

# AMP opposes exclusive licensing of NIH proteomics patent

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The Association for Molecular Pathology (AMP) opposed the National Institutes of Health (NIH) proposal to exclusively license the subject matter of a cancer-related proteomics patent application filed by the Agency. AMP's written remarks were submitted to NIH in response to a request for comments in the Federal Register Notice entitled, "Prospective Grant of Exclusive License: The Development of a Companion Diagnostic Kit for Predicting Therapeutic Efficacy of Anti-Cancer Agents." The proposed license grants exclusive worldwide rights to use the relationships between levels of three proteins, PTEN, Akt, and mTOR and cancers of the breast, lung, and kidney. Under the terms of the prospective agreement, the licensor could provide laboratory test services and/or sell test kits.

"The submitted patent application encompasses essentially all methods and techniques that allow practical use of the claimed biological relationships. The breadth of this patent application renders exclusive licensing of even a subset of the protein–cancer associations claimed contrary to the public interest," stated Roger D. Klein, MD, JD, Chair of the AMP Professional Relations Committee. "No one company should be permitted to monopolize medical information in this way."

In its comments, AMP set forth the reasons the organization believes NIH's proposed exclusive [license](#) fails to meet the regulatory constraints on exclusive licensing of federally owned inventions as set forth in 35 U.S.C. 209(a) and 37 C.F.R. 404.737 C.F.R. 404.7. According to U.S. law, such a license must serve the best interests of the public; must be a

"reasonable and necessary" incentive for the attraction of investments required to bring the invention to practical application; and must not lessen competition. Further, practical application of the invention must be unlikely under a nonexclusive license, and the scope of exclusivity cannot be broader than is necessary to bring the invention to practical application. AMP believes the proposed license does not meet any of these criteria.

"This patent application claims a virtually unlimited swathe of protein diagnostics, dramatically inhibiting the growth of potential diagnostic assays and methods, while substantially increasing the costs of and decreasing patient access to those tests that do manage to enter medical practice. By granting an exclusive license for any of the protein-cancer relationships claimed in this [patent application](#), NIH would stifle the practice of medicine, limit patients' access to second opinion tests and discourage innovation in this area," added Dr. Klein.

As a general principle, AMP opposes exclusive licensing of patents on governmental inventions that do not clearly advance the public interest. AMP believes that such licenses, in the rare circumstances in which they are granted, should be narrowly targeted and not reach beyond the extent necessary to ensure commercialization. Importantly, for inventions in which clinical laboratory testing is potentially impacted, sublicenses for confirmatory testing that include reasonable royalty rates and the right to use alternative test methodologies should generally be mandated.

Provided by Association for Molecular Pathology

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