



American Intellectual Property Law Association

May 3, 2023

Secretary
U.S. International Trade Commission
500 E Street, SW
Washington, D.C. 20436

Submitted via: *Commission's Electronic Document Information Systems*
(<https://edis.usitc.gov>)

**Re: Written Submission of the American Intellectual Property Law Association on
U.S. International Trade Commission Investigation No. 332-596
COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreements
Flexibilities**

Dear Commissioners:

The American Intellectual Property Law Association (AIPLA) is pleased to have the opportunity to submit comments in connection with the Commission's investigation of COVID-19 diagnostics and therapeutics in relation to the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

AIPLA is a national bar association of approximately 7,000 members that include professionals engaged in private or corporate practice, in government service, and in the academic community. AIPLA members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law, as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property (IP). Our mission includes helping to establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA strongly supports the equitable, widespread, and successful distribution of vaccines, medicines, diagnostics, personal protective equipment, and other measures in response to pandemics. Although not perfect, the global response of governments and businesses who researched, developed, tested, produced, and distributed vaccines and treatments, in response to COVID-19 has been extraordinary:

- More than 30 vaccines were developed and approved;
- Over 13 billion vaccine doses have been administered worldwide; and
- A host of therapies and treatments were developed and deployed.

AIPLA submits that predictable and stable IP rights throughout the world facilitated this unprecedented achievement. They encouraged the necessary investment, enabling innovators

to collaborate and share resources, technical know-how and knowledge required to counter the pandemic.

The International Trade Representative's request to the Commission to investigate may be based on the assumptions that local manufacturing is required and IP rights impede it. AIPLA strongly disagrees with these assumptions.

First, AIPLA is aware of no data that patents or other IP rights have hindered or in any way impeded the development or delivery of COVID-19 vaccines, therapies, or diagnostics. Quite the contrary. Proprietary technologies made them each possible in record time.

Second, the possibility of waiving TRIPS compliance by impairing IP rights, even temporarily, fosters unpredictability and undermines trust and confidence in intellectual property rights. Even were local manufacture considered a viable goal, the technology, know-how, and infrastructure required to enable local manufacture of sophisticated vaccines, therapies, and diagnostics goes far beyond the scope of patents. And the impairment of IP rights would reduce or eliminate incentives to assist and collaborate in the transfer of the required technologies, know-how, and infrastructure.

IP rights provide the foundation of the trust required for innovative businesses to invest resources and share with partners. Weakening or impairing IP protection would increase, rather than decrease, barriers to the creation and distribution of safe and effective pandemic countermeasures.

The experience of our members and their clients confirms that IP rights enhance innovation and manufacturing; weakening these rights would undermine these efforts and the ability to respond to future pandemics.

Further, an unintended consequence of IP waivers may be the increased threat of ineffective, unsafe, and/or poor-quality vaccines, therapies, and diagnostics because the parties producing them lack the requisite expertise or resources.

AIPLA, therefore, urges the Commission to focus on identifying the business and technical challenges that may continue to exist to the successful development and distribution of COVID-19 vaccines, therapies, and diagnostics. A fact-based report by the Commission, supported by evidence, will enable policymakers to develop solutions tailored to overcome these challenges.

We appreciate the opportunity to participate in the Commission's investigation of this important issue. We welcome the opportunity to provide any additional information that the Commission might find helpful.

Sincerely,

A handwritten signature in blue ink, appearing to read "B. Batzli", with a stylized flourish extending from the end.

Brian H. Batzli
President
American Intellectual Property Law Association