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**UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.**

In the Matter of

**CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1276

**COMMISSION OPINION DENYING RESPONDENT’S MOTION TO STAY THE
REMEDIAL ORDERS**

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I. INTRODUCTION

On October 26, 2023, the Commission issued its final determination in this investigation, finding Apple Inc. of Cupertino, California (“Apple”), the sole respondent, in violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, as to certain claims of U.S. Patent No. 10,912,502 (“the ’502 patent”) and U.S. Patent No. 10,945,648 (“the ’648 patent”). 88 Fed. Reg. 75032, 75032–33 (Nov. 1, 2023). The Commission issued: (1) a limited exclusion order (“LEO”) prohibiting the importation of light-based physiological measurement devices and components thereof that infringe one or more of those claims; and (2) a cease and desist order (“CDO”) directed to Apple. *Id.* Thereafter, Apple filed a motion to stay the LEO and CDO pending appeal and/or in light of a potential government shutdown. Masimo Corporation (“Masimo”) and Cercacor Laboratories, Inc. (collectively, “Complainants”) filed an opposition to this motion. For the reasons discussed herein, Apple’s motion is denied.

II. BACKGROUND

The Commission instituted this investigation on August 18, 2021, based on a complaint filed by Complainants on June 30, 2021, with an amended complaint filed on July 12, 2021, and supplemented on July 19, 2021. 86 Fed. Reg. 46275 (Aug. 18, 2021). The amended complaint alleged violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain light-based physiological measurement devices and components thereof by reason of infringement of certain claims of the ’502 and ’648 patents as well as U.S. Patent No. 10,912,501 (“the ’501 patent”); U.S. Patent No. 10,687,745 (“the ’745 patent”), and U.S. Patent No. 7,761,127 (“the ’127 patent”). *Id.* The notice of investigation named Apple as the sole respondent. *Id.* at 46276. The Office of Unfair Import Investigations did not participate in this investigation. *Id.*

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Before the presiding administrative law judge (“ALJ”) issued the final initial determination (“Final ID”), Complainants withdrew certain asserted patent claims from the investigation. *See* Order No. 25 (Mar. 23, 2022), *unreviewed* by Comm’n Notice (Apr. 12, 2022); Order No. 33 (May 20, 2022), *unreviewed* by Comm’n Notice (June 10, 2022). At the time of the Final ID, only claim 12 of the ’501 patent; claims 22 and 28 of the ’502 patent; claims 12, 24, and 30 of the ’648 patent; claims 9, 18, and 27 of the ’745 patent; and claim 9 of the ’127 patent remained in the investigation.

On October 26, 2023, the Commission found that Apple violated section 337 as to claims 22 and 28 of the ’502 patent and claims 12, 24, and 30 of the ’648 patent and issued an LEO and CDO. 88 Fed. Reg. 75032, 75032–33 (Nov. 1, 2023). The Commission determined that the public interest factors did not preclude issuance of the remedial orders. *See id.*; 19 U.S.C. § 1337(j)(3).

On October 30, 2023, Apple filed the pending motion to stay the remedial orders pending appeal and/or in light of a potential government shutdown. *See* Respondent Apple Inc.’s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, EDIS Doc. ID 807326 (Oct. 30, 2023) (“Motion” or “Mtn.”). On November 9, 2023, Complainants filed an opposition to Apple’s motion. *See* Complainants’ Opposition to Respondent Apple Inc.’s Motion to Stay Exclusion and Cease and Desist Orders Pending Appeal and/or in Light of the Potential Government Shutdown, EDIS Doc. ID 808262 (Nov. 9, 2023) (“Oppn.”).¹

¹ On November 20, 2023, Complainants filed Complainants’ Request for Judicial Notice of Recent Regulatory Developments for Masimo W1 Watch. EDIS Doc. ID 808970 (Nov. 20, 2023). Complainants asked the Commission to consider, in making its determination on Apple’s Motion, a decision of the United States Food and Drug Administration related to Masimo’s W1

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III. LEGAL STANDARD

The Administrative Procedure Act provides an agency with the authority to “postpone the effective date of action taken by it, pending judicial review” if the “agency finds that justice so requires.” 5 U.S.C. § 705. The Federal Circuit has set forth the following four-part test to assess whether to stay a lower court’s remedy pending appeal:

(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether the issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Standard Havens Prods., Inc. v. Gencor Indus., Inc., 897 F.2d 511, 512 (Fed. Cir. 1990)

(quotation omitted). The factors are subject to weighing, and each factor need not be given equal weight. *See id.* at 512–13.

The Commission evaluates motions for stay pending appeal under the *Standard Havens* test, with one exception. The Commission has recognized the futility of establishing a likelihood-of-success for a movant given that it is difficult to ask an agency to find its own decision is likely to be overturned on appeal. *See Certain Agric. Tractors Under 50 Power Take-Off Horsepower*, Inv. No. 337-TA-380, Comm’n Op. Denying Respondents’ Petition for Reconsideration and Motion for Relief Pending Appeal at 10 (Apr. 24, 1997) (“*Agric. Tractors*”) (denying respondents’ motion to stay a general exclusion order and cease and desist orders and discussing *Wash. Metro. Area Transit Comm. v. Holiday Tours, Inc.*, 559 F.2d 841, 844–45 (D.C. Cir. 1977)). Thus, in lieu of the *Standard Havens* “likely to succeed on the merits” factor,

Watch product and documents associated with that decision. *See id.* at 1–2. However, putting aside the applicability of judicial notice for the documents in question, the Commission does not rely on these documents and consideration of them would not alter the Commission’s determination.

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the Commission considers whether it has “ruled on an admittedly difficult legal question.” *See Certain Tobacco Heating Articles & Components Thereof*, Inv. No. 337-TA-1199, Comm’n Op. Denying Respondents’ Motion to Stay Limited Exclusion Order and Cease and Desist Orders Pending Appeal at 4 (Jan. 20, 2022) (“*Tobacco Heating Articles*”); *see also Holiday Tours*, 559 F.2d at 844–45 (“What is fairly contemplated is that tribunals may properly stay their own orders when they have ruled on an admittedly difficult legal question and when the equities of the case suggest that the status quo should be maintained.”). As the Commission stated in *Tobacco Heating Articles*, it has “repeatedly recited and applied this ‘admittedly difficult question’ test in previous investigations in which stays of its remedial orders were sought pending appeal.” Comm’n Op. at 4 (footnote collecting investigations omitted).

IV. APPLE’S MOTION AND ANALYSIS THEREOF

A. The *Standard Havens* Factors

1. Admittedly Difficult Legal Questions

Apple presents three separately-alleged “admittedly difficult legal questions,” discussed below, *see* Motion at 6–18; the Commission finds that none of these is admittedly difficult.

a. Domestic Industry—Whether a Patent-Practicing Article Must Exist at the Time the Complaint is Filed

According to Apple, “[b]y affirming the ALJ’s conclusion that Complainants ‘have shown the existence of a domestic industry,’ Comm’n Op. at 67, the Commission necessarily held that Section 337’s requirement that an industry ‘relating to the articles protected by the patent . . . exists’ . . . is satisfied even if the only article described in the complaint is a drawing of an imaginary product.” Mtn. at 6–7 (footnote omitted). Apple asserts that “this ruling is wrong in light of the Federal Circuit’s ruling in *Microsoft Corp. v. ITC* that ‘a company seeking section 337 protection must . . . provide evidence’ that ‘relates to an *actual article* that practices

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the patent, regardless of whether or not that article is manufactured domestically or abroad.” *Id.* at 7 (quoting *Microsoft Corp. v. Int’l Trade Comm’n*, 731 F.3d 1354, 1361–62 (Fed. Cir. 2013)) (Apple’s emphasis). Apple further argues that, “[a]t the very least, this case presents the difficult question [of] whether Complainants identified an ‘actual article’ within the meaning of the statute.” *Id.*; *see also id.* at 7–12.

Apple has not shown that this is an “admittedly difficult legal question” at least because, as Complainants point out, Apple is challenging a simple factual finding of the Commission (and the Final ID). *See Oppn.* at 9–13. The Commission did not find that a domestic industry exists based on a drawing of an imaginary product, as Apple alleges. Nor did the Commission base its finding on a product that did not exist at the time the complaint was filed. Apple’s motion ignores the evidentiary record and the Final ID’s and the Commission’s findings, which reflect the existence of, as of the filing of the complaint, numerous Masimo Watch articles and extensive related documentation, testimony, and investments. *See, e.g.,* Final ID at 56–85; *see also Oppn.* at 10–13.

b. Prosecution Laches

Apple argues that “Complainants’ conduct in this case falls squarely within the doctrine of prosecution laches, which bars them from receiving any relief on the asserted claims.” *Mtn.* at 12 (citing *Personalized Media Commc’ns, LLC v. Apple Inc.*, 57 F.4th 1346, 1354 (Fed. Cir. 2023)). Apple points out that “[l]aches applies if ‘(1) the patentee’s delay in prosecution . . . [is] unreasonable and inexcusable under the totality of the circumstances,’ and ‘(2) the accused infringer . . . suffered prejudice attributable to the delay.’” *Id.* (quoting *Personalized Media*, 57 F.4th at 1354). For the first element, Apple argues that “Complainants delayed for twelve years in filing the asserted claims—with no clear reason for doing so other than strategic gamesmanship.” *Id.*; *see also id.* at 12–14. For the second element, Apple asserts that it suffered

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significant prejudice because it “invested in, worked on, or used the claimed technology during the period of delay.” *Id.* at 14 (quoting *Personalized Media*, 57 F.4th at 1357).

Apple has not shown an “admittedly difficult legal question” because Apple waived its opportunity to challenge this issue by not properly presenting it in its petition for review of the Final ID. *See Oppn.* at 13. With respect to the content of such a petition, the Commission’s Rules require, in part, that “[t]he petition for review must set forth a concise statement of the facts material to the consideration of the stated issues, and must present a concise argument providing the reasons that review by the Commission is necessary or appropriate to resolve an important issue of fact, law, or policy.” 19 C.F.R. § 210.43(b)(2). Furthermore, this subsection specifies:

Petitions for review may not incorporate statements, issues, or arguments by reference. 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 (unless the Commission chooses to review the issue on its own initiative under § 210.44), 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.

Id.

Here, Apple improperly incorporated its argument by reference from its post-hearing briefing, which is not sufficient to raise the issue before the Commission. *See Respondent Apple Inc.’s Petition for Review of the Initial Determination of Violation of Section 337*, EDIS Doc. ID 788470, at 78–79, 99–100 (“RPet.”); 19 C.F.R. § 210.43(b)(2); *Tobacco Heating Articles*, Comm’n Op. at 10 (denying a motion to stay remedial orders and finding that the argument “raised now by Philip Morris comes far too late, and the Commission deems it abandoned”); *Hazani v. U.S. Int’l Trade Comm’n*, 126 F.3d 1473, 1476–77 (Fed. Cir. 1997) (finding argument waived when not timely presented to the ALJ); *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d

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1354, 1362–63 (Fed. Cir. 1999) (finding argument waived when not presented in petition for review of an ALJ’s determination).

c. Obviousness

Apple’s last argument relates to the Commission’s adoption of the Final ID’s rejection of Apple’s Lumidigm-based obviousness defense. The Final ID found that “persons of ordinary skill in the art would not have expected to successfully measure blood oxygen in a wristwatch at the time of the Poeze patents,” and thus a person of ordinary skill in the art would not have modified the wrist-watch embodiment of Lumidigm according to Apple’s theory to arrive at the claimed inventions. *See* Final ID at 115–18 (including n. 44) (discussing the limiting preamble of claim 22 of the ’502 patent).²

Apple asserts that, “[w]hen concluding that a patent claim is not invalid, it is impermissible to require the prior art to enable more than is required by the claim itself.” Mtn. at 14; *see also id.* at 14–18. Apple argues that the Commission found that “the asserted claims of the ’648 and the ’502 patent were not obvious because the prior art reference provided by Apple (Lumidigm) does not enable taking an ‘oxygen saturation’ measurement ‘at the wrist.’” *Id.* at 17 (citing Final ID at 113–17). Apple then asserts that the Commission erred because “none of the claims for which a violation was found recites or requires taking a measurement at the wrist.” *Id.* According to Apple, if the device “described in the prior art could take a blood oxygen measurement anywhere on the body, it would anticipate or render obvious the claimed subject matter.” *Id.* at 18. Finally, Apple asserts that the Commission found that “Lumidigm does

² The Final ID’s reasoning likewise applied to the other asserted claims (except for claim 12 of the ’501 patent), as Apple also alleged that those claims were obvious over combinations of references involving Lumidigm’s wrist-watch embodiment and those claims also recite measuring blood oxygen. *See, e.g.,* Final ID at 128, 140, 142.

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describe taking blood oxygen measurements via a user-worn device,” so it must anticipate or render obvious the claims at issue. *Id.* (emphasis omitted).

Apple has not shown an “admittedly difficult legal question” because Apple is challenging a simple factual finding of the Commission. *See* Oppn. at 18–20. Moreover, Apple misconstrues the Final ID, and Apple’s argument (also presented in its petition for review of the Final ID) was already considered and rejected by the Commission. *See* RPet. at 15–20. Neither the Final ID nor the Commission required Lumidigm to enable more than the asserted patent claims. *See* Oppn. at 18–20. Rather, the Commission properly analyzed Lumidigm and other evidence to determine if a person of ordinary skill in the art would have been motivated to modify Lumidigm’s wristwatch to measure oxygen saturation to arrive at the alleged invalidating device with a reasonable expectation of success. *See, e.g.,* Final ID at 113–18; *see also, e.g., id.* at 118 n.44 (“The evidence regarding the difficulty in achieving blood oxygen measurements at the wrist, as discussed above, also shows the lack of clear and convincing evidence of a reasonable expectation of success for the asserted obviousness arguments.”). While measuring oxygen saturation at the wrist is not claimed, Apple chose to base its invalidity theory on measuring blood oxygen saturation at the wrist being taught or suggested by Lumidigm to a person of ordinary skill in the art at the time of the invention.

Here, the Commission properly found that Lumidigm, alone or combined with knowledge in the art at the time of the invention, did not enable measuring oxygen saturation at the wrist, and therefore a person of ordinary skill in the art would not have reasonably expected success at arriving at the device serving as the basis of Apple’s obviousness theory. *See, e.g.,* Final ID at 113–18, 124, 128, 132, 140, 142; Oppn. at 19; *ActiveVideo Networks, Inc. v. Verizon*

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Commc'ns, Inc., 694 F.3d 1312, 1327 (Fed. Cir. 2012); *Raytheon Techs. Corp. v. GE Co.*, 993 F.3d 1374, 1380–81 (Fed. Cir. 2021).

2. Whether Apple Will Be Irreparably Injured Absent a Stay

Apple argues that it faces “unquantifiable harm if it is barred from importing its current Apple Watch models into the United States during the pendency of its appeal,” specifically a loss of “goodwill” and “significant damage to its reputation.” Mtn. at 18; *see also id.* at 18–19.

Apple additionally asserts that a “sudden dearth of Apple Watch products will inevitably harm the public’s perception of Apple,” and “Apple will undoubtedly lose goodwill it has built over the decades of providing high quality, innovative electronics in a timely manner, leading potential customers not to purchase any watch at all.” *Id.* at 19. Apple further argues that “allowing the Commission’s orders to go into effect will provide fodder to support Complainants’ baseless assertions that Apple improperly copied Complainants’ technology—fundamentally tarnishing Apple’s signature strong reputation as an innovator.” *Id.* (internal quotations omitted).

The Commission finds that Apple has not shown that it will suffer irreparable harm such that this *Standard Havens* factor supports a stay. As Complainants point out, Apple’s alleged irreparable injuries are “pure attorney argument supported by no evidence,” Oppn. at 22, and are thus unpersuasive. *See, e.g., Tobacco Heating Articles*, Comm’n Op. at 14 (“Philip Morris offers vague and unsupported declarations with generalizations, such as alleged loss of goodwill . . . without supporting calculations or substantiation of underlying assumptions. . . . Philip Morris’s motion is therefore speculative and unsupported.”) (internal citation omitted); *Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prods. Containing the Same, & Components Thereof*, Inv. No. 337-TA-921 (Modification), Comm’n Op. Denying Garmin Respondents’ Emergency Motion for Stay Pending Appeal at 13 (Oct. 20, 2016) (“Garmin has

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failed to cite to any evidence concerning the purported harms caused by issuance of the [remedial order].”). Here, Apple presented no evidence supporting the nature or extent of any alleged harm it faces from a denial of a stay of the remedial orders, which affect just a portion of one product line³ in Apple’s large suite of product and service offerings. Additionally, statements regarding Apple’s copying of Masimo’s technology and Apple’s pattern of “efficient infringement” are already in the public record. *See* Oppn. at 22.

3. Whether a Stay Will Substantially Injure Other Parties Interested in the Proceeding

Apple asserts that “Complainants will not suffer cognizable harm if the Commission stays its orders pending appeal.” Mtn. at 20. Apple points out that Complainants are suing it for infringement of the same patents in district court and thus Complainants can obtain monetary relief. *Id.* Apple further argues that Complainants are unlikely to suffer any harm from a stay because Masimo’s W1 Watch is not selling “in the United States in any meaningful quantity.” *Id.*; *see also id.* at 20–21. Apple adds that, even if the W1 Watch was selling “in material quantities in the United States, Mr. Kiani⁴ has stated on a recent quarterly earnings call that ‘customers that we’re targeting are people who have chronic illnesses and need a serious . . . measurement.’” *Id.* at 21 (citation omitted).

The Commission finds that Complainants would suffer some harm by granting the stay. The Commission has explained that a complainant “will be irreparably injured by a stay that denies its patents the full term to which they are entitled.” *Certain Lens-Fitted Film Packages*,

³ The Apple Watch SE is not affected by the Commission’s remedy. *See, e.g., Certain Light-Based Physiological Measurement Devices & Components Thereof*, Inv. No. 337-TA-1276, Comm’n Op. at 94, 118 (Nov. 14, 2023).

⁴ Mr. Joe Kiani is Masimo’s chief executive officer.

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Inv. No. 337-TA-406, Comm'n Op. at 17 (June 28, 1999); *Tobacco Heating Articles*, Comm'n Op. at 16; *see also Agric. Tractors*, Comm'n Op. at 16. That said, the Commission notes that Complainants do not contest Apple's assertion that Masimo is not selling its W1 Watch in the United States in any meaningful quantity and also does not intend to widely market that product in the United States, opting instead to market a different, not yet released product in the United States. *See Oppn.* at 22–23; *see also Mtn.* at 20–21. Thus, Complainants would not appear to miss out on substantial revenue in the event of a stay. The Commission further notes that Complainants' parallel pending district court proceeding provides a forum for Complainants to attempt recovery of monetary damages for infringement. *See Certain Dig. Models, Dig. Data, & Treatment Plans for Use in Making Incremental Dental Appliances*, Inv. No. 337-TA-833, Comm'n Op. at 8 (June 11, 2014) (granting stay of remedial orders). While Congress has provided for "Commission relief [to be] 'in addition to' relief provided by the district courts," the presence of a parallel pending district court proceeding, although not alone sufficient to support a stay, has at times been considered relevant by the Commission for this *Standard Havens* factor. *See id.* at 8 & n.8 ("Accordingly, the mere availability of a district court proceeding is not enough to tilt the harms factors in favor of a stay."); *see also Tobacco Heating Articles*, Comm'n Op. at 15–16. Thus, overall, the Commission finds that Complainants would suffer some injury from the grant of a stay pending appeal.

4. Where the Public Interest Lies

Apple argues that "allowing the Commission's orders to go into effect before Customs [and Border Protection] has approved Apple's proposed redesigned Watch would be detrimental to many consumers' daily lives." *Mtn.* at 22. Apple further argues that "the lack of a stay would also pose an immediate setback for medical research, where Apple Watch plays a critical role." *Id.*; *see also id.* at 22–23. Apple additionally declares that "without a stay, the Commission's

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orders will have a significant, negative effect on the economy in general.” *Id.* at 23. Apple points to the number of its U.S.-based employees and to the presence of U.S.-based components suppliers, developers, and accessory manufacturers. *Id.* at 23–24. Apple also makes a vague reference to a “detrimental impact on the healthcare field.” *Id.* at 24. Apple additionally asserts that “removing Apple Watches from the market virtually overnight may both ‘lessen competition’ and—at least in the short term—allow other companies to potentially impose higher prices.” *Id.*

The Commission finds that the public interest does not support a stay pending appeal, and in fact counsels against granting a stay. As Complainants point out, Apple’s arguments have already been considered and rejected by the Commission in the Commission’s final determination. *See Oppn.* at 23–24. In addition, the “public interest favors the protection of intellectual property rights by excluding infringing products.” *Tobacco Heating Articles*, Comm’n Op. at 16–17 (quoting *Certain X-Ray Breast Imaging Devices & Components Thereof*, Inv. No. 337-TA-1063, ID at 281 (July 26, 2018) and citing *Merial Ltd. v. Cipla Ltd.*, 681 F.3d 1283, 1306 (Fed. Cir. 2012); *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013)).

5. Balancing the *Standard Havens* Factors

Apple has not shown that the weighing of the *Standard Havens* factors, as modified via Commission jurisprudence, favors granting a stay pending appeal. Apple has failed to show the existence of an admittedly difficult legal question. Additionally, Apple has not shown that it will suffer irreparable harm from allowing the orders to remain in place pending appeal. Furthermore, Complainants would suffer some harm from a stay. Moreover, the public interest lies with denying a stay. Overall, after weighing the *Standard Havens* factors, the Commission has determined that Apple’s motion should be denied.

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B. Potential Government Shutdown

Apple also asserted in its Motion that a potential federal government shutdown may prevent or inhibit the Presidential review process of the Commission’s remedial order and thus the Commission should exercise its statutory authority to order a stay because “justice requires” it exercise its “inherent power” to order a stay “to protect the integrity of its own proceedings.” Mtn. at 25–27 (citing 5 U.S.C. § 705; *Tokyo Kikai Seisakusho, Ltd. v. U.S.*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)); *see also* 19 U.S.C. § 1337(j). However, after Apple filed its motion, the federal government was funded through at least the sixty-day period of Presidential review. Accordingly, this part of Apple’s motion is denied as moot.

V. CONCLUSION

Apple’s motion to stay enforcement of the exclusion and cease and desist orders pending appeal and/or in light of a potential government shutdown is denied.

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

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