AIPLA
American Intellectual Property Law Association

September 26, 2024

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U.S. Patent and Trademark Office
P.O. Box 1450, Alexandria, VA 22313–1450.

Re: PTO–C–2024–0023

Via Federal Rulemaking Portal at https://www.regulations.gov

RE: Comments on Experimental Use Exception (EUE) Request for Comments (89 Fed. Reg. 53963, June 28, 2024; Request) due September 26, 2024

Dear Sir/Madam:

The American Intellectual Property Law Association ("AIPLA") is pleased to have the opportunity to reply to the Experimental Use Exceptions Request for Comments (the "Request") from the United States Patent and Trademark Office ("USPTO" or "Office").

AIPLA is a national bar association of approximately 7,000 members that include patent attorneys, patent agents, and other IP 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 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.

The Request

The United States Patent and Trademark Office (USPTO) via its Office of Policy and International Affairs ("OPIA") is interested in "collecting the public's views on the current state of the common law experimental use exception and whether legislative action should be considered to enact a statutory experimental use exception."[1]

[1] Request at 56963, col. 1.

The time-limited exclusivity on patented technology as currently provided by statute is the *quid pro quo* for inventors to share the details of their inventions with the public. This does not mean, however, that there is no latitude for limited public use of a patented invention during its enforceable term.

Although the U.S. does not currently have a statutory research or experimental use exemption *per se*, the infringement statute does carve out certain acts as noninfringing, or if infringing, as acceptable. For example, 35 U.S.C. §271 provides, among other things, protection for acts performed while preparing a submission to a regulatory agency and shields physicians from certain acts of infringement when providing medical treatments.[2] This limited exception is designed to facilitate public access to medicines.

Historically the United States has recognized a "common law" research exemption that shielded certain academic pursuits. Recent case law has, however, limited the impact of the experimental use exception. Most notably, in *Madey v. Duke University*,[3] the Court of Appeals for the Federal Circuit ruled that the experimental use exception does not apply to a university's use of a patented invention in laboratory research. The court noted that acts may not be entitled to the experimental use defense if they are done "'in the guise of scientific inquiry but [have] definite cognizable and not insubstantial commercial purposes.'"[4]

Thus, a university professor conducting academic research may not qualify for an experimental use exception, and risks being sued for patent infringement for conducting an experiment in the university laboratory.[5]

AIPLA's Positions and Observations

1. In principle, AIPLA supports legislation to codify a narrow statutory experimental use exception ("EUE") under which uses of a claimed invention related to scientific, research, or experimental inquiries may be excepted from the consequences of acts of infringement.

2. AIPLA acknowledges the premise that exclusive reliance on the current common law EUE jurisprudence may not provide stakeholders a sufficiently defined and understood EUE.

   Although limited by case law, common law nominally provides for philosophical investigations and analyses, however the boundary of such excepted experimentation is unclear. Courts must determine on a case-by-case basis the nature of any infringing activity and then, without statutory guidance, conclude whether such activity falls within the scope of common law exceptions. Therefore, implementation of a statutory EUE, if carefully crafted, could provide more certainty as to the boundaries of acceptable experimental uses.

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[2] See also Russo AA, Johnson J. Research use exemptions to patent infringement for drug discovery and development in the United States. Cold Spring Harb Perspect Med. 2014 Oct 30;5(2):a020933. doi: 10.1101/cshperspect.a020933. PMID: 25359549; PMCID: PMC4315915.
[3] 307 F.3d 1351 (Fed. Cir. 2002).
[4] *Id*. at 1362 (quoting *Embrex, Inc. v. Service Engineering Corp*., 216 F.3d 1343, 1349 (Fed. Cir. 2000)).
[5] See also 331 F.3d 860, 874-75 (Fed. Cir. 2003) (Newman, J. concurring in part and dissenting in part), vacated by *Merck KGaA v. Integra Lifesciences I, Ltd.,* 545 U.S. 193 (2005) and *Whittemore v. Cutter,* 29 Fed. Cas. 1120, 1121 (C.C.D.Mass.1813) (No. 17,600).

3. Any statutory EUE must establish clearly articulated boundaries. For example, uncertainty regarding experimental use exceptions can negatively affect the purchasing decisions of researchers when it comes to procuring patented or potentially patented materials needed for experiments. In theory, researchers may be hesitant to buy patented materials, tools, or kits, fearing that their use may be deemed infringing, rather than qualifying for an experimental use exception if, for example, some noted commercial result is later derived from such use.

4. AIPLA notes that in crafting a statutory EUE, the nature of the underlying invention must be considered. For example, a patented research tool used for its intended purpose should not be excepted.

5. Uncertainty in the boundaries of experimental use exceptions may affect the decisions patentees make regarding maintaining and managing patent applications and patents. For example, patent holders may be unsure about the extent to which their own patents are exposed to the limitations of experimental use exceptions, resulting in uncertainty about the value of the patent and whether to continue to maintain the patent.

6. A well-crafted, relatively narrow, statutory experimental use exception may promote technology licensing by creating incentives for both the patent owner and anyone seeking the benefit of an EUE as an "experimenter" or "researcher" to avoid costly litigation in lieu of a relatively low licensing rate tailored to the activities in question.

   Thus, while AIPLA could support a narrow statutory experimental use exception, we urge that any such exceptions be narrowly focused to allow basic research without limiting a patentee's ability to enforce their patent against infringing activities.

7. Legal uncertainties in experimental use exceptions to patent infringement can have significant impacts on various aspects of fundamental research endeavors. Basic scientific research, uncoupled from commercial interest might be permissible even while such research could be *per se* patent infringement.

8. An experimental use exception should not supersede a finding of infringement; rather, it should provide an affirmative defense against damages. Any statutory language should provide for courts to continue to administer this jurisprudence – each infringement situation is highly fact dependent.

9. AIPLA is concerned that the absence of an experimental use exception in the United States could have a negative impact on research and development in all fields of technology because it puts many forms of research at risk for patent infringement. For example, the standard set forth in the *Madey v. Duke University*[6] decision means that a researcher is at risk of patent infringement anytime the patented subject matter in an experiment is practiced, solely for the purposes of studying the patented subject matter, or for seeking an improvement or alternative to the patented technology.

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[6] *Madey v. Duke University* 307 F.3d 1351 (Fed. Cir. 2002). "In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense."

10. Regarding global experimental use exceptions, the differences between current EUE jurisprudence in the U.S. and experimental use exceptions in the rest of the world puts researchers in the U.S. at a disadvantage relative to those in other countries. Researchers in many jurisdictions rely on an experimental use exception.[7]

11. AIPLA urges that, at its core, any statutory experimental use exception should be an affirmative defense based on the circumstances surrounding an alleged infringing activity. Thus, at a minimum, a two-step inquiry might be established.

    First, a finder of fact would determine that an enforceable patent exists, and that infringement has occurred. Second, an evidence-based approach would be followed to determine whether an infringer was engaging in mere experimental use of the patented invention. If so, this could serve as an affirmative defense against the consequences, such as monetary damages, of such infringing activities.

12. Regarding specific language that could be considered in crafting a statutory EUE, the following language is an example of starting principles or concepts that could be considered for an affirmative defense to patent infringement.

    Consider, for example, whether a statutory EUE should be available to allow persons to:

    a. determine the validity of the patent and the scope of protection afforded under the patent;

    b. determine features, properties, inherent characteristics or advantages of the patented subject matter;

    c. develop or refine methods of making or using the patented subject matter solely for non-commercial research purposes; or

    d. identify or develop alternatives to the patented subject matter, improvements thereto, or substitutes therefore;

    where such affirmative defense would not apply to any such methods, alternatives, improvements, or substitutes that are subsequently made, used, sold, offered for sale, or otherwise exploited through licensing, sales, transfers, assignments, or other similar transactions that are not likewise limited to research or experimental use.

    The above cited acts could be affirmative defenses against infringement consequences. These issues are complex, however, and the crafting of a statutory EUE should be done thoughtfully and with careful consideration of the potential impact of the language on all stakeholders.

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[7] The World Intellectual Property Organization has recognized the prevalence of experimental use exception to infringement. "Today, . . . statutory exceptions have become more common. For example, "exhaustion" in some form or other, and 'prior use' now appear explicitly in the laws of many countries. But other exceptions, such as experimental use . . . is now the most widespread exception." WIPO Standing Committee on the Law of Patents (SCP), "Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights," 2010, SCP/15/3, Annex I, page 29, available at https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf. See also, WIPO SCP, SCP/20/4, "Exceptions and Limitations To Patent Rights: Experimental Use and/or Scientific Research," 2013, available at https://www.wipo.int/edocs/mdocs/patent_policy/en/scp_20/scp_20_4.pdf.

Summary and Conclusion

A statutory experimental use exception that clearly articulates permissible experimental uses of a patented invention, while also clearly defining the limits of such experimental uses may better promote important scientific research.

As noted by the U.S. Court of Appeals for the Federal Circuit, patenting does not deprive the public of the right to experiment with and improve upon the patented subject matter. It is not necessary to wait for the patent to expire before the knowledge contained in the patent can be touched.[8]

AIPLA appreciates the opportunity to comment on the Request. We would be happy to discuss any of the above comments or provide additional detail if desired.

Thank you,

Ann M. Mueting
President
American Intellectual Property Law Association

[8] In re Rosuvastatin Calcium Patent Litigation, 703 F.3d 511, 527 (Fed. Cir. 2012).