

**PATENT COORDINATORS
CONTRACT AND GRANT OFFICERS
VICE CHANCELLORS - RESEARCH/ADMINISTRATION**

SUBJECT: Standing Exception to American Cancer Society (ACS) Patent Policy for University of California

Background

The American Cancer Society (ACS) has issued several versions of its patent policy over the years, each of which contains identical patent provisions that are not desirable to the University of California. This ACS patent language includes licensing restrictions and march-in rights (discussed below) that seriously compromise the University's ability to license the results of ACS-funded research. The OTT recently completed negotiations with ACS that resulted in a standing exception to ACS policy, approved by Ms. April Savoy-Lewis on July 30, 1998 (see Enclosure 1), which eliminates the licensing restrictions and relaxes the march-in rights by ACS.

Licensing Restrictions

The ACS policy language states:

"...the grantee will not grant an exclusive license under such patent to any for-profit person or organization for a period to exceed ten (10) years without written permission of the Society."

This provision was problematic because limiting an exclusive license to ten years is, in most cases, insufficient time to allow the licensee to fully develop the technology for the public benefit and recover its substantial investment in the marketplace (see Enclosure 2 for further discussion of this issue). Most potential licensees would not be willing to accept such a time limitation on their licenses.

ACS appreciates University's concerns regarding this issue and has agreed to a standing exception that replaces the above language with the following:

"...ACS grants to UC the discretion to give an exclusive license to any for-profit or organization as it deems appropriate for the greater public benefit."

March-In Rights

The ACS policy language states:

"If, after a reasonable period which in no case shall be less than two years, the not-for-profit institution, its grantee or licensee, has not brought the patented invention to practical application, the Society shall have the right: (a) to require justification on the part of the patent holder for this

failure or alternatively, (b) to require the not-for-profit institution, its assignee or licensee to grant a non-exclusive, partially exclusive or exclusive license to a responsible applicant, upon reasonable terms, and if such a request is refused, the Society reserves the right to grant such a license itself."

OTT's experience in licensing technologies is that companies must invest significant resources to develop a commercial product. A commercial entity wants a guarantee that its license will not be inappropriately terminated or reduced to a nonexclusive license. In addition, potential licensees are reluctant to accept a licensing agreement whereby ACS can second-guess both the licensee's and University's judgment on diligent commercial development and terminate the license (see Enclosure 2 for further discussion of this issue).

ACS appreciates University's concerns regarding this issue and has agreed to a standing exception to ACS policy that replaces the above language with the following:

"UC agrees that when it licenses any invention or intellectual property developed under ACS funding to a third party for commercialization that it will include provisions in the license to obligate the licensee to commercialize the technology in a diligent manner, and to include specific diligence requirements and milestones. UC will be responsible for monitoring such diligence provisions, and in the event that the licensee has failed to commercialize the technology in accordance with such diligence provisions, UC shall have the right to either terminate the license or convert an exclusive license to a non-exclusive license so that it may seek other licensees.

"UC shall provide to ACS copies of the diligence/milestone provisions of any executed license agreement relating to any ACS-funded technologies, and by February 1 of each year, an annual, confidential report regarding the status of the licensing and/or commercialization of such technologies. ACS understands that this information is to be handled in strict confidence and will not be disclosed to any third party without the prior written consent from UC. If ACS does not receive such an annual report within two consecutive years, and the licensee has not brought the patented invention to practical application in accordance with the diligence requirements and milestones as specified in the license agreement or any amendment thereof, then ACS retains the right: (a) to require immediate submission of the delinquent annual report, (b) to require the not-for-profit institution, its assignee or licensee to grant a non-exclusive, partially exclusive or exclusive license to a responsible applicant, upon reasonable terms, and if such a request is refused, the ACS reserves the right to grant such a license itself."

This revision to ACS patent policy should not be threatening to a potential licensee. As is the University's standard practice, a licensee would be required by the license agreement to bring the invention to "practical application" in accordance with diligence and milestone requirements of the license. This revision to ACS policy replaces ACS' judgment of diligent commercial development of the technology with a simple annual commercialization reporting obligation on the part of the University. Only in those circumstances where there is both a failure by the licensee to diligently commercialize the technology and a failure by the University to submit the annual report within two consecutive years would ACS retain march-in rights.

Disclosing Intellectual Property and Maintaining Reporting Requirements

Pursuant to the ACS policy language, the University has an obligation to report to ACS all inventions that arise from its sponsorship. ACS policy language states "copies of any patent application, invention disclosure and other pertinent material should be filed with the Society at the time the patenting process is commenced." This initial invention reporting requirement to ACS will be handled by the authorized licensing offices (UCB, UCI, UCLA, UCSD, UCSF, and OTT) at the time a patent application has been authorized for the ACS-funded invention.

As noted in the march-in rights discussion above, the University is required to provide ACS with an annual report, including copies of milestone and diligence requirements, by February 1 of each year. To achieve consistent reporting to ACS, a systemwide annual report to ACS will be coordinated by OTT. This report may be developed by OTT, in conjunction with the authorized licensing offices. If an authorized licensing office wishes to develop its own report, OTT can prompt the office prior to the due date of the report and provide guidance, as necessary.

Accepting ACS Awards

This standing exception applies to all active and future ACS-funded invention cases and awards to the University. Contract and Grant Officers should include the following sentence in all acceptance letters for ACS-funded awards:

"This award is subject to the standing exception to ACS patent policies approved by Ms. April Savoy-Lewis, Assistant Corporation Counsel of the American Cancer Society, on July 30, 1998."

If you have any questions concerning ACS patent policies or the management of inventions involving ACS support, please call M. Jeremy Trybulski.

Refer questions to: M. Jeremy Trybulski
(510) 587-6061
jeremy.trybulski@ucop.edu

Sincerely,



Joe Acanfora
Associate Director

Enclosures: 1. July 30, 1998 letter from Savoy-Lewis (ACS) to Trybulski
2. July 6, 1998 letter from Trybulski to Dalton (ACS)

cc: OTT Associate Directors and Managers