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UNIVERSITY RESEARCH RELATIONSHIPS**

Author: COGR

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COGR TALKING POINTS ON INTELLECTUAL PROPERTY ISSUES IN VA/UNIVERSITY RESEARCH RELATIONSHIPS

The VA and its university affiliates have enjoyed a long standing, harmonious research and clinical relationship that in numerous ways has benefited the public. This relationship began to experience some strains in 1999 when the VA changed its policy on intellectual property generated in the course of research cooperation with universities. Previously the VA typically had assigned ownership and management of intellectual property to its university affiliates. However, in 1999 the VA began to assert its rights to own and manage the intellectual property. The ramifications arising from this policy change were not appropriately anticipated and addressed by the VA with affiliated institutions. Several significant issues remain unresolved and are discussed below. The biggest problem is the current uncertainty regarding the ownership of intellectual property and the ability of the universities to commercialize the technology.

- The VA has stated that it views academic affiliations as critical to its mission and recognizes the need to work constructively with universities to attain common goals and objectives. However, the VA also has stated that it is seeking greater public recognition and to increase its funding base through aggressive pursuit of intellectual property generated by VA research, including VA-university collaborations and joint appointment situations. This has created problems in determinations and negotiations of intellectual property rights, and led to tensions between the VA and universities.
- Increasingly the VA has been issuing Determination of Rights (DORs) claiming the entire right, title and interest to inventions made by university employees who collaborate with VA employees and/or who have dual appointments with the university and the VA. Standards followed by VA for these determinations are unclear, although they concede that “entire right” may be too broad. However, the official DORs still need to be corrected. The result is uncertainty about the university’s right to the invention, including under the Bayh-Dole Act. There also are university concerns that the lack of timeliness, as well as notification to the universities, of DORs interfere with the ability of universities to commercialize inventions (the VA has just amended its Privacy Act regulations to allow disclosure of DORs to university partners as a “routine use”).
- Dual appointment situations (i.e. researchers with joint employment relationships with both a university and the VA) create special challenges. Where such employees have a “without (salary) compensation (WOC)” appointment with the VA, the Department of Commerce (which has jurisdiction to resolve Bayh-Dole Act rights disputes) recently has determined in several cases that the WOC employees are *not* VA employees for purposes of VA ownership rights to intellectual property. Commerce also stated that the VA’s position is inconsistent with the WOC inventors’ obligations “to assign to the university and the university’s right to own the invention pursuant to the Bayh-Dole Act.” The VA still has asserted that WOC employees are required to disclose inventions to the VA, and is considering asking Commerce to reconsider its rulings or requiring WOC employees to execute agreements assigning ownership rights to the VA. The VA also has threatened to seek “legislative solutions” to this situation.

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- The VA has developed “Cooperative Technology Administration Agreements” (CTAAs) (also called Inter-Institutional Agreements (IIAs)) for use with its university partners. The VA claims these agreements provide for equitable treatment of university rights and fair sharing of revenues and expenses. These agreements currently cover 13 of the VA’s academic affiliates. The VA Agreements are based on the premise of co-ownership of inventions and do not clearly recognize university Bayh-Dole Act rights, although they purport to “authorize” universities to have the exclusive right to prepare, file, prosecute, and maintain patent applications and patents and to negotiate, execute, and administer license agreements. They also are subject to expiration and termination by the VA, leaving the status of university ownership and license rights unclear. For these reasons, the majority of the VA’s university affiliates have refused to sign them.
- Universities share with the VA the common goals of ensuring effective and efficient technology transfer and promoting disclosure of research results for public benefit. However, the VA’s recent focus on asserting proprietary rights to inventions created through collaborative VA/university research and by VA/university dual appointees tends to ignore the legitimate rights and interests of its academic affiliates and undercuts this goal by introducing numerous issues of uncertainty for faculty, university and potential licensees.
- Universities also share with the VA the objectives of protecting the rights of inventors while providing for a fair and equitable distribution of revenues and providing for their use to promote research and education for the public benefit. The VA’s blanket assertion of full ownership rights is problematic in terms of other Federal regulations governing intellectual property to which VA-affiliated academic institutions are subject.
- NIH has specifically addressed the obligations of institutions receiving NIH funds that also maintain affiliations with the VA (April 23 NIH Grant Guide). The NIH guidance reminds institutions that they must ensure that rights to inventions arising out of NIH funding agreements are properly assigned to the institution to fulfill its Bayh-Dole obligations. The notice also stresses that any agreements with other parties must be consistent with the terms of NIH funding agreements. Any currently inconsistent agreements must be revised.
- Further, in a direct communication with the AAMC, NIH has stated that where NIH grantees have entered into agreements with the VA that involve compensation of grantee employees, the terms of such agreements must not impinge upon the ability of the grantee to meet their NIH grants policy and Bayh-Dole Act obligations. In anticipation of joint ownership issues, grantees should include terms that specify how ownership should be resolved. As recipients of NIH funds, ownership of inventions must be assigned to the grantee organization, and the grantee organization must report all “subject inventions” to NIH with notification to NIH in any case where the university elects not to take title so that NIH can determine disposition. NIH has requested that any VA involvement be reported on the university invention disclosure to NIH and that the VA be provided a

courtesy copy of the NIH notification. While the NIH position is supportive of university rights, it further complicates the situation with the VA.

- Three-way relationships between the VA, VA Foundation and the affiliated university raise questions about: 1) coordination of intellectual property obligations; 2) the university's ability to grant future option/license rights in university sponsored agreements where the research may involve the VA; 3) the potential for conflicting legal obligations if the VA Foundation precommits future intellectual property that is owned and committed by the university; and 4) IP rights in clinical trials conducted by universities in collaboration with VA facilities or staff.
- There are other unresolved issues. It is unclear whether "dual employee" inventors can take an equity position in start-up companies under VA policies (CTAAs provide only for distribution of royalty revenues to inventors pursuant to university policy) or if and how equity might be shared between universities and the VA. It has been pointed out that there are conflict of interest issues for the "dual employee" inventor if receiving the inventor share of royalties on a university invention, but the VA has not provided details to address the issue.

Conclusion:

The VA and universities need to focus on common goals in their relationships. Universities have gained valuable experience in effective technology transfer in the two decades that they have operated under the Bayh-Dole Act. The VA and its university affiliates both must assure that the intellectual property rights are properly acknowledged and protected in their research relationships.

June 11, 2001