

MARCH/APRIL 2024
VOLUME 30 NUMBER 2

DEVOTED TO
INTELLECTUAL
PROPERTY
LITIGATION &
ENFORCEMENT

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and Charles W. Grimes*

IP *Litigator*®



ITC Investigations

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Top Five Recent Developments in Section 337 Litigation

2023 was an exciting year for Section 337 litigation at the ITC and 2024 is off to an equally interesting start. In this article, Libbie DiMarco reviews five of the most interesting recent developments in Section 337 litigation.

1. **February 2023: The Commission Appoints Judge Doris Hines as the Newest ALJ.** One of the most delightful developments of 2023 was the appointment of Judge Doris Hines in February 2023 as the sixth ITC Administrative Law Judge (ALJ). ALJ Hines had a wealth of experience as an ITC practitioner before her appointment. And with her appointment, the ITC is back to a full roster of six ALJs, three of whom are women.
2. **February 2023: The Commission Sua Sponte Implemented the 100-Day Program (Inv. No. 337-TA-1352).** Also in February 2023, the Commission issued a surprising notice of investigation in *Certain Selective Thyroid Hormone Receptor-Beta Agonists, Processes for Manufacturing or Relating to Same, and Products Relating to Same* (Inv. No. 337-TA-1352). There, the Commission *sua sponte* implemented the 100-day early disposition program, ordering the presiding ALJ to

hold an early evidentiary hearing and issue an early initial determination on the issue of injury to the domestic injury. This ruling was unusual not only because it was done *sua sponte* but also because the ITC *rarely* invokes the 100-day program. Despite invoking the 100-day program over a year ago, the 1352 Investigation remains pending with the parties now proceeding to the post-100-day evidentiary hearing to address the remaining issues.

3. **October-December 2023: The ITC Banned Apple Watch Importation and Sales (Inv. No. 337-TA-1276).** The final quarter of 2023 saw rapidly evolving and often newsworthy developments in the dispute between Masimo Corporation and Apple, Inc. (*Certain Light-Based Physiological Measurement Devices and Components Thereof*, Inv. No. 337-TA-1276). One particularly noteworthy development came when the Commission issued, and the Biden administration upheld, remedial orders prohibiting the importation and sale in the U.S. of Apple's infringing Apple Watch products.

This ITC investigation (Inv. No. 1276) has been a hotly contested dispute filed by Masimo against the global market's dominant smart watch manufacturer, Apple. Relying on its market dominance, Apple urged the Commission to deny any remedial orders on the

basis that Masimo's requested relief (an exclusion order and a cease and desist order) ran afoul of the public interest factors enumerated in 19 U.S.C. 1337(d)(1) and (f)(1).

But on October 26, 2023, after finding a violation of Section 337, the Commission rejected Apple's public interest arguments and issued remedial orders that would prohibit the importation and sale in the U.S. of infringing Apple Watch products. That ruling kicked off the 60-day period known as the presidential review period (PRP), during which importation may continue and the President, via the appointed U.S. Trade Representative, has the right to review and potentially veto the remedial orders. The 1276 investigation's PRP expired on (of all days) December 25, 2023. The Biden administration declined to veto the remedial orders, which is akin to approving the orders. The 1276 remedial orders became enforceable beginning on December 26, 2023.

4. **December 2023-January 2024: The Federal Circuit First Granted Then Lifted a Stay of the ITC's Apple Watch Importation Ban (Inv. No. 337-TA-1276).** Arising out of the same dispute between Masimo and Apple, but worthy of its own spotlight, on December 27, 2023 (i.e., one day after the 1276 remedial orders became enforceable), the Federal Circuit issued an interim order temporarily staying the ITC's remedial orders that survived the PRP in the 1276 Investigation. The Federal Circuit's order came right on the heels of the expiration of the PRP and just one week after

the ITC denied Apple's request for the same relief.

In the underlying 1276 investigation, Apple had filed a motion to stay the remedial orders on October 30, 2023—just four days after the ITC issued its opinion finding a violation of Section 337 and accompanying remedial orders. On December 20, 2023, the ITC denied Apple's motion to stay.

On December 26, 2023, Apple filed two emergency motions with the Federal Circuit: one seeking a stay pending the outcome of the Federal Circuit appeal, and the other seeking “an immediate, interim stay” pending the court's ruling on the motion to stay pending appeal. The next day, in a highly unusual move, the Federal Circuit granted the interim stay of the remedial orders effective until the Federal Circuit issued its ruling on the motion to stay pending the outcome of the Federal Circuit Appeal.

On January 17, 2024, the Federal Circuit denied Apple's motion to stay pending the outcome of the Federal Circuit Appeal and lifted the temporary stay effective January 18, 2024. The Federal Circuit order did not analyze the relevant factors on the merits, but noted that the Court considered the governing legal test, as well as a recent decision from the U.S. Customs and Border Patrol's Exclusion Order Enforcement branch, which found that

redesigned Apple Watch products were outside the scope of the remedial orders—i.e., the Apple Watch redesigns can be imported while the Federal Circuit Appeal is pending.

5. **December 2023: The Commission's Partial Denial of Institution (Inv. No. 337-TA-1381).** In another unusual move in the final quarter of 2023, the ITC partially denied institution of certain causes of action alleged in the complaint in *Certain Disposable Vaporizer Devices and Components and Packaging Thereof* (Investigation No. 1381).

The complaint in the 1381 investigation was filed by the R.J. Reynolds Tobacco Company and R.J. Reynolds Vapor Company against more than two dozen respondents that sell tobacco vaping products. The complaint alleged solely non-patent claims for unfair competition, including claims based on false advertising and false designation of origin under the Lanham Act, violations of the Prevent All Cigarette Tracking Act (PACT), and violations of U.S. Customs laws and regulations. Though the ITC instituted the investigation, it rejected two types of causes of action alleged in the complaint.

First, ITC rejected causes of action based on alleged false statements that the accused products were authorized for sale under the Food, Drug, and Cosmetics Act (FDCA). The U.S. Food

and Drug Administration submitted a statement urging the Commission to deny institution of these claims—deemed the Authorization Claims—because allowing the Authorization Claims “would usurp” the FDA's enforcement authority under the FDCA. The Commission agreed and declined to institute the Authorization Claims.

Second, the ITC rejected causes of action based on alleged violations of Customs laws and regulation. Like the FDA, the U.S. Customs and Border Protection took the position that a private party lacked the right to pursue a cause of action based on alleged violations of Customs laws and regulations. The Commission agreed and declined to institute the claims based on violations of Customs laws and regulations.

Commissioners Kearns and Schmittlein both issued separate views.

Libbie DiMarco is an intellectual property litigator at Wolf Greenfield focusing her practice primarily on complex patent litigation in Federal District Court and before the US International Trade Commission (ITC). Libbie's experience covers all phases of litigation across a broad range of technologies, including data storage devices and systems, mobile and other electronic devices, chipsets, high-speed electrical connectors, printer cartridges, medical devices, and chemical products and processes.

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