Issues in Licensing Sponsored Research

Case histories with research at Caltech and Jet Propulsion Laboratory, government-sponsored projects

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California Institute of Technology, an independent, private university, traces it origins to an institution founded in 1891. The Institute is organized into six divisions: Biology; Chemistry and Chemical Engineering; Engineering and Applied Science; Geological and Planetary Sciences; the Humanities and Social Sciences; and, Physics, Mathematics and Astronomy.

Undergraduate enrollment for the fall of 1983 totaled 829, while the graduate enrollment was 936. Caltech scientists have received wide recognition for their distinguished achievements. Twenty-one Nobel prizes have been awarded to Caltech alumni and faculty. There is a considerable amount of sponsored research conducted at Caltech. Federal sponsorship of research at Caltech was almost $44 million in 1983, with several million dollars more in other sponsorship.

The Jet Propulsion Laboratory, is operated by Caltech and carries on a large-scale program of research for the National Aeronautics and Space Administration in the science and technology of unmanned space exploration. The laboratory launched the first U.S. satellite, Explorer I, in 1958, and held major responsibilities for the Ranger, Surveyor, Mariner, Viking, and Voyager programs of lunar and planetary exploration for NASA, with the Galileo program now underway. The Infrared Astronomical Satellite (IRAS) has recently provided a wealth of data on the Infrared Sky. The laboratory also operates the NASA worldwide deep-space tracking network and conducts a program of supporting research in space, science and engineering. JPL scientists are also tackling problems in medicine, pollution, transportation, and energy. Total JPL expenditures in Fiscal Year 1983 were $425 million.

To say that a lot of technology results from these efforts is obviously an understatement. There are many means of transferring this technology, and early publication in the open literature is one of them. The NASA Technology Utilization Program with wide dispersal of the results of NASA-sponsored programs is significant, particularly with respect to efforts conducted at Jet Propulsion Laboratory. And, of course, we are very much involved in licensing.

While much of the research is fundamental in nature, we do try to identify patentable items that appear to have commercial significance and file patent applications within the constraints of our resources. We are all familiar with the fact that late in 1980 Congress enacted Public Law 96-517, the "Bayh-Dole" Bill, allowing universities and small businesses the first option to retain ownership of inventions made with government funding. While previous regulations required a request or petition for waiver of title on properties we wished to patent, those government agencies having such regulations were fairly liberal in permitting Caltech to acquire title. It is my impression that the principal changes are that acquisition of title when desired is now a matter of right, and the amount of paperwork required has been substantially diminished. However, there is no doubt that this legislation encouraged renewed interest in the patent system and, I believe, industry sponsorship of Institute research.

Preference

I do not identify any particular issues of note with respect to licensing of patents that may arise from inventions made under government sponsorship, in those instances where the Institute has elected to retain title. We would prefer to license to responsible parties, on a nonexclusive basis, to insure that the technology is available to all interested parties. We recognize, however, there are some situations where, in order to attract sufficient investment capital to bring an invention from the "conceptual," to the practical stage, it may be necessary to grant certain exclusive rights.

If sufficient justification can be established, we have been known to do so, with such licenses containing appropriate cancellation provision, upon the failure to exercise "due-diligence." Licenses heretofore have usually been for less than the full term of the patent involved.

While President Reagan on November 8, 1984 signed Public Law 98-620, a Bill which removes the current five-year/eight-year limit on the duration of exclusive licenses entered into by nonprofit organizations with companies that are not small businesses, this does not necessarily mean that Caltech will automatically do so.

I am aware that case histories are always of interest to you. Let me, very briefly, relate a few of recent vintage. In one instance a license was granted which relates to a patented connector and system for sterile transfer of fluids, such as blood, between two containers. The licensee has made an investment in additional development, including improvements that may be patentable in their own right.

In another instance, we granted a license relating to instrumentation for medical ultrasonic imaging of the cardiovascular system. The licensee committed to a substan-

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tial program of additional research and development, engineering and design, prototype construction, and clinical testing. A detailed case history was presented at the Dallas Conference of the National Council of University Research Administrators on September 5, 1984, in a presentation entitled "Start-up Company Licensing of Patent Rights and High Technology From a Major University."

In yet another instance we licensed a series of software programs that run on personal computers and are generally useful to physiologists — particularly membrane biophysicists — for running and analyzing experiments that require analog control and analog data collection of time-varying events. To develop the programs as a commercial product, the licensee was required, at its own expense, to "debug" the programs and write a user's manual.

Common Thread

There is no unexpected revelation in these few, brief, case histories. But they do have a common thread. And that is that seldom is technology licensed from the university laboratory sector "market ready" without substantial additional investment often being required.

It is axiomatic that before a licensing arrangement can be made, there should be something which is the subject of the arrangement, a "product" so to speak. Most "product" is created under sponsored-research agreements.

Therefore, I will discuss relationships involving non-government-sponsored research agreements at both the Campus and Jet Propulsion Laboratory. Such types of arrangements are assuming more importance because of increased support of university research by industry. First of all, it is of utmost importance that principal investigators have an unrestricted right to publish the results of the sponsored research.

By way of implementation, research agreements generally provide that the sponsor will be provided a copy of any manuscript simultaneously with submission to the publisher. We would also agree to exert reasonable efforts to have an application filed on patentable subject matter prior to actual publication. As a matter of fact, since papers usually go through substantial peer review prior to selection for publication, and there is a subsequent lapse of time for galley preparation and author review, this has been found to provide adequate time for the identification of any possible patentable subject matter that the sponsor may wish to have covered. Furthermore, we are unable to agree that any information generated in the course of the sponsored research (foreground data) will be treated as proprietary, and held in confidence.

With respect to inventions made under sponsored research, our policies provide that research sponsors may be offered either (1) a nonexclusive, royalty-free license under any patent resulting from work supported by that sponsor; or (2) an exclusive royalty-bearing license under any patent that results from such work, with the length of exclusivity, the performance requirements, and the royalty rate to be negotiated.

Prudence indicates that great caution must be exercised in granting proposed research sponsors exclusive rights in (or options to) inventions not yet in being but which may result in the course of work at Caltech sponsored by that organization. Without knowing the nature and potential applications of prospective new inventions, it is usually impossible to determine whether an exclusive license is appropriate for the specific situation. Therefore, normally, a proposed sponsor would not be offered the right (or option) to an exclusive license to inventions not yet in being but which might be made in the course, or as the result, of, work funded by that sponsor.

However, where the purpose of the sponsored research is to develop an existing item or items, then, subject to any prior obligations we might have, the sponsor or sponsors of that research would be afforded the first opportunity to acquire exclusive rights if it were determined that exclusive rights to that item or items should be granted. In the event justification were established, a suitable license or option would be negotiated. It would include a commitment to further developmental expenditures to bring the product to market in a reasonable period of time, suitable cancellation clauses for failure to exercise "due-diligence," a limited period of exclusivity, and reservation of the right by the institute to practice the invention for research and educational purposes, among other provisions.

Technical Data

Similar considerations apply to technical data. I have already alluded to the fact that we will not agree to keep information generated under contract in confidence, and we must be free to publish. Trade secrets do not appear to play a role in university research and, indeed, are the antithesis of the widespread dissemination of knowledge, a prime mission of academe. This, of course, emphasizes the importance of the patent system.

This presentation would not be complete without saying a few words about rights in technical data arising under government-sponsored research. Two bills have been recently passed. On October 30, President Reagan signed into law, Public Law 98-577 the "Small Business and Federal Procurement Competition Enforcement Act of 1984." This Bill requires the issuance, no later than July 1, 1985, of regulations that will define the respective rights of Federal civilian agencies and government contractors in technical or other data.

The technical data rights provisions found in that law parallel those included in the "Defense Authorization Act of 1985," Public Law 98-525. In the later instance, it is left to the Secretary of Defense to issue regulations specifying the circumstances under which the department will require unlimited rights in technical data. You may be wondering why, in view of my previous statement concerning widespread dissemination of knowledge, that I should bother to mention technical data arising under government-sponsored research. The reason is that both bills define the term "technical data" in a manner encompassing software, including computer software documentation. Computer software is a licenseable product.

Contractors' rights to copyright software generated under contract, and contractors' rights with respect to software, have been areas that have not been subject to uniform treatment among the various government agencies. In that respect it is my precatory wish that the regulations that ultimately result will make it clear that, while the government has a nonexclusive royalty-free license to utilize software developed under its sponsorship, there will be no doubt that the contractor will be free to copyright and license it to other parties for nongovernmental purposes. In other words, software would be treated in a manner similar to patented inventions arising under government sponsorship.

In the past few moments I have attempted to highlight some of the special issues, within my universe, associated with the generation of "product" and licensing of the results of university and government-sponsored research. In most other respects, the problems encountered probably do not differ from those that each of you experience in licensing-out technology in accordance with the policies and guidelines of your industrial employers or clients.