## THE REGENTS OF THE UNIVERSITY OF CALIFORNIA OFFICE OF THE GENERAL COUNSEL



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November 7, 2011

U.S. Patent and Trademark Office Mail Stop OPEA, P.O. Box 1450 Alexandria, VA 22313-1450 ATTN: Elizabeth Shaw

## Re: Prior User Rights Written Comments

Dear Ms. Shaw:

The University of California thanks the U.S. Patent and Trademark Office for an opportunity to comment on prior user rights as it may be applied in the United States.

As research institutions that discover new technologies, universities patent and license university discoveries to companies since universities do not commercially develop and manufacture products directly. Universities seek patent protection as it provides an incentive for these industrial partners to invest in university technologies. Before significant investment, such as a new drug that needs FDA approval, however, companies evaluate and need to be assured of as objectively ascertainable, dependable protection as reasonably possible. The patent file history in the U.S. Patent and Trademark Office and any other prior art searches of publically available information provide such objectively available sources of information. These evaluations for strong, dependable protection are especially important to start-up companies (and their venture capital backers) who have not yet established themselves in the marketplace.

Applying a newly expanded legal doctrine, such as prior user rights that rewards a prospective competitor that has chosen to keep relevant information as trade secrets, limits the objectively available information to a prospective licensee or its investors. Small businesses are particularly vulnerable to the adverse effects that increased uncertainty may have on their funding due to having to go through multiple rounds of investment at various times.

The newly expanded reach of prior user rights in the America Invents Act (AIA) runs counter to the policy favoring disclosure of new developments underlying the patent system and already represents a disincentive to invest in new technology for a university's prospective licensees and their investors. The new law creates added uncertainty due to new interpretations of what the

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law means that will likely arise during its implementation. Uncertainty favors well-financed parties who can stretch out litigation based upon that uncertainty, regardless of the actual merits of the defense in that particular case.

In the foreign law study that the U.S. Patent and Trademark Office is conducting, the University of California recommends an emphasis on studying the application of prior user rights in Germany since a German attorney has advised the University that German courts interpret prior user rights narrowly, permitting only use of the specific embodiment of the invention that the prior user had been using at the date of priority. The attorney notes that German prior user rights cannot be expanded to any further developments of the patented subject matter that are still covered by the inventive teaching, and that the prior use right strictly refers to the needs of the company owned by the prior user. While the defense extends to affiliates and assigns, the scope of the defense does not expand into other businesses beyond activity measured as described above. Also, the firm notes that "making substantial preparation to commercialize" is not a part of German prior user rights law.

Accordingly, the University of California recommends that before any further attempts to amend the prior user rights law, the current expansion of prior user rights under the AIA should be interpreted in the courts to lessen the investment-inhibiting, new uncertainty in the protection that U.S. patents provide. In particular, there should be no new further expansion that would add to the uncertainty, for example, introducing indefinite concepts such as "make substantial preparation to commercialize."

Once again, thank you for your invitation to comment.

Sincerely,

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P. Martin Simpson, Jr. Managing Counsel