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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 eduniversity. vom activiti ado a li remento vasskia samaneg ku migli seki ik ikgombi e e

no 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 dicensing but the prospective licensee is "not satisfied" with the non-exclusive royaltybearing license offered by the institution: 300 and 10 18 decade and

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. tu a s been liebins outfo

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 3 4 4 3 3 4 5 4 5 6

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Two controls. The Committee has appointed a task force to initiate discussions so 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 vac sponsorship.

Patent Legislation

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S. 414 - The "Dole/Bayh" patent bill passed the Senate overwhelmingly in April. This bill will allow universities and small businesses to retain regarders of mownership 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.

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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	<u>Title</u> <u>Committee</u>
H.R. 2414		University and Small Committee on the Business Patent Pro- cedures Act (See committee on Courts,
EP HARD VIGNAMUR 1928 TOTAL REPORT OF TANK THUNG VIEW OF TANK QUE	in de la completa de La completa de la co La completa de la co	earlier discussion) Civil Liberties and the Administration of Justice
om aplaka k	Barbara Barbara	Science and Technology Research and Develop- ment Utilization Policy Act Committee on Commerce, Science and Transpor- tation, Subcommittee on Science, Technology and Space
g statestvar u s su mi sterior otic promenvas gay ti	et karalının en dan terdiş Kanlı İstan konusik oğrum Kolassik İstan Varik oğrum	Uniform Federal Research Committee on Science and Development Utiliza- and Technology, Sub- tion Act of 1979 committee on Science, Research and Technology
H.R. 6965	Tra Ertel nia i spilas 1999 m. – Kaling 1908 m. jangs (1990 m.)	(H.R. 6965 combined Committee on the H.R. 5715 with reexamin- Judiciary, Committee ation and an Independent on Science and Tech-Patent and Trademark nology office)

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STEW.	<u>Number</u>	Sponsor	Title	Committee
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	\$. 2079 	. Thus ever gries s	Independent Patent and Trademark Office Act	Senate Judiciary and Government Affairs
uvili godi godi godin	S. 1679 H.R. 5075	and the second of	Patent Law Amendments Act of 1979 (Reexamination - now pass	Committee on the Judiciary sed
·			in Senate as S. 2446)	J. Margerating
voisa CEC	H.R. 3806	Kennedy Representation of the second of the	Title III - Creation of Court of Appeals for the Federal Circuit	Claims and CCPA
	H.R. 6533	Railsback	(S. 414 plus Reexamina-	ett efunger
สเปียว	omal vzi alesét köly. <u>Grób</u> álam élét laga Millian sala librasi	ed to this eaget-	tion and Independent Patent and Trademark Office)	e međ Grejanski
	H.R. 6933	Kastenmeier	Administration's Bill (Broadens H.R. 2414 to include large busi- ness)	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 Govern- ment Operations, Sub- committee on Govern- ment 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 <u>Science Magazine</u>, May 16, 1980, Pages 688 through 693 and <u>Technology Review</u>, February 1980, edited at the Massachusetts Institute of Technology, Pages 57 through 63.

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