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November 15, 2023

The White House
1600 Pennsylvania Avenue, N.W.
Washington, DC 20500

Dear Mr. President,

On behalf of the Medical Device Manufacturers Association (MDMA), I write to urge you to uphold the decision by the United States International Trade Commission in Investigation No. 337-TA-1276 to impose an exclusion order on certain models of the Apple Watch that infringe on patents by Masimo for pulse oximetry.

MDMA is a national trade association that provides educational and advocacy assistance to innovative and entrepreneurial medical technology companies. Since 1992, MDMA has been the voice for medical technology innovation, playing a proactive role in helping to shape policies that impact the ecosystem.

In this case, the International Trade Commission found that Apple infringed at least two Masimo patents with certain models of the Apple Watch. The Commission issued a Limited Exclusion Order (LEO) as well as a cease-and-desist order to prohibit entry of the offending products into the United States.

According to court documents, Apple approached Masimo in 2013, seeking Masimo's medical technology for Apple products. Rather than acquiring Masimo or licensing its technology, Apple opted to recruit Masimo engineers and executives, and eventually released the infringing products subject to the Section 337 violation in this investigation.

Apple has a history of skirting patent protections, including in the medical technology space. Similar allegations have been made by AliveCor—in 337-TA-1266, which resulted in another finding of a Section 337 Violation by Apple. The infringement found was also by Apple Watches, but the infringing medical technology is different in each case. The use of Masimo's technology heightens this theft because Masimo is the leading pulse oximetry supplier to hospitals worldwide. Its technology has been shown to offer significant clinical benefits above other pulse oximeters and has proven to improve clinical outcomes.

Apple's conduct as alleged by Masimo, AliveCor and others indicates a pattern of "efficient infringement"—which has been described as "the use of another company's patents

without authorization on the understanding that litigation will be too slow to meaningfully stop the infringement and will ultimately only result in the payment of a royalty if the suit is lost. Apple's former patent chief stated that such a practice could be viewed as a "fiduciary responsibility" for "cash-rich firms that can afford to litigate without end." Apple subsequently repudiated these comments, but the conduct described above matches this Efficient Infringement strategy to curb competition. This strategy runs contrary to the public interest of protecting and enforcing intellectual property rights.

Any argument by Apple of the remedial orders should not be implemented due to the widespread purchasing and use of its infringing Apple Watch should be rejected and would cause grave harm to innovation and entrepreneurs. Apple is essentially arguing that if you can infringe in a huge manner, then you should escape the consequences. Such a policy would encourage infringement by large companies. And, intervening would send a loud message to those that import foreign infringing goods, that the United States is open to infringers.

MDMA strongly believes the public's interest in encouraging the investment in health technology innovation strongly outweighs any potential public interest in Apple's continued infringement of valid intellectual property rights. We believe that protecting intellectual property rights is particularly important in medical technology, where innovation has saved countless lives and improved the quality of life for countless others. For these reasons, and for the integrity of the United States patent system, we ask that you uphold the USITC's decision.

Sincerely,

A handwritten signature in dark ink, appearing to read "Mark H. Leahey", is written over a light blue horizontal line.

Mark Leahey
President and CEO
Medical Device Manufacturers Association

cc: Katherine Tai