Reducing New Risks In Commercializing University Research

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It is safe to say that many of the most inventive products originated from university based research. According to the Association of University Technology Managers, in 2002, U.S. federal government funding sources funded $23 billion of research to 206 universities reporting in their survey. In comparison, private industry funded $2.9 billion of research in 2003[1]. As a result of all funding, 7,741 new patent applications were filed by the 206 reporting Universities in 2002, and 4,673 new licenses and options to license were granted by these 219 of the reporting Universities.[2] Of 217 Universities reporting to the AUTM study, 26,086 licenses to technology were in effect in 2002.[3]

However, the nature of science research in universities can sometimes bring the university into sharp conflict with private/commercial interests. Those risks have been highlighted by several cases and private companies need to consider their impact upon how they do business with universities.

The Vanishing Research Exception. For years, scientists at universities had relied on the so-called "experimental use" or "research" exception to conduct their research. It was assumed that the research exception protected scientists from liability for patent infringement so long as the infringement was only due to the scientist's research activities, which impliedly were of a "noncommercial" nature. But in *Madey v. Duke University* (307 F.3d 1351 (CAFC 2002)), the Court of Appeals for the Federal Circuit (CAFC) narrowed this exception whereby to qualify, the research would have to be solely for "amusement", "to satisfy idle curiosity" or of a "strictly philosophical inquiry", and that the research could not be for legitimate business objectives. The Court further indicated that "legitimate business objectives" of universities included not only the obvious licensing and development of research activities, but also the furtherance of the "business" of the university in attracting students (and their tuition dollars), faculty, and grants, as well as enhancing the reputation of the university. With such a sweeping interpretation of "business objectives", it is now difficult to envision activities that might be protected by the exception.

The direct ramifications of *Madey* are that university and non-profit researchers will need to exercise great caution even when conducting pure research. However, it is also a warning to private companies to increase their diligence when licensing technologies from universities. It is the private company that will inevitably generate scrutiny of its behavior when they attempt to commercialize the fruits of the university scientist's labor.

Partner Liability in University/Non-Profit Licenses and Collaborations. The recent CAFC decision in *Integra Life Sciences I, Ltd. v. Merck KGaA* (331 F.3d 860 (CAFC 2003)), while addressing a number of other issues, is a notable example of partner liability. Integra was the patent holder (by way of acquisition of Telios Pharmaceuticals, Inc., which licensed the technology from the Burnham Institute) of patents regarding RGD-peptides. Scripps Research Institute had been found to have infringed these patents during the course of research for which Merck KGaA had hired them to perform. Merck KGaA was found liable for the infringing activities of its collaborative partner Scripps.

Similarly, in *Trustees of Columbia University v. Roche Diagnostics GmbH* (150 F. Supp.2d 191 (D. Mass. 2001); 272 F. Supp. 2d 90 (D. Mass. 2002)), the district court found Roche liable for inducing certain infringing activities of its partner, Genetics Institute (GI); however the outcome of a pending appeal is being awaited. Although this collaboration was between two industrial parties, the analysis is instructive for universities/non-profits as well.

The court focused on the nature of Roche's relationship with GI, and more specifically the control aspect of Roche in the relationship. Despite this analysis, the court was careful to emphasize that while control over a third party infringer is relevant, it is not a necessary condition to finding liability. Thus, this leaves open the potential for liability even in an arrangement that is not strictly collaborative or "controlled" by a licensee/collaborator.

Columbia alleged that Roche induced GI to make bulk erythropoeitin (EPO) under agreement between the parties, which infringed the Columbia process patents. Roche argued that because it did not exert control over the specifics of how GI would manufacture the EPO, it lacked the requisite intent for a finding of inducing infringement (effectively arguing that it was a mere "purchaser of goods"). The court, however, focused on the whether Roche encouraged GI to take actions that it knew or should have known would infringe Columbia's patent. Specifically, the court looked to the collaborative nature of the relationship and the agreement itself, including: (i) the description of the relationship as a "collaboration"; (ii) provisions for Roche's payment of milestone-based research fees; (iii) the exchange of confidential trade secrets; (iv) provisions for joint ownership of intellectual property generated during the "Project"; and (v) provisions permitting Roche to deduct from its royalty obligations to GI costs associated with third party licenses necessary to produce EPO. Based on this collaborative aura, Roche was found liable for inducing infringement for GI's production of bulk EPO.

Interestingly, however, Roche was not found liable for inducing infringement of the Columbia clone patents. Although a confidentiality agreement was in force and an agreement in principle was reached between Roche and GI prior to creation of the clones (under agreement between GI and a third party), the clones were created prior to the execution of the binding Roche-GI agreement. The court found that more than 90% of the work had been done by GI prior to execution of the Roche Agreement, thus Roche was not an inducing party for that work.

Because factors such as those considered by the court in *Columbia* are almost standard in typical relationships and agreements, It is worth examining more closely the timing of execution, exertion of control and degree of collaboration between the parties to decide how best to structure an industry – university/non-profit institution relationship to appropriately deal with liabilities of the parties.

Lessons Learned and Some Steps to Take. With these lessons in mind, parties to industry – university/non-profit licenses or collaborations should increase their awareness on these issues and take steps to better protect themselves including the following:

- Companies sponsoring research need to make it clear that researchers need to be diligent to ensure they have all necessary licenses in advance before conducting research.
- Companies need to be aware of the patent landscape in any research they license.
- Companies should consider provisions in their agreements making it clear that they are not directing the research at the institution and clarifying the independent relationship of the parties.
- Agreements for materials purchased or donated from third party suppliers should be examined to ensure no undue license limitations exist.
- Companies should inquire as to whether the University obtains licenses from all faculty and researchers granting a non-exclusive license to any intellectual property used in research at the University.
- Companies may want to discuss with the University its policies regarding freedom-to-operate by their researchers.
- Risk for infringing activity might be mitigated by insurance or by agreement provisions (e.g., compensation adjustments to payments or royalties due); however, such factors have been deemed to be probative in *Columbia University* in assessing liability of licensors for infringing activities of their partners post agreement execution.
- Companies should assure themselves that all researchers working on a subject project are under appropriate obligations of assignment; faculty, staff, post-doctoral researchers and students each may be treated differently, even within the same institution, based on their status. This issue should be explored to ensure the Company achieves its desires regarding the license of intellectual property developed by the University.

Some predict that cases such as *Madey* and *Columbia* might produce a "chilling effect" on industry – university/non-profit collaborations. Even further, predictions have been made that this might adversely impact U.S. institutions disproportionately in that some foreign jurisdictions have more lenient experimental use exemptions, thus encouraging ex-U.S. research activities. However, with deliberate education, planning, investigation and awareness on the part of all parties involved, potential risks and liabilities in industry – university/non-profit relationships can be appropriately managed. IPT

ENDNOTES

1. the Association of University Technology Managers' ("AUTM") report, AUTM Licensing Survey, FY 2002
2. Id.
3. Id.