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Christian Hannon, Senior Patent Attorney,
Office of Policy and International Affairs (OPIA)
U.S. Patent and Trademark Office,
Alexandria, VA 22313-1450

RE: Experimental Use Patent Exception, Patent and Trademark Office, Docket No.: PTO-C-2024-0023, Document Citation: 89 FR 53963

Dear Christian Hannon,

This is a response on behalf of Knowledge Ecology International (KEI) to the U.S.P.T.O. request for comments regarding a possible statutory experimental use exception.

The United States should have a statutory experimental use exception to patent rights. Patent rights should not extend to making and using inventions for the purpose of research and experimental uses, but rather for the commercial use of inventions.

To some extent, researchers in the United States have benefited from the 1999 decision of the U.S. Supreme Court that state institutions cannot be sued for patent infringement (under the doctrine of state sovereign immunity [*Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank, 527 U.S. 627, 637 (1999)*]), from the practice of the U.S. government to include research provisions in some federal patent licenses and to use FAR 52.227-1 authorization and consent clause in federal contracts, and from the so called “Bolar” amendment [35 U.S.C. § 271(e)(1)], which provides for the experimental use of a patented invention to collect regulatory approval data for medical devices or drugs. These limited flexibilities are not sufficient.

- The scope of state sovereign immunity from patent infringement could be narrowed or eliminated by a future court decision, and only applies to state government entities. The 1999 decision was decided by a slim 5-4 majority, and Justice Thomas is the only member from then still serving on the court.

- Damages under FAR 52.227-1 authorization and consent are uncertain, and the federal government is reluctant to extend the authorization and consent beyond areas of its core functions.

- The statutory exception in 35 U.S.C. § 271(e)(1) is irrelevant for many important areas of innovation.

A new statutory exception should not be limited to products that require a regulatory approval, since that is only a small fraction of innovative activity that is important. Likewise the exception should not be limited to uses by governments or non-profit entities (such as the public universities benefiting from state sovereign immunity doctrine), given the importance of non-government and for-profit entities and individuals in research and development. Harvard and Microsoft should both benefit from a statutory research exception.

One reason to adopt a statutory research exception for patents is the explosive rise of artificial intelligence (AI) services. Not only do these services need to be trained on lots of data, including patent applications, but generative AI presents the likelihood of a flood of new patent applications, making it more and more problematic to do anything without risking an infringement claim.

In fashioning a statutory research exception, the federal government can rely upon the space for limited exceptions to patent rights in Article 30 of the TRIPS Agreement, as well as the ability to limit the remedies for infringement in Part III of the TRIPS. The limitation on remedies for patent infringement in a FAR 52.227-1 authorization and consent clause are allowed under Article 44.2 of TRIPS.

The Federal Register notice provides a useful review of state practice outside of the United States, including examples of legislative language to define the scope of the exception. KEI encourages USPTO to also explore the room for limitations on the remedies for infringement in Part III of TRIPS, particularly if a remunerative right of use for inventions is appropriate for some situations.

Sincerely,

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