September 26, 2024

Via Electronic Submission
The Honorable Katherine K. Vidal
Under Secretary of Commerce for Intellectual Property and Director
of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Re: Docket No. PTO-C-2024-0023, Experimental Use Exception Request for Comments

Dear Director Vidal,

The Council for Innovation Promotion (C4IP) is pleased to submit this response to the June 28, 2024, Experimental Use Exception Request for Comments (Docket No. PTO-C-2024-0023), which seeks input on the current state of the law regarding the experimental use of patented inventions and whether the U.S. Patent and Trademark Office should recommend codification of an exception directed to that use.[1]

C4IP is a bipartisan coalition dedicated to promoting strong and effective intellectual property rights that drive innovation, boost economic competitiveness, and improve lives everywhere. Founded and chaired by former directors of the U.S. Patent and Trademark Office (USPTO) from previous Democratic and Republican administrations, our nonprofit organization aims to be a valued partner to those considering policies impacting America's intellectual property system.

Currently, C4IP is not aware of a widespread problem of basic, experimental research being subject to patent infringement allegations or lawsuits and understands that a primary purpose of this RFC is to obtain more information on this topic. This information-gathering exercise, along with other public opportunities for debate and comments, such as USPTO-hosted roundtables or Congressional hearings, are sensible steps that must be taken before deciding an appropriate path forward, particularly concerning whether legislation is needed.

[1] USPTO, Experimental Use Exception Request for Comments, 89 Fed. Reg. 53963 (June 28, 2024), https://www.federalregister.gov/documents/2024/06/28/2024-14164/experimental-use-exception-request-for-comments.

C4IP believes that some experimental use exception of an appropriately limited scope furthers the aims of patent law to incentivize innovation by taking advantage of the public disclosure requirement for obtaining a patent while ensuring proper remuneration to the inventor or inventors for any uses outside of this appropriately cabined scope. The desirability of such an exemption was also recognized by a wide-ranging report on patent law by the National Academies of Sciences in 2004 and by an explicit statutory exemption in the Plant Variety Protection Act.[2] Of course, the Federal Circuit, in the leading case of *Madey v. Duke University*, endorsed a common law version of this exception for utility patents.[3] This case-law-based approach may already sufficiently address the concerns outlined above.

Regarding codification of such an exception, as the National Academies wrote, "designing a targeted solution is an altogether more difficult matter than deciding whether one is needed."[4] In particular, a statutory provision would need to be drafted to avoid disincentivizing the research and development of research tools themselves, which can be resource-intensive to create but invaluable in fostering and accelerating further research. Indeed, while there are few lower court case law after *Madey* addressing this issue, whether use of a research tool is infringing or only "an experimental use" has arisen, suggesting this is likely to be a flashpoint that a statute would have to address carefully.[5]

The current common law experimental use exception is also appropriately skeptical of uses that may occur under the "guise of scientific inquiry" but which have "definite, cognizable, and not insubstantial commercial purposes."[6] Drafting a statutory test that strikes the right balance of determining when a use is experimental versus when it becomes a prelude to or a pretext for commercialization would presumably be one of the more difficult challenges. While true experimental use should not be hindered, neither should adequate protection for true innovators be unduly weakened, especially given that successful inventions are exactly the ones that others will want to copy. If the USPTO decides to recommend codification,

[2] National Academies of Sciences, Engineering, and Medicine, *A Patent System for the 21st Century* 110 (2004) https://doi.org/10.17226/10976 [hereinafter, "National Academies Report"]; Plant Variety Protection Act, Pub. L. 91-577, § 114, 84 Stat. 1542 (1970) ("The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an act of infringement of the protection provided under this Act."), https://www.congress.gov/91/statute/STATUTE-84/STATUTE-84-Pg1542.pdf.

[3] 307 F.3d 1351, 1362 (Fed Cir 2002) (providing that the exception applies "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry").

[4] National Academies Report, *supra* note 2, at 110.

[5] Third Wave Techs., Inc. v. Stratagene Corp., 381 F. Supp. 2d 891 (W.D. Wis. 2005); Applera Corp. v. MJ Research Inc., 311 F. Supp. 2d 293 (D. Conn. 2004).

[6] *Madey*, 307 F.3d at 362 (quoting Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000)).

or Congress turns its attention to this issue, we urge caution and deliberation so that a statutory exception does not overwhelm the protection a patent affords to inventors.

* * *

Ensuring the proper balance in our intellectual property laws is a constant undertaking, and C4IP appreciates the Office's attention to this issue. We stand ready to provide any further input that may be requested.

Sincerely,

Frank Cullen
Executive Director
Council for Innovation Promotion (C4IP)