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July 23, 2024

The Honorable Jim Jordan
Chairman
House Committee on the Judiciary
2138 Rayburn House Building
Washington, DC 20515

The Honorable Jerrold Nadler
Ranking Member
House Committee on the Judiciary
2138 Rayburn House Building
Washington, DC 20515

The Honorable Darrell Issa
Chairman, Subcommittee on Courts,
Intellectual Property, and the Internet House
Committee on the Judiciary
2138 Rayburn House Building
Washington, DC 20515

The Honorable Henry C. “Hank” Johnson, Jr.
Ranking Member, Subcommittee on Courts,
Intellectual Property, and the Internet
House Committee on the Judiciary
2138 Rayburn House Building
Washington, DC 20515

RE: “Hearing: IP Litigation and the U.S. International Trade Commission”

On behalf of the Medical Device Manufacturers Association (MDMA), I am writing to submit comments supporting the U.S. International Trade Commission’s (ITC) critical role in protecting U.S. inventions from theft.

MDMA is a national trade association that provides educational and advocacy assistance to hundreds of innovative companies in the field of medical technology. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering breakthrough therapies to treat chronic diseases and life-threatening conditions while lowering the cost of care.

MDMA’s mission is to ensure that patients have timely access to the latest advancements of safe and effective medical technologies that improve health outcomes. The companies developing these treatments rely on strong intellectual property protections to attract capital to develop their technologies. The investment required to bring innovative technologies to market is enormous, involving not only a commitment to product development but also to clinical research, which is necessary to validate the safety and efficacy of medical technology.

The ITC serves an essential role in protecting American innovation and encouraging companies to pursue lifesaving medical solutions. An exclusion order and cease-and-desist order preventing infringing companies that manufacture overseas from importing and distributing products that rely on the infringed technology of U.S. companies’ innovation are the appropriate remedies. Without it, we will see an increase in “efficient infringement” and a decrease in innovation. This will have a dramatic impact on the smaller companies that do not have the resources to compete unless they can protect their innovations.

The U.S. patent system provides the protection companies need to lead the world in innovation. The enforcement of that patent system by the International Trade Commission (“ITC”) against entities that import products that infringe on American intellectual property is vital to upholding the principles of fairness that our patent system is based on. MDMA companies rely on the ITC to help them protect their technology from importations that threaten to disrupt domestic industries and undermine innovation in the medical device industry.

It is no surprise that companies that attack the validity and the constitutionality of the ITC are companies that have been found by the ITC to have infringed intellectual property rights. These attacks reflect the parties’ disdain for the ITC generally and the remedies Congress authorized under Section 337.

It was the original intent of Congress to delegate authority to the ITC. Through Section 337, Congress authorized the ITC to issue remedial orders to address infringement of United States intellectual property rights by imported articles. In 1988, Congress amended section 337 to strengthen the enforcement of intellectual property rights to block infringing importations.

The ITC does not award relief at law in the form of money damages. Rather, Congress properly assigned to the ITC, a non-Article III tribunal, the power to investigate and adjudicate whether importations amount to an unfair trade practice because the imported articles infringe intellectual property rights.

Statistics published by the ITC show that patentees, particularly nonpracticing entities, are *not* flocking to the ITC to circumvent the equitable factors set forth in the Supreme Court’s *eBay* decision.

Rather than focus on the evidence and the findings made by the ITC in specific investigations, these detractors take broad swipes at the ITC and attack its legitimacy. But these broad accusations are unfair and do not pass any scrutiny.

Complainants must make a detailed showing before the ITC institutes a Section 337 investigation. 19 C.F.R. § 210.12(a). That detailed showing includes a statement as to how the ITC’s remedial orders, such as an exclusion order, would be in the public interest. 19 C.F.R. § 210.8(b). Failure to make these showings at the outset would prevent any investigation from proceeding. After the ITC conducts a full investigation, finds infringement and a Section 337 violation, and considers the public interest factors, it is unsurprising the ITC routinely issues exclusion orders under the legal framework set out by Congress.

We need to stand united in protecting American innovation and the integrity of our patent system. It is what propels our nation forward. We need innovation to survive and thrive.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark H. Leahey", written over a light blue rectangular background.

Mark Leahey
President & CEO
Medical Device Manufacturers Association