. 21103 (Hearing Tr. 804:09–804:22).

On appeal, Philip Morris argues that the ALJ applied “an erroneously heightened standard” in his corroboration analysis, and that, even under this heightened standard, Mr. Burton’s testimony was sufficiently corroborated. Appellants’ Br. 55–56. Philip Morris does not explain, however, how the ALJ erroneously applied a heightened standard or how the ALJ’s analysis differed from a proper rule of reason analysis. Philip Morris’s argument essentially boils down to claiming that, in its view, the ALJ erred because Mr. Burton’s testimony was too well-corroborated to be found not sufficiently corroborated. As we explained

above, however, the ALJ's finding was supported by substantial evidence.

Our precedent also supports the ALJ's conclusion. As we have previously held, uncorroborated testimony cannot be corroborated by uncorroborated evidence. *In re NTP, Inc.*, 654 F.3d 1279, 1291–92 (Fed. Cir. 2011). In *In re NTP*, we affirmed the Board's rejection of NTP's attempt "to corroborate [the affiants'] testimony with [a] document, but, at the same time, attempt to corroborate the date of [that] document with their testimony." *Id.* Similarly, here, Philip Morris attempts to use its 2006 presentation to corroborate Mr. Burton's testimony that the "Accord K" was in public use in Miami at least as of 2006. At the same time, Philip Morris attempts to use Mr. Burton's testimony to corroborate that the 2006 presentation (as well as other documents) refer to the same "Accord K" device notwithstanding references to different products. Presented with a similar "catch-22" situation in *Apator Miitors ApS v. Kamstrup A/S*, we dismissed Apator's "attempts to corroborate [a witness's] testimony with the emails and the drawings" that could "only provide that corroboration with help from [that same witness's] testimony." 887 F.3d 1293, 1296–97 (Fed. Cir. 2018). Following well-established precedent preventing parties from creating an ouroboros of corroboration, the ALJ reasonably rejected Philip Morris's circular path of corroboration. We cannot say that the ALJ erred in finding Mr. Burton's testimony not sufficiently corroborated by documents that are corroborated by Mr. Burton's testimony.

In an attempt to fill the gap identified by the ALJ, Philip Morris identifies a particular technical file and the identification number printed on the sticker on the battery assembly of the physical device presented to the ALJ to link the "Accord K" device presented in Miami in 2006 to the documents identifying a product with features that were alleged to anticipate the patent claims. At argument, Philip Morris's counsel argued "the technical file actually

uses an ID number for the Accord K device, and that’s the same ID number that is found on the picture of the Accord K device in the record at page 40073, it’s NHA-PL7.” Oral Arg. at 24:09–24:38, https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-1227_10032022.mp3. Philip Morris asserts that the technical file is therefore “an explicit document linking . . . this Accord K device to the photograph of the device” that bridges the gap that the ALJ identified between the “Accord K” that Mr. Burton testified was publicly used in Miami and the “Accord K” described in the documentation. *Id.* Counsel for Philip Morris argues that because Mr. Burton’s testimony regarding the events in Miami is undisputed, and because Philip Morris presented “all these documents using the same shorthand, the same way we refer to the device, the same identification number of the device linking it to that time frame,” reaching any conclusion other than one in which Mr. Burton’s testimony was sufficiently corroborated would be legal error and would impose an “impossible to meet” standard for corroboration. Oral Arg. at 25:19–26:11 (asking “[a]t what point is corroboration enough?”).

As an initial point, we note that it is of no import “that [Appellants’] evidence is ‘unrebutted,’ as [it] repeatedly points out. This criticism misunderstands [Philip Morris’s] burden of proof,” *Apator*, 887 F.3d at 1297, which requires that Philip Morris prove the “Accord K” was publicly used prior to the ’915 patent’s effective filing date, not that Reynolds prove it was not. Additionally, Philip Morris has still failed to address the problem that the device depicted in the photo at J.A. 40073 was presented at trial as a physical device with no provenance other than Mr. Burton’s testimony that it was the same device as presented in Miami. And even this testimony from Mr. Burton reveals that the device has been structurally modified from the state in which it was allegedly publicly used in Miami. J.A. 21100 (Hearing Tr. 794:01–795:04) (describing the various structural modifications that were made, including cutting away

portions of the device body and adding buttons). Philip Morris has failed to close the gap the ALJ identified in the evidence purportedly linking the device in public use with the device Philip Morris asserts anticipates the asserted claims and thus failed to meet its evidentiary burden.

Under the proper rule of reason analysis for evaluating the sufficiency of corroboration, we cannot say that the ALJ erred in his factual conclusion. We therefore affirm the Commission's final decision adopting the ALJ's findings and conclusions with respect to corroboration.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the Commission's decision in its entirety.

AFFIRMED