Masimo Suit Highlights Potentially Abusive CBP Power

U.S. International Trade Commission; Limited Exclusion Order; Investigation No. 337-TA-1276; Certain Light-Based Physiological Measurement Devices and Components Thereof (Aug. 1, 2025)

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Parties that believe their U.S. patents are being infringed by products being imported into the United States can ask the U.S. International Trade Commission ("ITC") to bar importation of those products into the U.S. Masimo did that, via its 2021 complaint, when it asked the ITC to bar importation of Apple Watches that allegedly infringed its patents. After extensive discovery and an evidentiary hearing before an Administrative Law Judge in late 2022 to early 2023, which included weeks of testimony, cross-examinations, and briefing, the ITC determined there was infringement and issued a limited exclusion order ("LEO") barring importation of the infringing products. Thereafter, Apple "redesigned" its products and then asked U.S. Customs and Border Protection ("CBP"), not the ITC, to allow importation of the redesigned products, which it did. In response, Masimo filed a complaint in district court seeking to overturn the CBP's decision as procedurally improper. Notably, CBP could have reached the opposite determination and found that products never at issue in the ITC hearing were in violation of the LEO. Masimo's suit may determine the scope of CBP's authority in determining whether products not at issue in the ITC proceeding violate the exclusion order.

In August 2021, Masimo and Cercacor Laboratories filed a complaint in the ITC seeking a LEO prohibiting Apple from importing Apple Watches that allegedly infringed Masimo's pulse oximetry patents, which are used to determine a person's blood oxygen saturation by analyzing light absorption through tissue. In October 2023, the ITC found that Apple's Watches infringed Masimo's patents. On December 26, 2023, the ITC issued a LEO barring Apple from importing "wearable electronic devices with light-based pulse oximetry functionality." Apple then sought permission from the CBP to import "redesigned" watches with the blood oxygen feature disabled. In January 2024, the CBP allowed Apple to import its redesigned products.

In addition, Apple split the oximetry functions between the Apple Watch and iPhone. Apple then petitioned the CBP to also allow it to import watch-plus-phone combinations because, at the time of importation, no single device directly practiced the patented method. On August 1, 2025, without hearing from Masimo, CBP determined that there was no direct infringement at the time of importation by a single device and authorized Apple to import watch-plus-phone combinations. In response, Masimo filed a complaint in district court arguing 1) CBP's August 2025 ruling was arbitrary and unlawful under the Administrative Procedure Act because it reversed course without notice to Masimo; 2) CBP exceeded its authority by narrowing the ITC's exclusion order; and 3) CBP violated the Fifth Amendment's Due Process Clause via issuing an *ex parte* ruling without notice or an opportunity to be heard. The case is currently pending.

This case illustrates a potential problem with ITC litigation -- after extensive litigation and final determination by the ITC, the CBP, in an *ex parte* hearing, can use its own judgment and nullify the ITC's decision undermining the integrity of the ITC process. While in this case, the CBP reversed in favor of the manufacturer, the CBP, using the same procedure, could also reverse an ITC order to favor the patent holder by finding a later imported product to be infringing. Unless this type of action by the CBP is prohibited, both parties to an ITC action should be aware of this administrative maneuver, consider how it might affect their strategy, and what steps it might take when it happens.