

Analyzing the ITC's impending import ban on Apple watches

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DECEMBER 7, 2023

News of a patent infringement ruling against Apple Watches a few weeks ago caused a flurry of investor and consumer concern, just as holiday shopping commercials began creeping into TV and internet broadcasts. Specifically, the International Trade Commission (ITC) granted medical-device maker Masimo Corp.'s request for a complete ban on imports of Apple Watch models in Series 6, 7, 8, and 9.

Apple was found to infringe two claims each for two different asserted patents, which were upheld as valid and enforceable under the ITC's jurisdiction.

The ITC also granted Masimo's request for a cease and desist order against continued sales of Apple watches already in the country. Both measures go into effect starting on Christmas Day (unless the Biden administration intervenes on Apple's behalf or the parties reach a settlement agreement).

The best course of action for those seeking to give Apple Watches as Christmas gifts is to buy them between now and December 25. Gift card redemption or post-holiday exchanges may be complicated by the ITC's rulings.

By way of background, the ITC is a quasi-judicial government agency that investigates and holds trials involving intellectual property and international trade disputes. While the ITC cannot award royalties or other damages like a district court, it can control the importation of foreign-made goods that it determines to infringe United States patents or violate other intellectual property rights. That is exactly what the ITC decided to do here.

The litigation giving rise to these rulings was filed in June 2021. Complainant Masimo told the ITC that Respondent Apple first met with Masimo in 2013 about integrating Masimo's pulse oximetry technology into the Apple Watch. Pulse oximetry is a noninvasive method of using light to measure the saturation of oxygen in a person's blood. Oxygen saturation reflects how well the lungs are transmitting oxygen into the capillaries throughout the body. Blood

oxygen levels were a central focus of medical practitioners during the COVID-19 pandemic, as low blood oxygen levels were a primary indicator that a COVID infection could become fatal.

Masimo argued that, after its first meeting with Apple representatives, Apple subsequently "began hiring Masimo employees, starting with Masimo's Chief Medical Officer. In the Fall of 2020, Apple introduced the Series 6, manufactured in Asia." According to Masimo, that Apple watch and the next three watches in the series included Masimo-patented light-based pulse oximeters.

Apple countered that it did not infringe the asserted claims of Masimo's patents and attempted to distinguish the technology underlying its pulse-oximetry technology. Apple also argued that Masimo's asserted patent claims were invalid as obvious over the prior art.

During the presidential review period, the parties and any interested members of the public can submit statements to the White House arguing for or against presidential intervention on an import ban.

In January of 2023, following a full investigation and patent infringement trial in Washington, D.C., the judge presiding over the investigation issued an initial finding that Apple violated Section 337 of the Tariff Act of 1930 by importing and selling in the United States Apple Watches with light-based pulse oximetry technology that infringed two of the three asserted claims of one of Masimo's four asserted patents. *See In re Certain Light-Based Physiological Measurement Devices and Components Thereof, Inv. No. 337-TA-1276* (U.S.I.T.C. Jan. 10, 2023).

The judge upheld the validity of the asserted patents and confirmed the Commission's jurisdiction over the matter.

The initial determination of the judge presiding over the investigation then went to the full six-judge Commission for

review, part of the standard protocol at the ITC. On Oct. 26, 2023, the full Commission affirmed many of the findings in the initial determination, while reversing several others. The net result was that Apple was found to infringe two claims each for two different asserted patents, which were upheld as valid and enforceable under the ITC's jurisdiction. The Commission issued a limited exclusion order and cease and desist order against Apple. *See Certain Light-Based Physiological Measurement Devices*, Inv. No. 337-TA-1276 (U.S.I.T.C. Oct 26, 2023).

A limited exclusion order bars Apple from importing the infringing products into the United States. A cease and desist order precludes Apple from continuing to sell infringing products that were previously imported. Both orders go into effect on Dec. 25, 2023. The timing of the order is dictated by the statutory decision period for ITC orders and the 60-day "presidential review period" for remedies.

During the presidential review period, the parties and any interested members of the public can submit statements to the White House arguing for or against presidential intervention in an import ban. Ultimately, the purpose of the ITC is to protect domestic industry and the public health.

In its statement to the White House, Masimo argued that banning imports and sales of the Apple Watch would not harm public health or welfare because the Apple Watch blood oxygen measurements are unreliable and "that the inaccurate physiological measurements of the Series 6 watch endanger public health."

Masimo also observed that "two dozen academic institutions, leading antitrust and intellectual property scholars, physicians, investors, nonprofits, and members of Congress" filed comments

in support of the exclusion order. Masimo sells its own wearable device, the Masimo W1™, which it says is "the first wearable device on the market to provide consumers with accurate, continuous health data, including oxygen level, hydration index, and pulse, heart, and respiration rates."

On the other side, an Apple spokesperson stated in a Reuters Legal News article that "Masimo has wrongly attempted to use the ITC to keep a potentially lifesaving product from millions of U.S. consumers while making way for their own watch that copies Apple. While [the ITC's] decision has no immediate impact on sales of Apple Watch, we believe it should be reversed, and will continue our efforts to appeal." "US trade tribunal issues potential Apple Watch import ban in Masimo patent fight," Reuters Legal News, Oct. 27, 2023.

Apple can appeal the ban to the U.S. Court of Appeals for the Federal Circuit after the 60-day presidential review period. If President Biden declines to set aside the ITC's remedial orders, then, even if Apple ultimately prevails in its appeal, the ban will remain in place for the year or so that it typically takes an appeal to be briefed, argued, and decided by the Federal Circuit. While Apple may request that the ITC stay the enforcement of the ban pending appeal, the ITC rarely grants such requests.

Other options for Apple to continue making its watches available on the market post-Christmas include reaching a settlement agreement with Masimo, or removing the patented functionality from Apple watches bound for the U.S. border. There is no indication yet of progress on either option.

The writers are regular, joint contributing columnists on intellectual property law for Reuters Legal News and Westlaw Today.

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This article was first published on Reuters Legal News and Westlaw Today on December 7, 2023.