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TELEFAX CONTROL SHEET

SENT TO: Mr. Joe Allen

DATE SENT: March 22, 1995

SUBJECT:

No. of pages (including this cover sheet): 8

Sent by: Erin Geraghty for Norman J. Latker

Remarks:

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March 16, 1995

Norman J. Latker
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RE: **ABA SPECIAL COMMITTEE ON UNIVERSITY INTELLECTUAL PROPERTY LAW - COMMITTEE 452**

Dear Norm:

Attached you will find a copy of the final report of Committee 452 for your review and vote. The report and resolution have been revised over that sent earlier to you. Please indicate your approval, disapproval or abstention by checking the appropriate places on the copy of this letter and returning it to me prior to March 30 so that I can submit the report and a vote tally on behalf of the Committee before the deadline. Your prompt response is needed so that a valid committee report can be submitted.

Sincerely,

Howard

Howard W. Bremer
Committee 452
1994-1995 Chairman

Joe
See pgs. 5 and 6
N

Report:

✓ approve _____ disapprove _____ abstain

Resolution:

✓ approve _____ disapprove _____ abstain

Mid-Year Report
Palm Beach, Florida
January, 1995

COMMITTEE NO. 452 Howard Bremer, Chair

SPECIAL COMMITTEE ON UNIVERSITY INTELLECTUAL PROPERTY LAW

Scope of Committee: Addresses intellectual property legal issues of special importance to universities.

Subject 1. TECHNOLOGY TRANSFER AND THE UNIVERSITIES.

NO PROPOSED RESOLUTION.

Past Action. None

Discussion. The scope of the Committee's interest is construed to include changes in Federal Agency regulations or practices, as well as legislatively mandated changes, which affect or have a potential to affect the technology transfer function, which function has become an important adjunct to university research. For example, changes in the tenor and the practical effects of the manner in which patent applications are examined by the Patent and Trademark Office can have a profound effect upon the ability of a university to transfer technology which has been generated during the course of research to the private sector for its further development to the marketplace. Witness, for example, the examining practices and the rejections of applications directed to biotechnological inventions based upon utility in Group 1800. Objection to such practices, aired in hearings held by the Patent and Trademark Office in October 1994, led to the generation by the Office of a "standards" paper for Examiners. The university sector's concerns were represented in those hearings in the interest of preserving a sound patent base under which the results of (biotechnology) research could be developed in the public interest. The premise was that, particularly with respect to inventions in the field of biotechnology, delays, narrow scope and extraordinary costs adversely affect the funding for biotechnology research and development thereby jeopardizing the United States' and the universities' leadership role and commercial position in this science which holds so much promise for the betterment of the life, health and safety of the populace.

Recognition of and appreciation for the role and contribution which university research has made and continues to make to the competitive position of the United States in a global economy appears to be on the rise. Indicative of that is the growing role for university research as the corporate research effort tends to decline. For example, the share of all R&D that was conducted in academic institutions grew from 9% in 1985 to 13% in 1993 while industrial firms' R&D performance share fell from 72% to 68% over the same period. During the 1980-1993

period, average annual growth was much stronger for the academic sector than for any other R&D performing sector, an estimated 5.2% compared to around 2 to 3% for federal, industrial and non-profit labs. More indirectly, the growth in the membership of and the broader recognition of the Association of University Technology Managers (AUTM) as a favored spokesman on university sector positions on intellectual property and other issues is another measure of the importance of the university sectors' contributions to competitiveness. This Committee has promoted coordination of its efforts with like efforts of AUTM, the Association of American Universities (AAU) and the Council on Governmental Relations (COGR) as well as other university-affiliated organizations in an effort to reach consensus on issues affecting university intellectual property law and particularly on those issues which would prospectively alter or adversely affect the operations of the university sector under the provisions of 35 U.S.C. 200-212 and attendant regulations and otherwise.

Subject 2. LEGISLATION ADVERSELY AFFECTING UNIVERSITIES' RIGHTS AND OPERATIONS UNDER 35 U.S.C. 200-212 AND 37 C.F.R. PART 401.

PROPOSED RESOLUTION 452-2.

RESOLVED, that the Section of Intellectual Property Law opposes in principle legislation containing provisions which hinder the ability of universities, non-profit organizations and small businesses to transfer the technology resulting from research and development supported in whole or in part with Federal funds under the provision of 35 U.S.C. 200-212 and 37 C.F.R. Part 401 and thereby militate against such technology being made available to the public in the absence, in such legislation, of a recognition of the limitation imposed by 35 U.S.C. 210(a) and a stated reason and justifiably supported and documented basis to support the proposition that such legislation shall take precedence over 35 U.S.C. 200-212.

Past Action. The Section passed R452-1 (1994 AR-R452-1, Past Action Book p 89) opposing in principle legislation containing

such provisions with specific reference to H.R. 1334 entitled "Federal Research Product Commercialization Act, introduced by Mr. Wyden (D-Oregon) in the 103rd Congress, 1st Session with regard to making drugs, devices and other tangible products resulting from research supported by the National Institutes of Health (NIH) available to the public.

The Section also passed R-TF-PUR-1 (8/94 AR-R-TF-PUR-1, Past Action Book, pg. 74) opposing S.2272, 103rd Congress, 2nd Session (DeConcini/Biden) in its current form or equivalent legislation which would grant prior user rights to a person who has used an invention as a trade secret in such a way as to have suppressed or concealed the invention under Section 102(g) Title 35, U.S.C.

Discussion. The Bayh-Dole Act, which is represented in 35 U.S.C. 200-212 (as amended by Public Law 98-620) is fundamental to the university technology transfer effort. That law and the regulations under it, as expressed in 37 C.F.R. Part 401, as a practical matter, function as the operations manual for university technology transfer offices. The passage of the Bayh-Dole Act after twenty years of effort and in the face of strong opposition from several Federal agencies was a recognition by Congress:

(1) that imagination and creativity are truly a national resource;

(2) that the patent system is the appropriate vehicle for the delivery of that resource to the public;

(3) that placing the stewardship of the results of basic research in the hands of the universities and small business was in the public interest; and

(4) that the existing federal patent policy was placing the nation in economic peril during a time when innovation was becoming the preferred currency in foreign affairs.

Also, and not insignificantly, it was a recognition that the inventor is an indispensable factor in the technology transfer equation.

Given the recognized seminal nature of that legislation and its projected effect in stimulating innovation, which has, since its passage, been amply documented, and given the opposition mounted by several Federal agencies to its passage, the Act was crafted with the following provision set forth at 35 U.S.C. 210(a):

> "The Act creating this Chapter shall be construed to take precedence over any future Act unless that Act specifically cites this Act and provides that it shall take precedence over this Act."

It is submitted that the recited limitation is fully in the interest of the public and permits the utilization of the universities, as a resource, unique in the world, to maintain, through collaboration between the universities and the private

sector, the competitiveness of the United States in a global economy.

Since the Bayh-Dole Act, its provisions and potential ongoing effects are as timely and viable today as when first enacted, it is imperative that every effort be made to preserve the Act so that we can continue to reap its benefits. The Administration is on record as seeking change. There is little question that change should be sought where change is needed to correct errors or mitigate damages and inequities. However, change, merely for the sake of change, or to satisfy a political agenda, particularly absent a perception or appreciation of the consequences of that change, should be avoided as counterproductive.

In conclusion, it is submitted that, by resolution, the Section should go on record as opposing changes which would lead to disenfranchising the university technology transfer effort, militate against private investment in innovation and, most importantly, detract from the investment in basic research upon which the future depends.

It is recognized that a number of pieces of legislation, the provisions of which, directly or indirectly, had a potential impact upon the technology transfer function of the university sector did not, of course, survive the transition from the 103rd to the 104th Congress, including both bills referred to in the Past Action reference above. It is anticipated that, at least, some sort of prior user rights bill will be introduced into the 104th Congress and will have to be given the Section's attention again.

Subject 3. OTHER PRACTICES AND INITIATIVES CONTAINED IN FEDERAL PROGRAMS WHICH WOULD ALTER OR ADVERSELY AFFECT THE OPERATIONS OF THE UNIVERSITY SECTOR UNDER 35 U.S.C. 200-212 AND 37 C.F.R. PART 401.

NO PROPOSED RESOLUTION

Past Action. None.

Discussion. The drive by the current Administration to reinvent government has led to certain initiatives within some agencies which appear to controvert the policy and objectives of the Bayh-Dole Act as set forth at 35 U.S.C. 200.

Under Bayh-Dole (35 U.S.C. 201(b)) the university sector's rights are derived from the following language:

> "(b) The term "funding agreement means any contract, grant or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal Government. Such term includes any

> assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as herein defined."

In addition, the right of universities to elect to retain title to any inventions made when they are functioning as a sub-contractor is clearly spelled out at 37 C.F.R. 401.14(g) which requires the contractor under any funding agreement to use the Standard Patent Rights Clause of 37 C.F.R. 401.14 which reads:

> "The contractor will include this clause.....in all sub-contracts regardless of tier, for experimental, developmental or research work to be performed by a small business firm or domestic non-profit organization. The sub-contractor will retain all rights provided for the contractor in this clause, and the contractor will not, as part of the consideration for awarding the sub-contract, obtain rights in the sub-contractor's subject inventions."

These directives have been ignored in the Advanced Technology Program through a controversial interpretation made by National Institute of Standards and Technology (NIST) attorneys that inventions made under the ATP program have to be assigned to the commercial participant in the program. Universities are not eligible to participate in the program as contractors and, despite the flow-down provision of the Bayh-Dole Act (reproduced above), have no Bayh-Dole-derived rights as a subcontractor. An effort made to correct this interpretation failed when the bill of which it was a part died with the 103rd Congress. The university sector will seek a new vehicle in the 104th Congress for appropriate amendment to preserve the universities' rights as derived from the Bayh-Dole Act.

Another program which appears to be attempting to avoid the directives of the Bayh-Dole Act is the Advanced Research Project Agency (ARPA) Technology Reinvestment Program (TRP). That program is utilizing a funding vehicle known as an "other transaction" (pursuant to 10 U.S.C. 2371) which is not subject to Bayh-Dole. In such cases non-profit institutions would have to negotiate with any for-profit collaborators under the TRP to determine disposition of inventions. This will, of course, bring into play employment and funding obligations of inventors at non-profit institutions and, perhaps, disparate negotiating strengths and postures.

In the 103rd Congress, 1st Session, Senator Rockefeller (D-W.VA) introduced a bill (S1537) which would direct federal laboratories to assign title to joint inventions made under Cooperative Research and Development Agreements (CRADAs) to the industrial research partner. Since the directive would include within its scope Federally Funded Research and Development Corporations (FFRDCs) several of which are run by universities,

there were concerns within the university sector about the bill and particularly since the requirement to assign extends to jointly-authored copyrighted works, including software.

The university sector was able to obtain amendments to the bill which would eliminate the perceived university problem. It is possible, if not probable, that the bill will be introduced in the 104th Congress in its amended form.

There are a variety of ways, through legislation, Agency program changes, regulation, and interpretation, which can adversely affect the ability of the university sector to carry out the technology transfer function under the Bayh-Dole Act. There is a general cognizance that that function has been highly successful and that it has been a positive contributing factor to U.S. competitiveness through its effect in establishing a collaborative university-private sector relationship. Such relationships have yielded new products, created high technology jobs and spawned a robust biotechnology industry. The Bayh-Dole Act, which embraces not only universities and other non-profit entities but small business as well, extends its protection and benefits to all sectors of society, the universities, small business, large business and the government because it is based upon fair and equitable principles.

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