Fermilab

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INFORMATION BULLETIN

In the course of negotiating patent license agreements at Fermilab, we have become increasingly aware of a disturbing term called product liability. With all the other problems involved in trying to pull together our first licenses, it was a concern that we would have liked to ignore. A more cautious approach prevailed and we raised the question of risk of liability with our Chicago-based patent attorneys. It also seemed appropriate to call several of the experienced laboratories and universities to see, first of all, if they were concerned about product liability and, if so, what they were doing about it.

Our probing resulted in the enclosed document which we call an "Executive Summary on Liability from Fermilab Patent Licensing Activities". The enclosure is the same as the document submitted to our Board of Trustees except the names of companies involved have been deleted. We understand that our Board of Trustees has concurred with the recommendations, at least for the time being.

With all imaginable disclaimers for content and accuracy, we now send the enclosure to you for information and with thanks to some for responding to our many questions. We don't think that the risk of product liability should be unduly magnified. On the other hand, we do see it as a common concern that bears close watching in the future.

I would appreciate hearing from you on your experience or additional views on this subject.

J. Paulk

Fermilab Licensing Officer

EXECUTIVE SUMMARY

LIABILITY FROM FERMILAB PATENT LICENSING ACTIVITIES

This summary has been prepared to assist Universities Research Association (URA) management in assessing the risk of liability associated with patent licensing activities at Fermilab. URA's potential exposure to liability will first be introduced, followed by a discussion of the approach taken in the proposed patent license between URA and _____ to insulate URA from claims that might arise from commercialization of the Drift Chamber Power Supply. The _____ license should be viewed as a test run, not a precedent establishing agreement. The subject of products liability insurance will also be discussed, as well as the approach mandated in the prime contract to avoid exposing the Government to product liability claims. Finally, the question of URA's exposure to patent infringement lawsuits will be discussed.

I. Introduction

Public Law 98-620 (the so-called Bayh-Dole law), enacted by Congress on November 8, 1984, gives operators of Government laboratories like Fermilab the option of retaining patent rights in inventions developed with Government funds. The URA/DOE prime contract effective January 1, 1987, contains provisions governing the patenting of inventions developed at Fermilab. Among those provisions is URA's right to license third parties, such as commercial manufacturers, to practice patented inventions developed at Fermilab.

Generally, a patent license is a contract whereby a patent owner like URA agrees to allow a manufacturer to make, use or sell a patented invention, on either an exclusive or nonexclusive basis, in return for the payment of a royalty. Royalties are generally paid either in a lump sum, in installments, or as a percentage of net sales of devices incorporating the patented invention.

The question of potential liability to URA arises from the manufacturer's public dissemination, under the license, of a device or method originally designed and developed at Fermilab and to which URA holds the patent rights and collects royalties. If a user of the device is injured by a foreseeable use of the device, the injured user will ordinarily seek to recover from all parties directly or indirectly involved in disseminating the device to the public. Such product liability claims are routinely brought against the manufacturer of the allegedly defective device, but in the case of a Fermilab invention, URA, DOE and even the inventor(s) could potentially be named as defendants. This does not mean that the injured user could ever actually recover from anyone other than the manufacturer who introduced the allegedly defective device into the stream of commerce. In fact, Illinois case law holds that product designers, inventors, and patent owners like URA are immune from product liability claims absent a showing of negligence.

Notwithstanding the extreme unlikelihood of a recovery, URA's obligation to defend against product liability claims is a foreseeable consequence of its patent licensing activities. Thus, while a court or jury award against URA is extremely unlikely, URA would be exposed to litigation defense costs (potentially amounting to several thousand dollars per month in attorney time). In addition, URA may decide in some instances that it would be more economical to

settle a claim for a relatively nominal amount rather than incur large litigation expenses.

Another facet of liability is the question of URA's exposure to patent infringement lawsuits. It is important to recognize that this is a question distinct from the question of URA's exposure to product liability lawsuits. The question of exposure to infringement suits will be discussed in a separate section of this summary.

II. Approach to Insulating URA from Liability Claims

The current approach taken in the license between URA and _____ Associates, Inc., covering patent rights to the Drift Chamber Power Supply involves three major aspects:

1. The requirements that _____ agree to indemnify and hold URA harmless from all claims arising from use of the Drift Chamber Power Supply;
2. The requirement that _____ provide URA with evidence of sufficient product liability to meet its obligation to indemnify URA;
3. An unqualified "escape" provision that allows URA to cancel the agreement upon 60 days notice to _____, should URA decide that the royalties and other benefits from the license do not justify the risk of product liability exposure.

In the proposed URA/_____ agreement, an indemnity provision is coupled with a requirement of insurance in order to help insulate URA from liability claims. Like other terms of a patent license, the degree of liability is subject to negotiation between URA and the potential licensee. Some licensees may find the _____ liability provisions excessively onerous, and may request that URA accept more risk (such as by dropping the insurance requirement) in return for a higher royalty rate. Of course, URA is free to set its own licensing terms, and can as a matter of general policy require indemnification and evidence of insurance from all its licensees. Other options which would provide URA with a greater or lesser degree of protection than the _____ provisions include:

1. The requirement that the licensee simply agree to indemnify and hold URA harmless from liability claims, without evidence of insurance, thereby relying only upon the assets of the licensee to cover potential liability claims (affords less protection);
2. The requirement that the licensee (1) agree to indemnify and hold URA harmless, (2) provide evidence of adequate insurance, and (3) include URA as a additional named insured on its product liability insurance policy (affords greater protection); or (4) include URA as an additional named insured and making licensee's insurer primary with no right of contribution from URA (in essence licensee's insurer would be protecting URA for any negligent design).
3. URA's agreement to share responsibility for liability claims, but only to the extent of royalties actually paid to URA (affords less protection).

Option (2) would afford URA the greatest protection, but would require the licensee to modify its product liability insurance policy. Most licensees

would expect commensurate concessions from URA on other license terms such as a lower royalty rate. URA's insistence upon option (2) might also dissuade certain major commercial manufacturers who might not care to adjust their liability coverage at URA's behest. Options (1) and (3) would only be appropriate in circumstances in which the economics justify a lesser degree of protection. The _____ liability provisions attempt to recognize the need to adequately protect URA from potential liability claims, while accommodating the business requirements of commercial licensees and recognizing that the likelihood of URA becoming involved in a product liability suit is speculative, and that the likelihood of any actual recovery is remote.

III. Further Measures for Protection.

Additional measures for liability protection, beyond those provided by the licensee, may be considered necessary. In such case, one or more of the following actions could be pursued:

1. Obtain URA product liability insurance as umbrella protection for all licensing activities. Although the limited survey (see summary table) found only one university which carried such a policy, a meeting with a local insurance broker concluded that such coverage could be arranged. The idea of course is to have backup protection in the event the licensee's insurance or net assets proved inadequate. This added layer of protection would be highly desirable, particularly for a license with a small business firm that could not afford or possibly even obtain adequate insurance. For such insurance to be seriously considered, the cost would have to be reasonable. Coverage limits in the range of $5 to $10 million would appear appropriate.

2. Establish guidelines for additional protection as a function of risk assessment. Each invention contemplated for license should be reviewed for safety hazards that could be attributed to a defect in Fermilab design. It is conceivable, for example, that some inventions would be judged to be perfectly safe and therefore entail virtually no risk for design liability. In that case, no additional protection would be required. Some inventions at the other extreme might be judged to present a life threatening risk under certain circumstances. Such an assessment might result in a decision not to license. Some universities now follow this practice. Intermediate degrees of risk might call for URA to take out special liability insurance or for the invention to be subjected to further testing comparable to that provided by the Underwriters Laboratory.

3. Encourage DOE to shoulder or share the burden of liability protection. It could be argued, with support from other labs, that the liability risk jeopardizes the entire technology transfer program. Hundreds of federal institutions are involved in technology transfer and liability litigation involving any of them could seriously diminish licensing activity. Notwithstanding the disclaimer clause (see Part IV) required in each license, DOE is not immune from a liability suit. For the good of the program, DOE could be encouraged to take a more active role in liability litigation by agreeing to defend not only itself but the labs who are acting in its behalf under terms of the prime contract. As a fall-back position, DOE could consider allowing the cost of insurance against the operating budget. The survey of labs and universities disclosed increasing concern over the issue of product liability and

the role of the federal government. It is the subject of newsletters, seminars and testimony before the congress. Universities with large endowments are particularly sensitive to the attractive targets they present for product liability suits. It is increasingly held that revised legislation at the federal level is needed to limit the reach of such litigation.

IV. Avoiding Exposure to the Government

Under the URA/DOE prime contract effective January 1, 1987, all license agreements entered into by URA must contain the following provision:

> "This license [assignment] is entered into by the Licensor, independent from its Prime Contract with the Department of Energy. The Licensor is acting independently from the Government and in its own private capacity and is not acting on behalf of the U.S. Government, nor as its contractor nor its agent. Correspondingly, it is understood and agreed that the U.S. Government is not a party to this license and in no manner whatsoever shall be liable for nor assume any responsibility or obligation for any claim, cost or damages arising out of or resulting from this license agreement, the subject matter licensed, or any action or lack thereof by the Licensor with respect thereto."

The Government expects this provision to insulate it from liability claims that might arise from activities carried out pursuant to URA's license agreements. So long as URA includes this provision in its license agreements, URA need not take any further measures to protect the Government from liability. Once again, however, there is nothing to prevent someone who is injured by a device developed with Government funds from suing the Government (or filing a claim under the Federal Tort Claims Act), along with all other parties involved in some way with the device.

V. Patent Infringement Exposure

As indicated at the outset, in addition to product liability, patent licensing activities could also expose URA to potential patent infringement lawsuits. URA would only get involved in a patent infringement suit (1) if the patented invention it licenses happens to infringe an existing, broader patent or (2) if URA decides to sue an unlicensed manufacturer for infringing a URA patent. Under the first scenario, it is quite possible for URA to obtain a patent on a device or method only to find out later that the device or method infringes another patent that was not turned up by the Patent Office during examination. In other words, obtaining a patent is no defense to a charge that the patented device or method infringes someone else's broader patent. Patents issue routinely covering improvements to basic inventions that were patented earlier by someone else. In the URA/_____ license, however, URA has made no warranties that the device does not infringe another patent. Consequently, the general indemnity provision covering product liability would also make _____ liable for any patent infringement. Moreover, if URA happened to be sued along with _____ for patent infringement, the indemnity provision would require _____ to cover URA's litigation defense costs.

Under the second scenario, in order for a license to remain valuable, a licensee must be able to prohibit, directly or indirectly, unlicensed infringers from practicing the patented invention. Otherwise, the licensee would be at a severe competitive disadvantage, being obligated to pay a royalty rate of say 5, 10, or 15 percent to practice the invention, while his unlicensed competitors practice the invention for free. In the case of an exclusive license, the sole licensee himself is ordinarily required to assume the burden of policing infringements. In the case of nonexclusive licenses, the licensee will ordinarily look to the licensor (URA in the case of _____) to police infringements. If URA fails to bring suit to stop infringement, the licensee (_____) will probably terminate the license (and obligation to pay further royalties). In the proposed URA/_____ license, however, it is important to recall that URA has a built-in escape clause, so that if the burden of stopping infringers is unreasonable in view of the value of the license to URA, URA can simply cancel the license, leaving the licensee(_____) with six months in which to deplete his inventory of licensed product (but still obligated to pay royalties on that inventory). After six months, the licensee would be required to stop manufacturing licensed products or risk an infringement suit from URA. At that time, if the licensee sees that URA is allowing his competitors to freely infringing URA's patent, then he will probably also choose to infringe. The escape clause, thus, avoids obligating URA to initiate any economically unsound patent infringement suits.

VI. Conclusions and Recommendations

Although our survey of laboratories and universities on the issue of product liability revealed widespread concern, the problem does not appear so large that institutions have purchased insurance or stopped licensing. It is apparent, however, that the general level of worry is increasing. In all cases, reliance is placed upon a strong indemnity clause. This is probably sufficient in light of no known case where a licensor has been a defendant in a product liability law suit for merely granting a bare patent liability license. The State of Illinois, whose laws would govern any URA patent liability issue arising from work done at Fermilab, provides additional comfort. That is because in Illinois it is held that inventors and patent owners are immune from product liability claims absent a showing of negligence. Notwithstanding, URA must be aware of the consequences of negligence in product design as well as the possible legal costs associated with defending liability claims.

To minimize URA's exposure to liability, the following measures are recommended:

1. Routinely have the Fermilab safety committee assess any invention being offered for license. This is not only a good management practice, but a documented finding and appropriate follow-up could serve to defend against a claim of negligence. If the safety committee did not believe it to be fully qualified to assess a particular invention that may be used by the general public, further review by an outside testing facility might be indicated. Results of the safety assessment could be the basis for product redesign, setting the limits of liability coverage, or possibly a decision not to license.

2. At a minimum, insist on a strong, but reasonable indemnity and hold harmless (disclaimer) clause in all license agreements and license product liability insurance which makes URA an additional named insured for that product. As with all laboratories and universities, the indemnity would be the primary defense against liability suits. Provisions of the clause which would cause the licensee to modify its product liability insurance policy could vary according to company size, resources and product risk. In certain circumstances, we might need them to cover our potential liability for design defects by making their policy primary with no right of contribution from URA.

3. In the event that it was decided that URA should take out additional insurance in its own behalf, this should be done on a case-by-case basis. The _____ Agency, liability insurance broker for Fermilab, has indicated that _____ Insurance Company is receptive to issuing a design errors and omissions policy for URA on specific items of technology. Cost estimates for some representative inventions have been requested. It is believed that this approach, that is coverage for specific licenses as opposed to an umbrella product liability policy, would cost less. Licenses not requiring additional protection would not be covered and the insurance company would be able to deal with a known item of technology in each case.

4. Encourage DOE to become more directly involved in relieving the threat of product liability claims, particularly for not-for-profit M & O contractors. They may not be receptive. However, as a minimum, it would appear worthwhile to ask DOE to consider allowing the costs of additional insurance coverage, either as an allowable cost under the contract or as an increase in the management allowance.

5. Be alert to review the changing need for protection in on-going licenses. If the risk associated with a particular license decreases, possibly due to a phase-out of the product, it might be appropriate to decrease the amount of protection. On the other hand, the need for added protection could increase. For example, if a product were to go from limited to mass production, the exposure due to the product being in wider use would increase. Hence the need for additional protection should be considered on a phased basis.

SUMMARY OF LABORATORY-UNIVERSITY SURVEY

Institution	Main Concerns	Protection Mechanism	Insurance	Product Litigation History
ANL	General threat of litigation	Indemnity clause in all licenses	None for product liability	None
Anonymous	Medical application	Disclaimer clause in all licenses	None for product liability	None
BNL	General threat of litigation. Problem with small businesses	Indemnity clause in all licenses	None for product liability	None
LLNL	General threat of litigation. Exposed only for gross negligence	Indemnity clause in all licenses	None for product liability	None
ORNL	General threat of litigation	Indemnity clause in all licenses. Don't receive royalties	None for product liability	None. (Martin Marietta has but, not at ORNL.
Stanford & SLAC	Medical applications. Prob with small business	Indemnity clause in all licenses.	None for product liability	$300K for legal costs
Brown	None	Indemnity clause in all licenses.	None	None
Chicago	Sizeable endowment. Medical applications	Indemnity clause in all licenses	Self insured but not specific	None
Illinois	None	Disclaimer clause in all licenses. Deny warranty	Self insured but not specific	None (UPI would handle)
MIT	Sizeable endowment. Problem with small business	Indemnity clause in all licenses. No license if high risk	None for product liability	None
Wisconsin	Protection for inventor. Problem with small business	Indemnity clause in all licenses. Help from State.	Coverage for inventor	Inventor once named