June 5, 2023

Via Electronic Submission
Ronald A Traud, Esq
Office of the General Counsel
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

Re: Inv. No. 337-TA-1276

Dear Mr. Traud,

The Council for Innovation Promotion (C4IP) submits this response to the Commission's May 15, 2023 request for written submissions on the issues of remedy, the public interest, and bonding in the investigation cited above.

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. C4IP is a non-party in this case and takes no position on the substantive claims of the parties regarding infringement. C4IP has no financial interest related to the relief recommendations.

Should the Commission ultimately affirm the final initial determination by the Administrative Law Judge that Apple engaged in unfair trade practices by infringing on patents held by the American medical device manufacturer Masimo, we urge its members to take decisive action to remedy this infringement. We also agree that, in principle, an exclusion or "import ban" on the infringing products, as well as a cease-and-desist order directed to Apple, is the proper course of action.

Failure to impose such an exclusion would carry devastating consequences for the public interest -- specifically with regard to public and personal health, U.S. economic vitality, and American consumer interests. Strong, consistently-enforced patent protections are a basic

precondition for technological innovation in a wide range of areas, and especially in patent-intensive industries such as life sciences and medical devices. Such IP-driven innovation moves medical science forward, improves the quality of life for the American public, and spurs economic dynamism and job creation.

Some propose weakening vital IP protection through the adoption of certain broad categories of "exemptions" from exclusion orders on so-called public interest grounds. The proposed grounds for exemptions in this case include medical research, substitution availability, and repair and replacement of broken devices. While there may be instances where narrowly-tailored medical research exemptions make sense, the contention that these products must be made widely available on the market for research purposes raises numerous concerns. Rather than "tailoring" the remedy to accommodate urgent matters of public interest, their intention is plainly to allow the importation and profitable domestic sale of as many products containing illegally infringed IP for as long as possible. As the Commission clarifies and carefully examines these requests for exemptions, the evidence will show how ill-founded they are and that granting any of them would ultimately undermine the confidence in IP protection that drives future innovation in this country.

The sought-after exemption due to supposed requirements of medical research, for example, rests on studies currently underway -- or possibly arising in the future -- of the aggregated data collected from the devices. Proponents effectively embrace the view that infringing devices should continue to be imported because they increase the research sample size and because of vaguely-documented personal health benefits that individuals who purchase them may enjoy. The implication of an exemption on such questionable grounds is that makers of any product with even the slightest claim to a health benefit or a research concern can freely infringe without fear of exclusion.

Some contend that the Apple Watch is uniquely convenient for researchers as a data collection device and to wearers for purposes of monitoring health metrics. Yet if true, this convenience is due in no small part to the patents on which Apple has infringed. As the Commission is considering this exclusion order, it should exercise caution before granting any sort of research exemption. In particular, the Commission should question whether granting an exemption here would create a precedent that would incentivize device manufacturers to infringe in the future to gain the benefit of having a research exemption apply in their case, whether there are devices available on the domestic market that can act as a substitute (even if made by the accused infringer if made domestically), or whether there is an appropriately cabined scope of exemption that can be explicitly attested to by medical professionals to provide for ongoing research, without indiscriminately allowing for the sale or usage of an infringing medical device to provide for a pool of potential future research subjects. It would be especially problematic to create an exemption that allows broad use of infringing products imported into the United States under the guise of a medical research need, without clear evidence of a proportional medical or national necessity.

The question of convenience also goes to another matter on which the Commission has sought comment: substitution. Proponents of the medical research exemption themselves do not make the claim that the data they seek is available exclusively via the Apple Watch. Certainly Apple stands to gain a great deal from continued sales of imported infringing watches, especially at the trivial cost of making data collected from them available to researchers. The use of access to such a database to justify potentially perpetual infringement, especially when other sources are available, is untenable.

Other claims purport to show that consumers would lack access to a substitute for the Apple Watch. That Apple's product has a unique configuration is true -- in part due to Apple's

willingness to infringe. By implication, according to proponents of an exemption here, the infringement itself becomes an essential element of the exemption's justification.

Needless to say, Apple's ongoing ability under an exemption to sell an infringing import will also hinder further development of competing or even substitute products that do not infringe.

Another proposed avenue for exemption is for service and repair. That Apple has obligations to consumers in this regard is true. But patent infringers should have to live with the consequences of their violations. Replacing a broken or defective product with a new infringing import may be convenient for the infringing manufacturer, but the manufacturer has done nothing to merit this convenience.

It is the Commission's dual responsibility to protect the rights of patent holders and to help rights-holders seek relief and remedy when a violation has occurred. A trade exclusion is a powerful tool for achieving that end, and a proper remedy in this case if a violation is found.

For America's patent system to fulfill its function as an engine of innovation and prosperity, it is essential that IP rights be enforced firmly and consistently. This means that no product or company -- no matter how popular or ubiquitous -- can be permitted to abridge these rights without facing substantial repercussions, including the trade exclusion under consideration in this case.

Any attempt to carve out exemptions will only invite additional future infringements relying on similar exemptions. Adopting such carve-outs would also serve as an open invitation to other infringers to seek expansion of unfounded public-interest exemptions to other areas. This is a slippery slope in the weakening of IP protections essential to a fair, innovative and competitive economy. The Commission must reject efforts under the color of the "public interest" to protect the private interest of patent infringers.

Thank you again for the opportunity to comment.

Sincerely,

Frank Cullen

Executive Director

Council for Innovation Promotion (C4IP)