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CTEP IP Option Policy

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COGR

an organization of research universities

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May 6, 2010

Dr. Jason Vittoria Cristofaro
Intellectual Property Advisor
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Division of Cancer Treatment and Diagnosis
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Re: CTEP IP Option Project (April 6 2010 Federal Register Notice)

Dear Dr. Cristofaro,

The Council on Governmental Relations (COGR) is an association of 182 U.S. research-intensive universities, affiliated hospitals, and research institutes that is specifically concerned with the impact of government regulations, policies, and practices on the performance of research conducted at its member institutions.

COGR values its close working relationship with NIH on issues involving intellectual property that may arise in NIH funding awards to COGR member institutions. We appreciate the acknowledgment in the Notice of COGR's role in the policy development process for the revised intellectual property policy for the Cancer Therapy Evaluation Program (CTEP). We are pleased to see that NIH/NCI has made changes to the IP Option to bring it more in line with similar agreements that are commonly entered into between industry and academic institutions. Some of the specific language has been problematic for the academic community since inception of the IP Option policy and we also are pleased to see that some of the COGR suggestions have been incorporated in the proposed policy.

However, we consistently have expressed concerns to NIH/NCI about certain aspects of the policy that unfortunately persist in the policy proposed in the Notice. Also the proposed policy introduces some new and troubling issues. We have two major issues with the proposed revised policy and some more specific concerns as discussed below.

Major Issues

1. The IP Policy Options should be limited to clinical trials involving both Agents and Collaborators as defined in the proposed policy. The Notice indicates that institutions will have to agree to the IP Option if they wish to be considered for funding support to carry out “any CTEP-sponsored clinical trial for which CTEP holds the investigational new drug (IND) application.” However, we note that the actual language of the IP Option is not in fact limited to clinical trials, but appears to apply to NCI-funded research more broadly. Our member institutions may agree to IP language in clinical trial agreements where the work tends to be more prescribed and inventions less likely to arise that would not be acceptable in funding agreements for fundamental research. Also our member institutions have advised us that NIH has applied IP option language in situations where no Agent is involved and there is no company Collaborator. We urge that the IP Option policy apply only in clinical trial situations where there are both Agents and Collaborators as defined in the policy. The policy statement should be clarified accordingly.
2. The scope of Section B inventions is overbroad and not reasonably related to the purposes of the policy. The IP Option for Section B inventions extends to inventions conceived or first actually reduced to practice pursuant to clinical studies that utilize clinical data or specimens from patients, including CTEP-Funded Tissue Banks. It appears to cover inventions made that may arise through use of patient records or specimens in related clinical studies and may not even relate to the Agent. We believe it is entirely inappropriate to allow a Collaborator to reach beyond the specific study to any future use of data or specimens generated from patients, including those obtained from tissue banks, especially when the Collaborator is providing no funding for the study. This raises issues of fairness and the public interest.

The problem is exacerbated by the fact that the IP Option may apply to inventions arising up to five years after completion of the CTEP clinical trial that generated the clinical data and/or specimens. It is not only contrary to standard practice, but also raises complex and perhaps prohibitive tracking and monitoring issues since there could be many intervening factors during this period related to the invention (e.g. funding from other sponsors). It also may place a financial burden on the Institution which must cover all patent costs without knowing whether the Collaborator will actually license in the invention and then reimburse patent costs and without the opportunity to find another licensee to cover these costs. This is an excessive length of time for the IP Option to apply to future reductions to practice. If NCI retains this provision we request that this period be reduced to no more than one year. However, we also believe that NCI needs to reconsider the current broad scope of inventions covered by this Option as discussed above.

Other Concerns

Our more specific concerns with the revised policy are summarized below.

1. The option periods linger too long, for both Section A and Section B inventions. The revised policy provides that for Section A inventions the commercial license options lingers for six months of Collaborator’s receipt of an invention report notification (three months of receipt of patent application). For Section B inventions, the commercial license option lingers for eighteen months of receipt of an invention report (and one year of a patent application). While universities occasionally will agree to six-month options with company partners, a three or four month period is

preferable and more typical. The eighteen month period in particular is far too long. This puts the burden of filing patents and incurring patent costs entirely on the institution, as the university will be unable to find other licensees during this period. It also does not serve the public interest, since the Collaborator effectively can “shelve” the invention for eighteen months. The previous version of this policy included a three month period from receipt of notice. We urge NCI to return to this option period in both cases. It is not clear why there should be a difference in the length of the option periods.

2. There is no mention of an obligation to cover patent prosecution and maintenance costs for exclusively licensed Section B Inventions. Since these costs are specifically addressed in Section A Inventions, to omit mention of them in Section B may create the perception that the Collaborator will not be responsible for them. This result is to leave an item open for negotiation that should be a "given" under the policy.
3. The penalty provision for unauthorized use is generally too severe. We appreciate that NCI has revised the penalty to include only an exclusive or co-exclusive license to Unauthorized Inventions, rather than ownership (which might have raised Bayh-Dole Act issues, among others). However, we believe the penalty provision should be eliminated, and perhaps replaced with a clear statement prohibiting the institution from using the Agent outside the CTEP-funded project. We note that the determination of what is outside the scope and therefore what is an unauthorized invention is subject to interpretation. If NCI or a Collaborator believes that an Unauthorized Invention has occurred, we believe this is a matter that should be negotiated between the parties, and not subject to a predetermined penalty, particularly where damages may be minimal. We also question whether the requirement to grant Collaborators exclusive licenses in such cases is fully consistent with the Bayh-Dole Act mandate to achieve practical application.
4. The IP Options for both Section A and B inventions should apply only to inventions conceived and reduced to practice pursuant to CTEP-funded studies. As presently stated they apply to inventions conceived or reduced to practice. As we have repeatedly discussed with NIH, while this language reflects the Bayh-Dole Act scope of “subject inventions” for federal funding agreement purposes, Bayh-Dole only speaks to the rights to inventions provided to funding recipients and the government. The IP Option, however, applies to rights that funding recipients grant to third party Collaborators. The Bayh-Dole scope of inventions therefore does not apply to these rights.

In agreements with industry universities typically seek to limit their obligations to inventions that are both conceived AND reduced to practice in the performance of the studies. Agreement to the “OR” language means that the Collaborating company would get rights to prior conceptions (that are reduced to practice in this study) and future reductions to practice (of conceptions made in the study). This greatly increases the risk of conflicting obligations. To avoid such a conflict universities would have to inventory all researchers for prior conceptions and assess whether there were any obligations attached, and would have to carefully monitor, and potentially restrict, all funding and other agreements associated with any follow-on research for all researchers – in effect, this obligation would place a cloud over their ability to seek future funding.

Because of these issues, universities often go to great lengths to avoid the “conceived OR...” construction, especially in industry agreements. We believe the IP Option language should reflect this standard practice, especially since the rights of a Collaborator are NOT governed by Bayh-Dole.

5. There is no indication of when the 90-day clock starts for agreement to be reached on exclusive license terms for either Section A or Section B inventions. There should be specific language that starts the clock on Institution's receipt of written notification of the Collaborator's intent to exercise the option.
6. The disclosure provision for Section B inventions for regulatory agencies and promotional materials should include a confidentiality provision to avoid jeopardizing patent rights. Also NCI should restrict the Collaborator's ability to use the institution's name without consent in promotional materials.
7. The reference in Section D to treating invention disclosures or patent applications in accordance with 37 CFR 401 is unclear. 37 CFR 401 contains many provisions. NCI should specify the applicable provision of this regulation.

We appreciate NIH/NCI's commitment to obtain widespread comment and participation in development of the revised IP Option policy from a wide range of stakeholders in the biomedical research community. We agree that such participation is critical in developing an effective policy. We appreciate the opportunity to discuss this policy with NIH in the past, and would be happy to continue the discussion with regard to these comments or any questions or concerns that NIH/NCI may have.

Sincerely,

Anthony P. DeCrappeo