PATENTS, COPYRIGHTS AND RIGHTS IN DATA

Committee: Thomas E. Stelson, Chairman; Winifred R. Widmer; Howard Bremer, University of Wisconsin; Roger Ditzel, University of California; Lawrence Gilbert, Boston University; Clark A. McCartney, University of Southern California; Niels Reimers, Stanford University; Arthur Smith, Massachusetts Institute of Technology; Edwin T. Yates, Johns Hopkins University.

NSF Proposed March-In on University Patent

The National Science Foundation has announced a hearing to determine whether the Foundation should exercise its march-in right on a patent held by a COGR institution. At this point, the record shows that the invention in question, has been offered for licensing but the prospective licensee is "not satisfied" with the non-exclusive royalty-bearing license offered by the institution.

COGR has written the Foundation expressing its concern that a university needs to have a predictable environment in order that its investments in patent filing and licensing can be recovered through reasonable royalties negotiated at arm's length. The prospect of second guessing through public hearings of the negotiable terms of a license, including royalty terms, creates a significant uncertainty and is likely to set a government-wide precedent.

The taking back of patent rights should only be exercised in situations where there is clear abuse or where march-in is necessary because of overriding national interest. Neither condition is evident from the available records.

Restrictive Patent Policies of Nonprofit Sponsors

The Committee has appointed a task force to initiate discussions with some nonprofit sponsors of research in an effort to overcome the growing number of restrictive patent policies of these sponsors. Initially, the task force will concentrate on the American Heart Association policies that: (1) restrict the amount of royalty that an institution may share with its inventors and (2) provide for Association participation in income derived from inventions under Association sponsorship.

Patent Legislation

S. 414 - The "Dole/Bayh" patent bill passed the Senate overwhelmingly in April. This bill will allow universities and small businesses to retain ownership of inventions developed in the performance of government sponsored research. In order to become law, the House must agree on a companion bill, H.R. 2414. Because of the success of the Senate bill, the Administration is attempting to broaden the scope of the House bill to provide exclusive licenses in a designated field of use for large business for a five year period.

Our experience in the Senate shows that broadening the bill to include big business, even in a limited way, is likely to be fatal to any patent policy improvement efforts. Action on whatever version emerges from the House is expected in late June.

S. 2397 - Preservation of Confidential Information Act - Senator Robert Dole (R-Kansas) has introduced legislation to check abuses of the Freedom of Information Act. This legislation will require an agency to give written notice to the submitter describing the nature and scope of the request for release of such information. The submitter will be advised of his right to present written objection to the disclosure. The submitter also has the right to appeal for de novo review of the case if not satisfied with earlier decisions.

The Committee believes this bill is a good vehicle in which to incorporate a separate provision treating material contained in unfunded university proposals as confidential. Having this provision contained specifically in legislation would remove the tenuous reliance on exemption b(4) of the FOIA as a means of protecting proprietary proposal data.

S. 2397 stems principally from the Supreme Court decision in Chrysler vs. Brown in which the Court held that a government contractor cannot file a "reverse" FOIA suit to prevent government disclosure of data to third parties. The Court's arguments centered on whether the FOIA exemption b(4) bars the government from disclosing confidential data submitted to it.

Pending Patent Legislation Introduced in the Senate or House

Number	Sponsor	Title	Committee
H.R. 2414	Rodino	University and Small Business Patent Procedures Act (See earlier discussion)	Committee on the Judiciary, Subcommittee on Courts, Civil Liberties and the Administration of Justice
S. 1215	Schmitt	Science and Technology Research and Development Utilization Policy Act	Committee on Commerce, Science and Transportation, Subcommittee on Science, Technology and Space
H.R. 5715	Ertel	Uniform Federal Research and Development Utilization Act of 1979	Committee on Science and Technology, Subcommittee on Science, Research and Technology
H.R. 6965	Ertel	(H.R. 6965 combined H.R. 5715 with reexamination and an Independent Patent and Trademark office)	Committee on the Judiciary, Committee on Science and Technology

Number	Sponsor	Title	Committee
S. 1860	Nelson	Small Business Innovation Act	Small Business Committee
S. 2079	Bayh	Independent Patent and Trademark Office Act	Senate Judiciary and Government Affairs Committee
S. 1679 H.R. 5075	Bayh	Patent Law Amendments Act of 1979 (Reexamination - now passed in Senate as S. 2446)	Committee on the Judiciary
S. 1477 H.R. 3806	Kennedy	Title III - Creation of Court of Appeals for the Federal Circuit	Combines Court of Claims and CCPA
H.R. 6533	Railsback	(S. 414 plus Reexamination and Independent Patent and Trademark Office)	
H.R. 6933	Kastenmeier	Administration's Bill (Broadens H.R. 2414 to include large business)	Committee on the Judiciary
S. 2397	Dole	Preservation of Confidential Information Act (See earlier discussion)	Committee on the Judiciary
H.R. 5861	Preyer	Reverse Freedom of Information Litigation Act	Committee on Government Operations, Subcommittee on Government Information and Individual Rights

Patenting and Licensing Biological Organisms

The question of whether life forms can be patented is before the Supreme Court in the Chakrabarty case. At issue is a bacterium which has been genetically engineered so as to digest oil slicks. The government believes to grant patent rights on living organisms would be an unprecedented extension of the patent law. Biological organisms have enjoyed patent protection in the past, but the patents have been awarded not for the organisms but for the process in which they are used. Chakrabarty is significant in and of itself, but more so because it may be viewed to extend to recombinant DNA research even though the precise case is not before the court.

Biological organisms that were in the past often traded or given away among investigators, now may have significant commercial potential. From this basic discussion derives the fundamental issue of how to treat the patenting and licensing of Hybridoma technology. A new technology that permits artificially induced fusion of living cells and then permits the selecting out of pure antibodies to be therapeutically useful in the treatment of diseases. This new technology is being actively pursued by many investigators on our campuses and has lead to a handful of new businesses. It has also raised many questions of patentability. For example: Are hybridomas products of nature? If so, how are they different from those made in the laboratory? Is the man made organism sufficiently different from that found in nature to "cloak it with patentability?"

This topic is covered here because it appears that our institutional patent offices will be dealing with the patenting and licensing of biological organisms as both recombinant DNA and Hybridoma technology expands in the near future.

For a quick basic discussion of both DNA and hybridoma technology see Science Magazine, May 16, 1980, Pages 688 through 693 and Technology Review, February 1980, edited at the Massachusetts Institute of Technology, Pages 57 through 63.