

STATEMENT

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BEFORE
THE MONOPOLY AND ANTICOMPETITIVE ACTIVITIES SUBCOMMITTEE
SENATE SMALL BUSINESS COMMITTEE

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COMMENTS ON THE DESIRABILITY OF INSTITUTIONAL
PATENT AGREEMENTS FOR UNIVERSITIES

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INTRODUCTION

THANK YOU FOR THE OPPORTUNITY AFFORDED ME TO PARTICIPATE IN THIS PUBLIC HEARING ON THE PROPOSED IMPLEMENTATION OF A UNIFORM, GOVERNMENT-WIDE PROGRAM OF INSTITUTIONAL PATENT AGREEMENTS, SPECIFICALLY AS APPLIED TO UNIVERSITIES. MY COMMENTS TODAY ARE OFFERED ON BEHALF OF THE ASSOCIATION OF AMERICAN UNIVERSITIES, THE AMERICAN COUNCIL ON EDUCATION AND THE NATIONAL ASSOCIATION OF STATE UNIVERSITIES AND LAND GRANT COLLEGES. THEY ALSO REPRESENT THE POSITION OF THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY. I SINCERELY HOPE THAT THIS EXCHANGE OF IDEAS AND PHILOSOPHIES IN APPROACHING THE PATENT IMPLICATIONS OF GOVERNMENT-SPONSORED RESEARCH AT UNIVERSITIES WILL SERVE AS A CONSTRUCTIVE MEANS OF CONTINUING COMMUNICATIONS ON THIS MATTER BETWEEN UNIVERSITIES, THE GOVERNMENT AND THE PUBLIC.

UNIVERSITIES GENERALLY SUPPORT INSTITUTIONAL PATENT AGREEMENTS, NOT BECAUSE OF POTENTIAL FINANCIAL RETURN (WHICH IS MINIMAL), BUT BECAUSE OF THEIR VALUE AS EFFECTIVE INSTRUMENTS FOR TECHNOLOGY TRANSFER. FOR THIS REASON, WE BELIEVE THAT SUCH AGREEMENTS ARE IN THE BEST INTEREST OF THE PUBLIC AND HENCE THE UNITED STATES. WITH YOUR INDULGENCE, I WOULD LIKE TO SPEND THE REMAINDER OF MY TIME DEVELOPING THIS THEME.

NATURE OF UNIVERSITY INVENTIONS

AS YOU WELL KNOW, THE UNITED STATES GOVERNMENT, THROUGH ITS

VARIOUS AGENCIES, SPENDS HUNDREDS OF MILLIONS OF DOLLARS PER YEAR TO SUPPORT RESEARCH AT AMERICAN UNIVERSITIES. BECAUSE OF THE UNIQUE NATURE OF THE UNIVERSITIES, THE TYPE OF RESEARCH DIFFERS FROM THAT PERFORMED UNDER OTHER GOVERNMENT-FUNDED CONTRACTS. FURTHER, THE UNIVERSITY'S SPECIAL GOALS OF EDUCATION AND RESEARCH RESULT IN UNIQUE PATENT CONCERNS AND HENCE DIFFERENT TECHNOLOGY TRANSFER PROCESSES.

THE UNIVERSITY, BY ITS VERY NATURE, IS ORIENTED TO BASIC AND FUNDAMENTAL RESEARCH AS AN INTEGRAL PART OF ITS EDUCATION PROCESS. THE UNIVERSITY IS NOT AND SHOULD NOT BE A BUSINESS OR COMMERCIAL ENTERPRISE. IT DOES NOT DEVELOP PRODUCTS NOR SELL GOODS. INVENTIONS MADE IN THE PERFORMANCE OF GOVERNMENT-SPONSORED RESEARCH ARE USUALLY INCIDENTAL TO THAT RESEARCH, I.E., BY-PRODUCTS RATHER THAN SPECIFIED OBJECTIVES. THE GOVERNMENT DOES NOT FUND A UNIVERSITY TO CREATE PATENTABLE INVENTIONS, BUT RATHER TO EXTEND THE KNOWLEDGE OF MAN IN AREAS OF VITAL IMPORTANCE TO THE COMMUNITY. UNIVERSITIES ARE NOT FUNDED TO PRODUCE MARKETABLE PRODUCTS, BUT TO EXPLORE THE FRONTIERS OF SCIENCE AND TECHNOLOGY IN ORDER TO ADD TO OUR FUND OF KNOWLEDGE.

CONSEQUENTLY, IT IS RARE THAT A UNIVERSITY, IN THE COURSE OF PERFORMING GOVERNMENT-SUPPORTED RESEARCH, WILL DEVELOP AN INVENTION CAPABLE OF BEING TRANSFERRED IMMEDIATELY TO THE MARKET.

TO TRANSLATE TECHNOLOGICALLY USEFUL CONCEPTS CREATED AT THE UNIVERSITY INTO COMMERCIALLY VIABLE DEVELOPMENTS FROM WHICH THE PUBLIC CAN DIRECTLY BENEFIT REQUIRES A CONSIDERABLE AMOUNT OF ADDITIONAL DEVELOPMENT, TESTING AND MARKETING.

UNIVERSITY-DEVELOPED INVENTIONS--TRANSFER TECHNOLOGY

EXPERIENCE SHOWS THAT IT OFTEN COSTS ORDERS OF MAGNITUDE MORE TO TRANSFER A BASIC, UNIVERSITY-GENERATED INVENTION TO THE MARKET-

PLACE THAN IT DID INITIALLY TO INVENT IT. THIS IS BECAUSE THE REPORT, THE DATA OR THE BREADBOARD MODEL DEVELOPED AT THE UNIVERSITY, HOWEVER INTERESTING OR POTENTIALLY WORTHWHILE, WILL NEVER BENEFIT SOCIETY AS A WHOLE UNLESS SOMEONE IS WILLING AND HAS BEEN PROVIDED WITH SUFFICIENT INCENTIVE TO TAKE THE NECESSARY FOLLOW-ON STEPS TO TRANSFER THE BASIC TECHNOLOGY INTO A FORM CAPABLE OF ASSUMING COMMERCIAL UTILITY.

IT FOLLOWS THAT THE TRANSFER OF TECHNOLOGY TAKES TIME, REQUIRES SPECIALIZED EXPERTISE AND COSTS CONSIDERABLE AMOUNTS OF MONEY. TO ENCOURAGE INDUSTRY TO SPEND THIS TIME, EFFORT AND MONEY, IT IS OFTEN ESSENTIAL TO OFFER PROSPECTIVE LICENSEES SOUND PATENT PROTECTION, COUPLED WITH REASONABLE LICENSE TERMS. WITHOUT SUCH INDUCEMENTS, MANY EXCELLENT INVENTIONS WOULD NEVER BE EFFECTIVELY RECOGNIZED OR USED; AND, WHEN THAT HAPPENS, IT IS THE PUBLIC WHICH SUFFERS THE GREATEST HARM. WITHIN OUR FREE ENTERPRISE SYSTEM, THE PROFIT MOTIVE REMAINS AN ESSENTIAL INGREDIENT TO THE EFFECTIVE TRANSFER OF TECHNOLOGY. THE SOCIAL VALUE OF THIS PHILOSOPHY IS EXPLICITLY RECOGNIZED BY THE FRAMERS OF THE CONSTITUTION AND IS INCLUDED IN ARTICLE I, SECTION 8, WHICH DIRECTS CONGRESS TO "PROMOTE THE PROGRESS OF SCIENCE AND USEFUL ARTS BY SECURING FOR LIMITED TERMS TO AUTHORS AND INVENTORS THE EXCLUSIVE RIGHT TO THEIR RESPECTIVE WRITINGS AND DISCOVERIES." THE PATENT SYSTEM RESULTING THEREFROM WAS NOT CREATED TO BENEFIT A SELECT FEW BUT TO PROVIDE AN INCENTIVE TO DEVELOP AND COMMERCIALIZE INNOVATIVE IDEAS TO HELP THE PUBLIC.

SINCE THE COMMERCIALIZATION PROCESS CANNOT APPROPRIATELY BE DONE BY A UNIVERSITY OR, FOR THAT MATTER, BY THE GOVERNMENT, THIS PHASE OF TECHNOLOGY TRANSFER SHOULD BEST BE HANDLED BY THE PRIVATE SECTOR OF OUR ECONOMY. UNDERSTANDABLY, COMPANIES ARE USUALLY RELUCTANT TO TAKE ON THESE TASKS UNLESS THEY ARE ASSURED OF REASONABLE

LEGAL AND BUSINESS PROTECTION AND INDUCEMENTS IN THE FORM OF PATENTS AND LICENSING ARRANGEMENTS.

M.I.T.'s EXPERIENCE, AND I AM SURE THAT OF OTHER UNIVERSITIES TENDS TO ILLUSTRATE THESE POINTS. FOR EXAMPLE, METHODS OF PRODUCING VITAMIN A AND PENICILLIN WERE BOTH DISCOVERED AT M.I.T. ALTHOUGH THE TECHNICAL FEASIBILITY OF THESE INVENTIONS WAS SUCCESSFULLY DEMONSTRATED IN THE LABORATORY, A CONSIDERABLE AMOUNT OF CLINICAL TESTING AND GOVERNMENT APPROVALS WERE NECESSARY PRIOR TO MARKETING. THIS, IN TURN, COST CONSIDERABLE MONEY AND REQUIRED THE MAKING OF NUMEROUS RISK DECISIONS. THE UNIVERSITY ITSELF WAS CERTAINLY NOT IN A POSITION, NOR DID IT HAVE THE MOTIVATION OR EXPERTISE TO ASSUME THIS BURDEN. COMMERCIAL LICENSEES WITHIN THE PRIVATE SECTOR WERE EVENTUALLY LOCATED, AND THESE LICENSEES DID RISK THEIR MONEY, TIME AND EFFORT IN COMMERCIALIZING THE INVENTIONS. CONSEQUENTLY, THESE INVENTIONS WERE, AND STILL ARE, MADE WIDELY AVAILABLE TO THE PUBLIC WITH RESULTANT BENEFIT TO ALL. THE UNIVERSITY'S OWNERSHIP OF PATENTS AND ABILITY TO NEGOTIATE REASONABLE LICENSES CONSTITUTE, I BELIEVE, A MAJOR INDUCEMENT TO THIS TECHNOLOGY TRANSFER.

THE MAGNETIC CORE MEMORY, WHICH WAS ALSO DEVELOPED AT M.I.T., BECAME A PRIMARY ELEMENT IN THE GROWTH OF THE COMPUTER INDUSTRY AS WE KNOW IT TODAY. THIS INVENTION, WHICH WAS DEVELOPED THROUGH GOVERNMENT FUNDING (AND FOR WHICH THE GOVERNMENT RECEIVED A ROYALTY-FREE RIGHT AND LICENSE), CONSTITUTES ANOTHER SIGNIFICANT EXAMPLE OF THE VALUE OF A GOVERNMENT, INDUSTRY AND UNIVERSITY COOPERATING IN AN ATMOSPHERE THAT ENCOURAGES PATENT LICENSING AND COMMERCIALIZATION OF USEFUL IDEAS.

DR. FORRESTER, DIRECTOR OF THE WHIRLWIND PROJECT, CONCEIVED THIS INVENTION AND PERSONALLY PROVED THE CONCEPT IN PRACTICE THROUGH NUMBERLESS OVERTIME HOURS. THIS INVENTION BECAME A SIGNIFICANT PART OF THE AMERICAN TECHNOLOGICAL MYSTIQUE!

THE POINT I WISH TO MAKE IS THAT COMMERCIAL INCENTIVES AND THE EFFECTIVE USE OF THE PRIVATE SECTOR OF OUR SOCIETY WERE NECESSARY TO TRANSFER THE UNIVERSITY-DEVELOPED INVENTIONS IN A WAY TO HELP EACH OF US AS CITIZENS, BOTH IN THE IMPROVEMENT OF OUR HEALTH AND IN THE ADVANCEMENT OF OUR TECHNOLOGICAL GROWTH. ASSUMING THAT WE ALL AGREE ON THESE NEEDS, WE COME TO THE ISSUE OF WHETHER THE GOVERNMENT OR THE UNIVERSITY IS BEST SUITED TO EFFECTUATE THIS TRANSFER.

GOVERNMENT OWNERSHIP OF RESEARCH INVENTIONS

AT FIRST BLUSH, A VERY STRONG ARGUMENT WOULD SEEM TO EXIST THAT INVENTIONS MADE IN THE COURSE OF GOVERNMENT-SPONSORED RESEARCH SHOULD BE OWNED BY THE GOVERNMENT SINCE TAXPAYER'S MONEY HAS BEEN USED. IF THE PEOPLE PAY MONEY THROUGH THEIR GOVERNMENT TO ENCOURAGE THE CONDUCT OF RESEARCH AT EDUCATIONAL INSTITUTIONS, THEN WHY SHOULDN'T THE PEOPLE (AGAIN THROUGH THEIR GOVERNMENT) ENJOY THE FRUITS OF THE TECHNOLOGY PRODUCED FROM SUCH RESEARCH. THE ANSWER, OF COURSE, IS THAT THE PEOPLE SHOULD INDEED BENEFIT AND THAT THE TAXPAYER SHOULD BE GIVEN A RETURN FOR HIS INVESTMENT BY WAY OF TECHNOLOGY TRANSFER. THE UNIVERSITIES DO NOT CONTEST THIS RIGHT IN THE TAXPAYER AND, IN FACT, ARE COMPLETELY IN AGREEMENT WITH IT.

THE KEY QUESTION TO BE ANSWERED IS WHETHER GOVERNMENT OWNERSHIP OF PATENTS PRODUCED THROUGH FEDERALLY-SPONSORED RESEARCH IS REALLY AN EFFICIENT AND REASONABLE WAY OF ACCOMPLISHING THAT GOAL. AS YOU KNOW, OVER THE YEARS, A NUMBER OF GOVERNMENT AGENCIES HAVE OPERATED WITH A SO-CALLED "TITLE" PROVISION. AS OF 1972, THE UNITED STATES GOVERNMENT HAD IN ITS PORTFOLIO APPROXIMATELY 24,000 GOVERNMENT-OWNED PATENTS. SINCE THAT TIME, MANY THOUSANDS MORE HAVE BEEN ADDED. TO MY KNOWLEDGE, ONLY A RELATIVELY SMALL NUMBER OF THESE PATENTS HAVE ACTUALLY BEEN LICENSED.

THIS IS NOT A REFLECTION ON THE ABILITIES OF THE VARIOUS GOVERNMENT AGENCIES, BUT RATHER A COMMENTARY ON THE NATURE OF THE LICENSING PROCESS, VIS-A-VIS THE OBJECTIVES OF THE GOVERNMENT.

THE GOVERNMENT IS NOT PHILOSOPHICALLY OR PRAGMATICALLY ATTUNED TO LICENSING AS AN EFFECTIVE TOOL OF TECHNOLOGY TRANSFER. IN THIS COUNTRY, IT HAS TRADITIONALLY BEEN THE NORM THAT, WHEREVER POSSIBLE, TECHNOLOGY DEVELOPMENT SHALL BE THROUGH THE PRIVATE SECTOR OF OUR ECONOMY ALTHOUGH OFTEN WITH THE HELP AND STIMULUS OF THE GOVERNMENT. PRESIDENT CARTER, IN HIS STATE OF THE NATION ADDRESS, EMPHASIZED THIS POINT WHEN HE PROMISED THAT, UNDER HIS ADMINISTRATION, ECONOMIC GOALS WOULD BE ACHIEVED IN CONJUNCTION WITH THE PRIVATE ECONOMY AND IN TERMS OF A TRUE PARTNERSHIP BETWEEN THE GOVERNMENT AND ITS PEOPLE.

THE UNIVERSITIES BELIEVE THAT A GOVERNMENT "TITLE" PROVISION IS UNDESIRABLE FOR A NUMBER OF REASONS

1. GOVERNMENT PERSONNEL ARE IN A MUCH LESS FAVORABLE POSITION TO ASCERTAIN OR PURSUE THE COMMERCIAL MARKETABILITY OF AN INVENTION SINCE THEY CANNOT BE AS INTIMATELY FAMILIAR WITH THE INVENTION AS A UNIVERSITY INVENTOR HIMSELF. HENCE, THE TRANSFER OF NECESSARY KNOW-HOW WOULD BE DRASTICALLY CURTAILED. THIS, IN TURN, WOULD SERIOUSLY IMPAIR THE LICENSING PROCESS.
2. MOST GOVERNMENT AGENCIES DO NOT NOW POSSESS MECHANISMS FOR LICENSING AND MARKETING. TO PERFORM THESE FUNCTIONS WOULD, THEREFORE, REQUIRE SIGNIFICANT INCREASES IN ADMINISTRATION COSTS AND PERSONNEL.
3. IT IS FEARED THAT TITLE IN THE GOVERNMENT WOULD HAVE A DEPRESSING EFFECT ON THE AMOUNT AND QUALITY OF INVENTION DISCLOSURES FROM INVENTORS SINCE THERE WOULD TEND TO BE FEWER INCENTIVES FOR THE CONSIDERABLE ADDITIONAL EFFORT NEEDED OVER AND ABOVE MERELY A LEGAL COMPLIANCE WITH THE PROVISIONS OF THE RESEARCH CONTRACT.

FOR EXAMPLE, MY STAFF WORKS AT ENCOURAGING THE FILING OF

DISCLOSURES. UNIVERSITY SCIENTISTS, BY THE NATURE OF THEIR PERSONAL DEDICATIONS, DO NOT THINK IN TERMS OF PATENTS AND COMMERCIALIZATION UNTIL WE STIMULATE THEM TO DO SO.

4. GOVERNMENT OWNERSHIP (EVEN WHERE WAIVER PROCEDURE IS CONTEMPLATED) WOULD TEND TO DISCOURAGE UNIVERSITY/INDUSTRY/GOVERNMENT COOPERATIVE RESEARCH PROJECTS SINCE THE UNIVERSITY WILL BE UNABLE TO PROVIDE INDUSTRY WITH A QUICK AND CERTAIN DEFINITION OF LICENSING RIGHTS AT THE INITIAL CONTRACTUAL STAGE. THIS SITUATION WOULD BE CONTRARY TO THE COOPERATIVE RESEARCH PROGRAMS THAT THE GOVERNMENT ITSELF IS ACTIVELY SUPPORTING.

A POLICY OF GOVERNMENT OWNERSHIP WILL REMOVE ANY INCENTIVES THAT UNIVERSITIES WITHOUT AN ESTABLISHED LICENSING PROGRAM MAY HAVE TO EXPLORE THE POSSIBILITIES OF CREATING SUCH A CAPABILITY; AND, FOR THOSE UNIVERSITIES WITH AN EXISTING, VIABLE LICENSING PROGRAM, THIS POLICY WILL, AT BEST, SIGNIFICANTLY INCREASE THE PAPERWORK AND ADMINISTRATION WHILE DECREASING LICENSING OUTPUT, THEREBY DECREASING TECHNOLOGY TRANSFER.

IN SHORT, THE UNIVERSITY COMMUNITY BELIEVES THAT SUCH A POLICY WILL RESULT IN EFFECTIVELY DENYING TO THE PUBLIC MANY WORTHWHILE TECHNOLOGICAL DEVELOPMENTS. SUCH A RESULT IS, OF COURSE, NOT IN KEEPING WITH THE GOALS EITHER OF GOVERNMENT OR THE UNIVERSITY, NOR DOES IT BENEFIT THE TAXPAYING PUBLIC.

UNIVERSITY OWNERSHIP OF RESEARCH INVENTIONS

THE UNIVERSITIES PROPOSE THAT THEY BE ALLOWED TO RETAIN OWNERSHIP OF INVENTIONS MADE IN THE COURSE OF GOVERNMENT-SUPPORTED RESEARCH AT THEIR INSTITUTIONS. IN MAKING THIS PROPOSAL, THE UNIVERSITIES CERTAINLY DO NOT INTEND TO HOLD THEMSELVES OUT AS POSSESSING ALL OF THE ANSWERS TO COMPLEX PROBLEMS OF TECHNOLOGY TRANSFER. WE RECOGNIZE OUR MANY AND VARIED IMPERFECTIONS IN THIS AREA.

BUT WE ARE LEARNING, AND THIS LEARNING IS VALUABLE. THE LICENSING PROCESS DRAWS THE RESEARCH UNIVERSITY CLOSER TO INDUSTRY, WHICH EVERYONE

RECOGNIZES TO BE A DESIRABLE GOAL.

AS I STATED AT THE OUTSET, IN TERMS OF DOLLARS EARNED, UNIVERSITY LICENSING IS HARDLY TO BE CONSIDERED A SOURCE OF FINANCIAL SECURITY. FOR EXAMPLE, A RECENT SURVEY OF RESEARCH UNIVERSITIES BY THE ASSOCIATION OF AMERICAN UNIVERSITIES DETERMINED THAT, OF 29 UNIVERSITIES, 19 HAD GROSS ROYALTY INCOME IN 1977 OF LESS THAN \$80,000; 7 HAD ANNUAL GROSS ROYALTY INCOME OF LESS THAN \$500,000; 2 HAD ROYALTIES IN THE AREA OF APPROXIMATELY \$900,000; AND ONE OF APPROXIMATELY \$1,000,000.

MY INSTITUTION, THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY, IS ONE OF THOSE TOP THREE. OUR GOVERNMENT RESEARCH, INCLUDING THE LINCOLN LABORATORY WHICH WE MANAGE FOR DOD, TOTALS APPROXIMATELY \$200,000,000 PER YEAR. MOST PATENTS ARE SO FUTURISTIC THAT THEIR 17 YEARS RUN OUT BEFORE SIGNIFICANT USE!

I WOULD POINT OUT THAT NOT ALL OF THE INCOME-EARNING INVENTIONS RESULTED FROM GOVERNMENT-SUPPORTED RESEARCH. IT IS DIFFICULT, HOWEVER, TO ARRIVE AT THE APPROPRIATE RATIO. THE SURVEY ALSO INDICATED THAT MOST OF THE UNIVERSITIES REPORTED THAT MORE THAN 20% OF PATENT FILINGS GENERATED INCOME. ALTHOUGH THE SURVEY RESULTS ARE NOT BROAD ENOUGH TO BE CONCLUSIVE, THEY DO TEND TO AGREE WITH PREVIOUS, MORE DETAILED STUDIES.

FOR EXAMPLE, A 1974 SURVEY BY DHEW OF OVER 60 INSTITUTIONS MANAGING 329 PATENT PROPERTIES GENERATED UNDER DHEW-SPONSORED RESEARCH INDICATED THAT 122 LICENSES WERE GRANTED ON AT LEAST 79 DIFFERENT PATENT ENTITIES. IN OTHER WORDS, THE DATA SHOWED THAT ABOUT 24% OF THE PATENT PROPERTIES WERE LICENSED. (THIS FIGURE IS A MINIMUM, AND MAY WELL HAVE BEEN AS HIGH AS 37%, DEPENDING ON THE INTERPRETATION OF THE DATA.)

A 1973 SURVEY BY NORTHWESTERN UNIVERSITY OF 50 INSTITUTIONS MANAGING 236 PATENT PROPERTIES INDICATED THAT 86 LICENSES WERE GRANTED ON AT LEAST 56 DIFFERENT PATENT PROPERTIES. IN OTHER WORDS,

THE DATA SHOWED THAT, AS A MINIMUM, 24% OF THE PATENT ENTITIES WERE LICENSED (ALTHOUGH, AGAIN, THE FIGURE COULD BE AS HIGH AS 37%, DEPENDING ON THE INTERPRETATION OF THE DATA IN THE SURVEY). LIKEWISE, AN EARLIER NACUBO* SURVEY SHOWED SIMILAR RESULTS. A 1977 SURVEY BY THE SOCIETY FOR UNIVERSITY PATENT ADMINISTRATORS SHOWS THAT APPROXIMATELY 50% OF PATENTS ISSUED WERE LICENSED OVER THE LAST 10 YEARS. IT SHOULD BE RECOGNIZED THAT THE ABOVE FIGURES REPRESENT AN AVERAGE, AND THAT THE SIZE AND AGGRESSIVENESS OF THEIR PATENT MANAGEMENT PROGRAMS MAY DIFFER SUBSTANTIALLY. HOWEVER, THE POINT TO BE MADE IS THAT THOSE UNIVERSITIES WITH A PATENT LICENSING PROGRAM, ALTHOUGH THEY MAY NOT GENERATE MAJOR ROYALTY INCOME, DO TRANSFER A REASONABLE AMOUNT OF TECHNOLOGY VIA THE LICENSING PROCESS.

THE M.I.T. EXPERIENCE IS NEARER 10% OF PATENTS LICENSED AND 5% THAT YIELD SIGNIFICANTLY BEYOND PATENT MANAGEMENT COSTS.

A UNIVERSITY IS BETTER ABLE THAN GOVERNMENT TO EFFECT THIS TRANSFER. IT IS THE ORIGIN OF THE INVENTION. FURTHERMORE, IN MANY CASES, THE DIRECT INTERACTION BETWEEN THE INVENTOR AND HIS UNIVERSITY ON THE ONE HAND, AND THE COMMERCIAL LICENSEE ON THE OTHER HAND IS MOST PRODUCTIVE IN ENSURING AN EFFECTIVE TRANSFER, SINCE IT ENCOURAGES THE FREE FLOW OF KNOW-HOW AND DATA WHICH IS ESSENTIAL TO STRENGTHEN AND SUPPORT THE LICENSED INVENTION. WHO BUT THE INVENTOR IS BEST QUALIFIED TO PROVIDE THE TECHNOLOGICAL BACKGROUND MATERIAL AND KNOW-HOW THAT IS NEEDED TO ENABLE THE LICENSEE TO FULLY DEVELOP THE INVENTION? TECHNOLOGICAL QUALIFICATION, OF COURSE, IS ONLY PART OF THE NEED. AS NOTED PREVIOUSLY, THE UNIVERSITY INVENTION IS OFTEN ONLY AN EMBRYONIC COMMERCIAL IDEA AT ITS INCEPTION. IT REQUIRES CONSTANT ATTENTION, CONTINUING INTEREST AND SUSTAINED FAITH IN ITS ULTIMATE WORTH IF ITS POTENTIAL FOR PUBLIC BENEFIT IS EVER TO BE REALIZED. MY EXPERIENCE LEADS ME TO BELIEVE THAT THIS NEED IS BEST MET BY THE INVENTOR WITHIN THE CONTEXT OF THE UNIVERSITY ENVIRONMENT.

*NATIONAL ASSOCIATION OF COLLEGE AND UNIVERSITY BUSINESS OFFICERS

THE UNIVERSITY ENCOURAGES THIS INTERACTION BETWEEN THE INVENTOR AND THE UNIVERSITY AND THE COMMERCIAL LICENSEE BY THE MECHANISMS OF ADDITIONAL INDUSTRIAL SUPPORT AND/OR BY THE CONSULTING PROCESS. THE IMPORTANCE OF AN INSTITUTIONAL PATENT AGREEMENT IN THIS REGARD CANNOT BE OVEREMPHASIZED. THE CERTAINTY OF OWNERSHIP AFFORDED THE UNIVERSITY AT THE OUTSET OF ITS CONTRACTING WITH THE GOVERNMENT ALLOWS THE UNIVERSITY, IN TURN, TO EXPEDITE THE PROCESS OF ENCOURAGING THE INDUSTRIAL INTERFACE NEEDED FOR COMMERCIALIZATION.

OUR INSTITUTE, AND OTHER MAJOR RESEARCH UNIVERSITIES, PROVIDE FORMAL MECHANISMS BY WHICH INDUSTRY CAN KEEP INFORMED OF RESEARCH ACTIVITIES AND NEW DEVELOPMENTS. THESE PROGRAMS FUNCTION HAND IN HAND WITH THE LICENSING PROGRAM.

THE UNIVERSITY COMMUNITY GENERALLY FOLLOWS A POLICY, WHEREVER FEASIBLE, OF GRANTING NON-EXCLUSIVE, ROYALTY-BEARING LICENSES TO ALL QUALIFIED APPLICANTS. HOWEVER, EXCLUSIVE LICENSES MAY BE GRANTED IF IT IS DETERMINED THAT THIS IS REQUIRED AS AN INCENTIVE TO ENCOURAGE THE MARKETING AND EVENTUAL PUBLIC USE OF THE INVENTION. BEFORE GRANTING AN EXCLUSIVE LICENSE, HOWEVER, A BONA FIDE EFFORT IS MADE TO INTEREST COMPANIES KNOWN TO HAVE THE NECESSARY EXPERTISE TO FURTHER DEVELOP THE INVENTION THROUGH THE GRANTING OF A NON-EXCLUSIVE LICENSE. IF THESE ATTEMPTS ARE NOT SUCCESSFUL AND AN EXCLUSIVE LICENSE APPEARS TO BE THE ONLY EFFECTIVE WAY TO TRANSFER THE TECHNOLOGY, THEN SUCH A LICENSE WILL BE LIMITED IN DURATION AND WILL INCORPORATE A NUMBER OF RESTRICTIONS AND SAFEGUARDS TO INSURE THAT THE LICENSEE ACTIVELY DEVELOPS THE INVENTION IN ORDER TO MAKE IT AVAILABLE TO THE PUBLIC AT REASONABLE RATES AS SOON AS POSSIBLE. IN DETERMINING THE LENGTH OF EXCLUSIVITY, THE STATED POLICIES OF THE VARIOUS GOVERNMENT AGENCIES ARE USED. FOR EXAMPLE, UNDER THE INSTITUTIONAL PATENT AGREEMENT WITH THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,

UNIVERSITIES ARE RESTRICTED TO AN EXCLUSIVE LICENSING TERM OF NO MORE THAN 3 YEARS FROM THE FIRST COMMERCIAL SALE OR ~~3~~ 8 YEARS FROM THE DATE OF THE LICENSE AGREEMENT, WHICHEVER OCCURS FIRST. SUCH LICENSES WILL ALSO INCORPORATE DEVELOPMENT SCHEDULES AND REQUIREMENTS IN THE FORM OF MILESTONES TO BE MET BY THE LICENSEE IN ORDER TO ENSURE A TIMELY COMMERCIALIZATION OF THE INVENTION.

RETENTION OF LICENSING RIGHTS BY THE UNIVERSITY ENCOURAGES IN A PRACTICAL WAY THE PARTNERSHIP OF THE GOVERNMENT, THE UNIVERSITY AND INDUSTRY AND HENCE GREATLY ENHANCES THE PROBABILITY OF A SUCCESSFUL TECHNOLOGY TRANSFER. THE ULTIMATE BENEFICIARY IN THIS RESPECT IS THE PUBLIC.

INSTITUTIONAL PATENT AGREEMENTS

THE UNIVERSITIES PROPOSE THAT THE INSTITUTIONAL PATENT AGREEMENT IS MOST SUITABLE TO ANSWERING THE NEEDS OF THE UNIVERSITY FOR OWNERSHIP AND LICENSING OF INVENTIONS, WHILE MEETING THE CONCERNS OF THOSE ADVOCATING GREATER GOVERNMENT CONTROL. WE BELIEVE THAT AN INSTITUTIONAL PATENT AGREEMENT SUCH AS THAT PUBLISHED IN THE FEBRUARY 2, 1978 FEDERAL REGISTER, WILL MOST EFFECTIVELY ATTAIN THE GOALS OF GOVERNMENT AND THE UNIVERSITIES IN ENSURING THAT TECHNOLOGY DEVELOPED BY PUBLIC FUNDS IS MADE AVAILABLE FOR PUBLIC USE AS QUICKLY, EFFICIENTLY AND INEXPENSIVELY AS POSSIBLE."

ANY UNIVERSITY DESIRING TO ENTER INTO AN INSTITUTIONAL PATENT AGREEMENT WOULD FIRST BE REQUIRED TO DEMONSTRATE THAT IT HAS A VIABLE TECHNOLOGY TRANSFER PROGRAM. THE INFORMATION REQUIRED OF A UNIVERSITY TO MEET THIS REQUIREMENT IS DETAILED AND EXTENSIVE, INCLUDING THE UNIVERSITY'S STATEMENT OF PURPOSE, SOURCE OF FUNDING, PATENT POLICY, DISCLOSURE PROCEDURE, INVENTOR/EMPLOYEE AGREEMENT, ROYALTY SHARING PRACTICES, LICENSING PROGRAM AND OTHER CRITERIA DESIGNED TO GIVE THE SPONSORING AGENCY A DETAILED PICTURE OF THE UNIVERSITY'S OPERATIONAL PROCEDURES AND PHILOSOPHIES IN THE AREA OF PATENT LICENSING.

THE INSTITUTIONAL PATENT AGREEMENT ITSELF WILL REQUIRE THAT UNIVERSITY INVENTIONS BE QUICKLY AND EFFICIENTLY IDENTIFIED AND DISCLOSED TO THE SPONSORING AGENCY AND FURTHER THAT THE UNIVERSITY PROMPTLY FILE PATENT APPLICATIONS ON THOSE INVENTIONS IT ELECTS TO ATTEMPT TO LICENSE. THERE ARE MANY ADDITIONAL PROVISIONS DESIGNED TO ENCOURAGE TECHNOLOGY TRANSFER WHILE ENSURING ADEQUATE GOVERNMENT CONTROLS. FOR EXAMPLE, THE UNIVERSITY MUST FURNISH THE SPONSORING AGENCY WITH A TECHNICAL DISCLOSURE FOR EACH INVENTION WITHIN A SPECIFIED TIME PERIOD; INTERIM AND FINAL PROGRESS REPORTS ARE ALSO REQUIRED. FURTHER, DETAILED TIME PERIODS ARE ESTABLISHED FOR THE FILING OF PATENT APPLICATIONS AND FOR THE EXECUTION AND DELIVERY OF CONFIRMATORY LICENSES TO THE GOVERNMENT. IN THIS LATTER RESPECT, THE INSTITUTIONAL PATENT AGREEMENT RECOGNIZES, OF COURSE, THAT EVEN IN THOSE INSTANCES WHERE A UNIVERSITY ELECTS TO RETAIN OWNERSHIP OF AN INVENTION, IT MUST PROVIDE THE GOVERNMENT WITH A ROYALTY-FREE RIGHT TO USE.

ONCE A UNIVERSITY QUALIFIES FOR AN INSTITUTIONAL PATENT AGREEMENT AND AFTER IT HAS MET THE OBLIGATIONS OF REPORTING INVENTIONS TO THE GOVERNMENT AND FILING PATENT APPLICATIONS ON THOSE INVENTIONS IT WISHES TO LICENSE, THE UNIVERSITY CONTINUES TO BE REQUIRED TO MEET CERTAIN SAFEGUARDS. FOR EXAMPLE, THE GOVERNMENT CAN REQUIRE THE UNIVERSITY TO LICENSE ALL RESPONSIBLE APPLICANTS ON REASONABLE TERMS, UNLESS THE UNIVERSITY CAN DEMONSTRATE THAT IT HAS BEEN EFFECTIVE, WITHIN GIVEN TIME CONSTRAINTS, IN TRANSFERRING THE TECHNOLOGY. THE AGENCY MAY ALSO REQUIRE COMPULSORY LICENSING WHERE THIS IS NEEDED FOR GOVERNMENT REGULATION, TO MAINTAIN PUBLIC HEALTH OR SAFETY STANDARDS, OR FOR OTHER PUBLIC PURPOSES STIPULATED IN THE APPLICABLE CONTRACT. IN ADDITION, LICENSES GRANTED BY THE UNIVERSITY MUST BE AT REASONABLE ROYALTY RATES AND MUST BE IN ACCORD WITH OTHER PRESCRIBED SAFEGUARDS. ALL NET ROYALTY INCOME (AFTER DEDUCTION OF EXPENSES, INCLUDING PAYMENTS TO INVENTORS) MUST BE UTILIZED BY THE UNIVERSITY

Proposed IPA

FOR THE SUPPORT OF EDUCATION OR RESEARCH. THERE IS A FURTHER PROVISION THAT THE AGREEMENT WITH THE UNIVERSITY MAY BE TERMINATED AT ANY TIME BY EITHER PARTY UPON 30 DAYS' WRITTEN NOTICE.

TO SUMMARIZE, THE UNIVERSITY COMMUNITY SUPPORTS THE CONCEPT OF AN INSTITUTIONAL PATENT AGREEMENT FOR THE FOLLOWING REASONS:

1. THOSE UNIVERSITIES THAT QUALIFY WILL BE ASSURED FROM THE OUTSET OF OWNERSHIP RIGHTS, THEREBY EXPEDITING THE TECHNOLOGY TRANSFER PROCESS.
2. AN INSTITUTIONAL PATENT AGREEMENT WILL ENCOURAGE CONTINUED COOPERATION BETWEEN THE UNIVERSITY AND INDUSTRY.
3. IT WILL PROVIDE A SIMPLE AND UNIFORM PROCEDURE FOR THE DISPOSITION OF GOVERNMENT-FUNDED RESEARCH INVENTIONS.
4. UNDER SUCH AN AGREEMENT, UNIVERSITIES WOULD BE ALLOWED TO LICENSE INVENTIONS AT REASONABLE ROYALTY RATES. THE ROYALTY INCOME WOULD BE RETURNED TO THE UNIVERSITY TO MEET ITS DUAL COMMITMENTS OF TEACHING AND ADVANCING RESEARCH.
5. THE INSTITUTIONAL PATENT AGREEMENT WILL ^{ASSIST} ALLOW THE UNIVERSITY TO FULFILL ONE OF ITS PRIMARY OBJECTIVES, I.E., ADVANCING THE FRONTIERS OF KNOWLEDGE.

SUCH AN AGREEMENT WILL ALSO BE OF BENEFIT TO THE GOVERNMENT FOR THE FOLLOWING REASONS:

1. BY ENCOURAGING INTERACTION BETWEEN THE UNIVERSITY COMMUNITY AND THE PRIVATE SECTORS OF OUR ECONOMY, THE GOVERNMENT WILL MEET ITS OBJECTIVE OF ENSURING THAT THE BENEFITS OF PUBLICLY FUNDED RESEARCH ARE MADE AVAILABLE TO THE PUBLIC ITSELF AS QUICKLY AS POSSIBLE.
2. UNDER AN INSTITUTIONAL PATENT AGREEMENT, THE GOVERNMENT'S RIGHT TO USE THE INVENTION WILL BE ASSURED, AND ADEQUATE SAFEGUARDS WILL EXIST TO ENABLE THE GOVERNMENT TO MONITOR

THE UNIVERSITY'S PERFORMANCE OF TECHNOLOGY TRANSFER AT ALL STAGES OF ITS DEVELOPMENT.

3. THE INSTITUTIONAL PATENT AGREEMENT WILL MINIMIZE UNNECESSARY ADMINISTRATIVE BURDENS ON THE GOVERNMENT AND WILL ENCOURAGE UNIVERSITIES TO MORE FULLY PARTICIPATE WITH INDUSTRY IN THE TRANSFER OF TECHNOLOGICAL DEVELOPMENTS.
4. OF MAJOR IMPORTANCE, THE GOVERNMENT WOULD HAVE ACTED IN ITS PROPER ROLE AS THE CATALYST FOR TECHNOLOGY TRANSFER, THUS ENSURING THAT THE REQUIREMENTS OF THIS ADMINISTRATION SHALL BE MET.

THE UNIVERSITIES RECOGNIZE THAT THERE MAY, ON OCCASION, BE PARTICULAR RESEARCH PROJECTS THAT MUST BE EXEMPTED FROM AN INSTITUTIONAL PATENT AGREEMENT DUE TO THEIR PARTICULAR NATURE. THEY ALSO RECOGNIZE AND ACCEPT THE NEED FOR THE RESTRICTIONS AND LIMITATIONS EMBODIED IN THE INSTITUTIONAL PATENT AGREEMENTS TO ENSURE THAT GOVERNMENT MONEY IS PROPERLY SPENT. WE APPRECIATE THE INTENTIONS OF THIS COMMITTEE AND ITS NEED TO CAREFULLY SCRUTINIZE THE PROPOSED REGULATIONS. WE ARE HAPPY TO WORK WITH YOU IN SEEKING TO ACCOMPLISH WHAT WE BELIEVE TO BE IDENTICAL OBJECTIVES.

SUBSEQUENT TO PREPARATION OF THIS TESTIMONY, A SERIES OF QUESTIONS WERE RECEIVED FROM THE COMMITTEE. MY ANSWERS TO THOSE QUESTIONS ARE APPENDED. I WILL GLADLY DISCUSS EACH OF THEM IN MORE DETAIL IF YOU WISH. THANK YOU.

ADDENDUM

THE HONORABLE GAYLORD NELSON, CHAIRMAN OF THE SELECT COMMITTEE ON SMALL BUSINESS, HAS POSED A NUMBER OF QUESTIONS FOR THE AAU SPEAKER TO BE ANSWERED AT THE HEARING ON MAY 23^D 1978.

1. QUES. HOW MANY ACTUALLY COME OUT AHEAD--ROYALTIES AND OTHER INCOME COMPARED WITH EXPENSES--BY RETAINING RIGHTS TO INVENTIONS AND ATTEMPTING TO SEE THEM THROUGH TO THE POINT OF PRACTICAL APPLICATION?

ANS. AS I NOTED IN MY PRESENTATION, THE VALUE OF THE INSTITUTIONAL PATENT AGREEMENT DOES NOT LIE PRIMARILY IN THE INCOME TO BE EARNED BY UNIVERSITIES, BUT RATHER IN ITS EFFECTIVENESS AS AN INSTRUMENT FOR TECHNOLOGY TRANSFER. CLEARLY, THOSE UNIVERSITIES SUCH AS M.I.T., STANFORD, WISCONSIN AND OTHERS WHO HAVE AN ACTIVE VIABLE LICENSING PROGRAM EARN SUFFICIENT ROYALTIES TO MORE THAN OFFSET THE COST INVOLVED. THOSE UNIVERSITIES LACKING SUCH A PROGRAM SHOULD BE VIEWED AS IN A DEVELOPING STAGE. AS THEIR PROGRAMS BECOME MORE EFFECTIVE, THEY WILL BE CAPABLE OF PAYING FOR THEMSELVES. FROM THE RETURNED QUESTIONNAIRES OF 22 RESEARCH UNIVERSITIES, I ESTIMATE THAT ABOUT ONE OUT OF THREE ARE OPERATING "IN THE BLACK."

2. QUES. HOW IS IT THAT INSTITUTIONS NOT HOLDING IPAs MAKE ALMOST AS MANY PATENTABLE DISCOVERIES AS THOSE THAT DO (162 TO 167 FOR THE FIVE YEARS THROUGH 1974, ACCORDING TO FIGURES FROM THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE)?

ANS. I BELIEVE THAT THE REFERENCED STUDY RELATED TO PATENT APPLICATIONS FILED RATHER THAN TO PATENTABLE DISCOVERIES. ALSO, I DO NOT BELIEVE THAT THE DHEW FIGURES CAN NECESSARILY BE CONSIDERED REPRESENTATIVE OF THE OVERALL GOVERNMENTAL EXPERIENCE IN THIS MATTER. AT THE TIME THAT THIS STUDY WAS CONDUCTED, DHEW WAS WELL KNOWN FOR AN EXTREMELY LIBERAL WAIVER POLICY. CONSEQUENTLY, YOU WOULD EXPECT TO SEE A RELATIVELY HIGH NUMBER OF

WAIVER PETITIONS BEING MADE AND GRANTED. MORE TO THE POINT, WE SHOULD EXAMINE THE EXPERIENCE OF AGENCIES SUCH AS THE DEPARTMENT OF THE INTERIOR, AEC, AND THE DEPARTMENT OF TRANSPORTATION WHICH HAVE NEVER HAD IPA PROGRAMS AND WHICH HAVE VERY RARELY GRANTED WAIVER REQUESTS. I BELIEVE THAT YOU WILL FIND THAT UNIVERSITIES FILE VERY FEW WAIVER PETITIONS WITH THESE AGENCIES AND CONSEQUENTLY, VERY FEW PATENT APPLICATIONS ARE FILED.

WE UNDERSTAND, OF COURSE, THAT THE PRESENT SITUATION AT DHEW IS CONSIDERABLY DIFFERENT FROM THAT IN 1974. WE HAVE BEEN INFORMED THAT DHEW HAS NOT GRANTED A PETITION FOR WAIVER FOR AT LEAST THE LAST NINE MONTHS AND THAT APPROXIMATELY 30 PETITIONS HAVE BEEN FROZEN AND NO ACTION IS BEING TAKEN. CONSEQUENTLY, I WOULD ASSUME THAT A SIMILAR STUDY TODAY WOULD HAVE MARKEDLY DIFFERENT RESULTS.

EVEN PRESUMING A REASONABLY GOOD ATMOSPHERE TOWARDS UNIVERSITY LICENSING, IT IS LOGICAL THAT AN IPA PROGRAM IS A MUCH MORE EFFICIENT ADMINISTRATIVE MECHANISM THAN A CASE-BY-CASE WAIVER POLICY. THE WAIVER PROCEDURE IS UNPREDICTABLE AND MAY WELL BE SUBJECT TO CHANGES IN ADMINISTRATION AND POLICIES NOT DIRECTLY RELATED TO THE AVOWED CRITERIA FOR GRANTING THE WAIVERS.

3. QUES. WHAT IS THE RATIO OF LICENSES GRANTED TO PATENTS SOUGHT BY OR FOR IPA-HOLDERS? DO INSTITUTIONS NOT HOLDING AN IPA HAVE A HIGHER OR LOWER RATIO?

ANS. AS I NOTED IN MY PRESENTATION, SURVEY DATA INDICATES A HIGH PERCENTAGE OF PATENTABLE INVENTIONS HAVE BEEN LICENSED BY UNIVERSITIES. HOWEVER, THE DATA IS NOT SUCH AS TO READILY DRAW ANY BROAD CONCLUSIONS AS TO WHETHER IPA HOLDERS LICENSE MORE OR FEWER OF THEIR PATENT APPLICATIONS THAN THOSE WHO SECURED OWNERSHIP VIA WAIVER. MY M.I.T. COLLEAGUES AND I HAVE

OBSERVED THAT INSTITUTIONS THAT HAVE IPAs TEND TO BE MORE ACTIVELY ENGAGED IN THE LICENSING PROCESS. THOSE WHO HAVE NOT SOUGHT IPAs HAVE EITHER BEEN CONSTRAINED BY INSTITUTIONAL CONSIDERATIONS, OR MAY NOT BE AWARE OF THE ADVANTAGES TO BE GAINED.

4. QUES. HOW OFTEN DO IPA-HOLDERS GRANT EXCLUSIVE LICENSES? HOW MANY LICENSES HAVE THEY GRANTED TO THE INVENTOR OR TO PERSONS ASSOCIATED WITH THE RESEARCH THAT LED TO THE INVENTION?

ANS. THE FREQUENCY OF THE GRANTING OF EXCLUSIVE LICENSES HAS NO DIRECT RELATIONSHIP TO WHETHER A UNIVERSITY HOLDS AN IPA OR NOT. THERE MAY BE AN INDIRECT RELATIONSHIP IN THAT IPA HOLDERS GENERALLY WOULD TEND TO HAVE MORE LICENSING EXPERIENCE AND THUS MORE READILY RECOGNIZE THE NEED FOR SOME FORM OF EXCLUSIVITY UNDER CERTAIN CONDITIONS. EXCLUSIVE LICENSES ARE GRANTED ONLY WHERE IT IS JUDGED ESSENTIAL FOR THE EFFECTIVE TRANSFER OF TECHNOLOGY. IN THOSE CASES WHERE EXCLUSIVE LICENSES ARE GRANTED, THEY ARE DONE IN ACCORDANCE WITH THE RESTRICTIONS AND GUIDELINES I PREVIOUSLY MENTIONED IN THE PRESENTATION. IN OTHER WORDS, EXCLUSIVE LICENSES ARE GRANTED AS OFTEN AS THEY ARE NECESSARY, ALTHOUGH UNIVERSITIES SEEK NON-EXCLUSIVE LICENSEES WHENEVER TECHNOLOGY CAN BE TRANSFERRED EFFECTIVELY THAT WAY.

I WOULD SAY THAT LICENSES TO THE INVENTOR ARE NOT THE USUAL CASE SINCE THE INVENTOR IS NORMALLY NOT IN A POSITION TO EFFECTIVELY COMMERCIALIZE THE INVENTION BECAUSE OF A LACK OF FINANCIAL RESOURCES, MARKETING EXPERTISE, AND PRODUCTION FACILITIES. OCCASIONALLY, HOWEVER, THE INVENTOR DOES HAVE SUCH CAPABILITIES AND IN THOSE CASES MIGHT APPLY FOR AND RECEIVE A LICENSE.

SOME GOVERNMENT AGENCIES REQUIRE PERMISSION BEFORE A UNIVERSITY CAN LICENSE AN INVENTOR IN ORDER TO ENSURE THAT THE INVENTOR DOES HAVE THE NECESSARY TRANSFER CAPABILITIES AND TO PROTECT AGAINST ANY APPEARANCE OF A CONFLICT OF INTEREST.

5. QUES. DON'T LICENSEES FAIL MORE OFTEN THAN THEY SUCCEED AND FOR THE REASONS BUSINESSES USUALLY DO--MISCALCULATION OF THE MARKET, INADEQUATE FINANCING, AND SO ON?

ANS. THE ANSWER TO THIS QUESTION IS YES. THERE ARE OTHER REASONS INVOLVED, HOWEVER, FOR FAILURE OF LICENSEES OF UNIVERSITY INVENTIONS. A PRIMARY FACTOR IS THAT THE UNIVERSITY INVENTIONS BEING LICENSED INVOLVE THE INTRODUCTION TO THE MARKETPLACE OF NEW PRODUCTS AND NEW TECHNOLOGY OF A NATURE CONSTITUTING A HIGH-RISK VENTURE. GENERALLY, SUCH TECHNOLOGY ADDRESSES NEEDS WHICH HAVE EITHER NOT BEEN FULLY RECOGNIZED OR REPRESENTS NEW APPROACHES IN AREAS WHICH ARE ACCUSTOMED TO THE OLD EXISTING SOLUTIONS. THIS TYPE OF TECHNOLOGY TRANSFER IS OBVIOUSLY FRAUGHT WITH RISKS AND HIGH FAILURE POTENTIALS. THIS IS ANOTHER REASON WHY THE GOVERNMENT SHOULD ENCOURAGE LICENSEE INCENTIVES VIA INSTITUTIONAL PATENT AGREEMENTS.

6. QUES. SOME RESEARCH INSTITUTIONS COME TO REGARD THEMSELVES AS INVENTING UNIVERSITIES, AND OTHERS DO NOT. WHAT MAKES THE DIFFERENCE?

ANS. ~~THIS QUESTION SHOULD BE RESTATED.~~ SOME RESEARCH INSTITUTIONS ARE PATENT CONSCIOUS AND DEEPLY CONCERNED ABOUT THEIR RESPONSIBILITIES TO TRANSFER TECHNOLOGY AS PART OF THEIR PUBLIC SERVICE AND IN THEIR ROLE AS PUBLIC AGENTS. I SUPPOSE THAT THESE INSTITUTIONS COULD BE DESCRIBED IN TERMS OF THE QUESTION "AS INVENTING UNIVERSITIES." IT IS TRUE THAT OTHER

UNIVERSITIES MAY NOT HAVE VIABLE LICENSING PROGRAMS AND HENCE, BE LESS CAPABLE OF TRANSFERRING TECHNOLOGY. THIS IS PRECISELY WHY THE GOVERNMENT SHOULD SUPPORT THE INSTITUTIONAL PATENT AGREEMENT AS A MEANS OF ENCOURAGING THOSE WITHOUT LICENSING PROGRAMS TO DEVELOP THEM.

7. QUES. AN IPA IS A FAIRLY COMPLEX BUSINESS ARRANGEMENT, REQUIRING INVENTION DISCLOSURES AND INTERIM REPORTS, THE FILING OF DOMESTIC PATENT APPLICATIONS, THE LICENSING OF SUBJECT INVENTIONS, AND SO ON. GIVEN EXAMPLES OF INEPT CAMPUS ADMINISTRATION OF FEDERAL RESEARCH CONTRACTS, WHY SHOULDN'T WE BE SKEPTICAL ABOUT THE ABILITY OF RESEARCH INSTITUTIONS TO ADMINISTER IPAS?

ANS. M.I.T.'S EXPERIENCE IS THAT THE REQUIREMENTS UNDER AN INSTITUTIONAL PATENT AGREEMENT ARE NO MORE COMPLEX THAN THOSE UNDER THE WAIVER PROCEDURE. UNIVERSITIES HAVE BEEN OPERATING UNDER INSTITUTIONAL PATENT AGREEMENTS FOR MANY YEARS NOW (IN FACT, 72 UNIVERSITIES HAVE IPAS FROM DHEW ALONE). I AM NOT AWARE OF ANY SUBSTANTIVE PROBLEMS IN ADMINISTERING THESE AGREEMENTS. IN ANY EVENT A UNIFORM INSTITUTIONAL PATENT AGREEMENT AS HAS BEEN PROPOSED WOULD TEND TO FURTHER MINIMIZE THE PROBABILITY OF ADMINISTRATIVE ERRORS.

YOUR QUESTION, OF COURSE, REFERS TO PROBLEMS IN CONTRACT ADMINISTRATION RATHER THAN THE ADMINISTRATION OF IPAS. ~~ALTHOUGH I AM NOT SURE THAT THE QUESTION AS POSED IS GERMAINE TO THIS DISCUSSION,~~ IT IS CERTAINLY TRUE THAT MISTAKES HAVE BEEN MADE FROM TIME TO TIME BY UNIVERSITIES IN THEIR ADMINISTRATION OF FEDERAL RESEARCH CONTRACTS. AS THEY CONTINUALLY ATTEMPT TO IMPROVE THEIR ADMINISTRATIVE CAPABILITY IN THIS AREA, THE FREQUENCY OF THESE MISTAKES WILL DIMINISH, ~~AND THE INCIDENCE OF FRAUD HAS BEEN MINIMIZED.~~ I BELIEVE THE COMPLETE RECORD WILL SHOW THE UNIVERSITIES' RECORD OF ADMINISTRATION IS AS GOOD AS, OR BETTER THAN, ANY OTHER KIND OF SOCIAL INSTITUTION. I SEE

NO ADEQUATE REASON FOR SKEPTICISM ABOUT THE ABILITY OF UNIVERSITIES TO ADMINISTER IPAs.

8. QUES. DOESN'T AN IPA SUBORDINATE AN INVESTIGATOR-INVENTOR'S INTELLECTUAL PROPERTY RIGHTS AND SCIENTIFIC STANDING TO THE INSTITUTION'S COMMERCIAL INTERESTS? DOESN'T AN IPA REQUIRE OR AT LEAST ENJOIN HIM TO WITHHOLD PUBLICATION OF SCIENTIFIC RESULTS UNTIL HIS INSTITUTION'S COMMERCIAL RIGHTS HAVE BEEN ASSERTED?

ANS. THE UNIVERSITY VIEWS THE INVENTOR AS A PARTNER IN THE LICENSING ENDEAVOR. ROYALTIES EARNED BY THE UNIVERSITY ARE SHARED WITH THE INVENTOR AS CONTRASTED TO MUCH MORE RESTRICTIVE POLICIES OF INDUSTRY AND THE GOVERNMENT IN THIS RESPECT. CONSEQUENTLY, INVENTORS AT UNIVERSITIES ARE SUPPORTIVE OF IPAs AS A MEANS OF EFFECTIVE TECHNOLOGY TRANSFER.

AS I STATED IN THE PRESENTATION, UNIVERSITY INVENTIONS ARE BY-PRODUCTS OF THE RESEARCH. FOR EXAMPLE, M.I.T. CONDUCTS \$120 MILLION OF RESEARCH ON CAMPUS AND ANOTHER \$100 MILLION OF RESEARCH FOR DOD AT THE LINCOLN LABORATORY, BUT PATENT ROYALTIES ARE APPROXIMATELY \$1 MILLION PER YEAR--THE "COMMERCIAL INTEREST" IS ONLY ABOUT 1/2 PERCENT.

BECAUSE OF THE NATURE OF THE EDUCATIONAL PROCESS, PUBLIC DISSEMINATION OF INFORMATION IS OF PRIMARY IMPORTANCE. CONSEQUENTLY, UNIVERSITIES DO NOT CONSTRAIN AN INVENTOR FROM PUBLISHING THE SCIENTIFIC RESULTS OF HIS/HER RESEARCH. RATHER, THE UNIVERSITY RELIES ON EARLY DISCLOSURE OF INVENTIONS AND PROMPT FILING OF PATENT APPLICATIONS TO PROTECT ITS LICENSING RIGHTS. COMPARE THIS WITH THE POLICY OF THE DEPARTMENT OF ENERGY WHICH REQUIRES SUBMITTAL OF PAPERS 60 DAYS PRIOR TO THE PUBLICATION TO ALLOW THAT AGENCY TO MAKE DECISIONS

ON THE FILING OF PATENT APPLICATIONS AND WHICH CONTAINS THE FURTHER PROVISION GIVING THE DEPARTMENT OF ENERGY THE RIGHT TO PROHIBIT PUBLICATION INDEFINITELY IN ORDER TO PRESERVE ITS PATENT RIGHTS.

9. Ques. IT IS SOMETIMES ARGUED THAT CAMPUS INVENTIONS TEND TO BE EMBRYONIC, NEEDING A GREAT DEAL OF FURTHER WORK BY THE INVENTOR AND ADDITIONAL INVESTMENT TO BE DEVELOPED TOWARD THE POINT OF PRACTICAL APPLICATION. WHY SHOULD WE CONVERT BENCH SCIENTISTS INTO ENTREPRENEURS? IF ADDITIONAL INVESTMENT IS NEEDED AT THAT POINT, WHO SHOULD MAKE IT?

Ans. I AM NOT AWARE OF ANY UNIVERSITY POSITION THAT EXPECTS THE INVENTOR TO COMMERCIALIZE THE UNIVERSITY INVENTION. BECAUSE OF THE NECESSARY FINANCIAL INVESTMENT, PRODUCTION FACILITIES, AND MARKETING EXPERTISE, THE COMMERCIALIZATION PROCESS IS MOST EFFECTIVELY DONE BY INDUSTRY. THE INVENTOR, OF COURSE, MAY CONSULT AS PART OF THIS PROCESS; HOWEVER, IT IS THE LICENSEE THAT IS RESPONSIBLE FOR DEVELOPING THE INVENTION IN A FORM SUITABLE FOR THE MARKETPLACE. ADDITIONAL INVESTMENT, IF NEEDED, SHOULD BE PROVIDED BY THE LICENSEE.

10. Ques. A 1974 HARBRIDGE HOUSE STUDY FOR THE NATIONAL SCIENCE FOUNDATION OF LEGAL INCENTIVES AND BARRIERS TO UTILIZING TECHNOLOGICAL INNOVATION EXPLAINED:

MANY EDUCATIONAL INSTITUTIONS ADMINISTER PATENT PROGRAMS THROUGH INDEPENDENT FOUNDATIONS FOR VARIOUS LEGAL, FINANCIAL AND POLICY REASONS THAT ARE ONLY OCCASIONALLY RELATED TO INVENTION UTILIZATION. IN THESE INSTANCES, THE INVENTION IS ASSIGNED TO THE FOUNDATION EITHER BY THE INSTITUTION OR BY THE INVENTOR HIMSELF.

THESE WERE AMONG THE REASONS IT LISTED FOR WORKING THROUGH SUCH FOUNDATIONS:

- *INSULATING PATENT FUNDS FROM USE BY THE STATE GOVERNMENT, OR EVEN BY THE UNIVERSITY ITSELF, FOR PURPOSES OTHER THAN SCIENTIFIC RESEARCH
- *CREATING A BUFFER BETWEEN THE NONPROFIT INSTITUTION AND INDUSTRIAL LICENSEES IN THE EVENT OF LITIGATION
- *LIMITING CONTRACTUAL AND TAX LIABILITIES

TO THE EXTENT THAT THIS IS TRUE OF INSTITUTIONS HAVING OR WANTING AN IPA, HOW DID OR DO THEY DEMONSTRATE THE REQUISITE TECHNOLOGY TRANSFER CAPABILITY? WHAT QUALIFIED AS "CAPABILITY?"

Ans. M.I.T. ITSELF DOES NOT USE AN INDEPENDENT FOUNDATION TO ADMINISTER ITS PATENT PROGRAM. HOWEVER, THE PROPOSED INSTITUTIONAL PATENT AGREEMENT REQUIRES THAT WHERE A FOUNDATION IS USED, IT MUST MEET THE SAME CRITERIA AND BE SUBJECT TO THE SAME RESTRICTIONS AND SAFEGUARDS AS THE UNIVERSITY WOULD BE IF IT WERE ADMINISTERING ITS PATENT PROGRAM IN HOUSE. A TECHNOLOGY TRANSFER CAPABILITY PRESUMES PATENT AND LICENSING EXPERTISE AS WELL AS PROPER ADMINISTRATION WITHIN AN ATMOSPHERE WHICH RECOGNIZES THE VALUE TO SOCIETY OF THE PATENT SYSTEM. THE INVENTOR REMAINS A HIGHLY NECESSARY INGREDIENT IN THIS PROCESS. I WOULD ALSO NOTE FOR THE RECORD THAT ALL PATENT ROYALTIES EARNED BY M.I.T. AND I AM SURE BY OTHER UNIVERSITIES ARE USED TO SUPPORT FURTHER RESEARCH AND EDUCATIONAL PROGRAMS.

11. Ques. PRESIDENT CARTER'S BUDGET FOR FISCAL YEAR 1979 PROPOSES THAT THE FEDERAL GOVERNMENT SPEND NEARLY \$3.6 BILLION FOR RESEARCH AND DEVELOPMENT AT COLLEGES AND UNIVERSITIES. WHAT WOULD THE FEDERAL GOVERNMENT BE RECEIVING IN EXCHANGE? WHAT IS THE CASH VALUE TO THE PUBLIC OF THE SCIENCE THE FEDERAL GOVERNMENT WOULD BE SPONSORING?

Ans. THE CASH VALUE TO THE PUBLIC OF THE RESEARCH SPONSORED BY THE GOVERNMENT AT UNIVERSITIES IS INESTIMABLE. ALL INDICATIONS ARE THAT THIS RESEARCH PROVIDES THE BASIS ON WHICH OUR TECHNOLOGICAL SOCIETY STANDS. 3.6 BILLION DOLLARS IS ABOUT ONE PERCENT OF OUR GROSS NATIONAL PRODUCT. IS OUR TECHNOLOGICAL SOCIETY WORTH THAT INVESTMENT? THIS, OF COURSE, IS A QUESTION WE ALL MUST ANSWER. THE UNIVERSITIES, AND I

BELIEVE THE PUBLIC, THINK THAT IT IS MONEY WELL SPENT.

SPEAKING OF "CASH VALUE," ALL OF THE UNIVERSITIES IN THIS COUNTRY COULD NOT HAVE EARNED MORE THAN \$9 MILLION IN PATENT ROYALTIES DURING THE LAST FISCAL YEAR. THIS FIGURE IS LESS THAN THE NATIONAL SCIENCE FOUNDATION PROPOSED TO INVEST THIS YEAR IN UNIVERSITY/INDUSTRY COOPERATIVE RESEARCH ALONE. THE UNIVERSITY LICENSING PROGRAM IS HELPING TO BUILD A BRIDGE WITH INDUSTRY, A BRIDGE WHICH GOVERNMENT ITSELF CONSIDERS VITAL AND IS CONTINUALLY SEEKING WAYS TO STRENGTHEN. THE VALUE OF SUCH A BRIDGE CANNOT SIMPLY BE EQUATED TO DOLLARS AND CENTS, BUT IF IT COULD, IT WOULD BE ORDERS OF MAGNITUDE GREATER IN TERMS OF ITS VALUE TO THE COUNTRY THAN THE FEW MILLIONS OF GROSS INCOME EARNED BY THE UNIVERSITIES IN THEIR LICENSING PROGRAMS.

12. Ques. ADVOCATES OF THE IPA CONTEND IT HAS HELPED TRANSFER PROMISING NEW DRUGS FROM CAMPUS LABORATORIES TO THE MARKET-PLACE. THE NATIONAL INSTITUTES OF HEALTH HAVE DECIDED THAT, AT LEAST FOR THE TIME BEING, DISCOVERIES RESULTING FROM RECOMBINANT DNA RESEARCH CAN BE PATENTED UNDER THE IPA, YET THE PATENT AND TRADEMARK OFFICE LAST YEAR DECLARED THAT SUCH RESEARCH "APPEARS TO HAVE EXTRAORDINARY POTENTIAL BENEFIT FOR MANKIND," AND POINTED OUT THAT DNA TECHNOLOGY "HAS BEEN LIKENED IN IMPORTANCE TO THE DISCOVERY OF NUCLEAR FISSION AND FUSION." WHY SHOULD THE FEDERAL GOVERNMENT AGREE IN ADVANCE TO CEDE THE PRINCIPAL RIGHTS IN THESE POTENTIALLY MOMENTOUS DISCOVERIES? BY DOING SO, DOESN'T THE FEDERAL GOVERNMENT SURRENDER ITS PREROGATIVES AS A PRIME SPONSOR OF RESEARCH AND DEVELOPMENT? WOULDN'T IT THEN BE A WHOLLY PASSIVE PATRON OF SCIENCE?

Ans. DNA RESEARCH IS EXPECTED TO BE SIMILAR TO UNIVERSITY RESEARCH IN OTHER SCIENTIFIC FIELDS IN THAT IT SHOULD BE TRANSFERRED FROM THE LABORATORY INTO SOCIALLY USEFUL AND BENEFICIAL END-PRODUCTS AND REQUIRE CONSIDERABLE INVESTMENT OF MONEY AND PERSONNEL, PROPER FACILITIES, AND MARKET EXPERTISE-- ALL OF THE SAME INGREDIENTS FOR TECHNOLOGY TRANSFER THAT I MENTIONED PREVIOUSLY. THE SAME ARGUMENTS EXIST THAT THIS

TRANSFER SHOULD BE BETWEEN THE UNIVERSITY AND THE PRIVATE SECTOR WITH THE ENCOURAGEMENT OF GOVERNMENT. SINCE WE HAVE VERY LITTLE EXPERIENCE IN DNA APPLICATIONS, I WOULD SAY WE SHOULD PROCEED WITH CAUTION. ANY LICENSING PROGRAM IN THIS AREA SHOULD BE CAREFULLY CONTROLLED AND HAVE ADEQUATE SAFEGUARDS. ANY NECESSARY ADDITIONAL CONTROLS COULD EASILY BE INCLUDED WITHIN THE INSTITUTIONAL PATENT AGREEMENT.

13. QUES. IN THE VIEW OF THE PRESIDENT'S BIOMEDICAL RESEARCH PANEL, THE FREEDOM OF INFORMATION ACT, FEDERAL ADVISORY COMMITTEE ACT AND OTHER "SUNSHINE" LAWS POSE A THREAT TO THE SYSTEM OF PEER REVIEW OF GRANT APPLICATIONS AND CONTRACT PROPOSALS FOR SCIENTIFIC AND TECHNICAL MERIT. IN MARCH 1977, NIH CHANGED THE WORDING OF ITS FEDERAL REGISTER NOTICES OF CLOSED MEETINGS OF PEER REVIEW PANELS, INSERTING THE PHRASE "PATENTABLE MATERIAL" INTO ITS STANDARD JUSTIFICATION OF CLOSURE ON EXEMPTION 4 (TRADE SECRETS) GROUNDS. DO YOU KNOW OF A STATUTORY OR JUDICIAL BASIS FOR THIS TREATMENT OF "PATENTABLE MATERIAL?" WHAT IS PATENTABLE MATERIAL?

ANS. I BELIEVE THAT I WILL LEAVE THE ANSWER TO THIS QUESTION TO THE LAWYERS. AS YOU KNOW, PATENTABLE SUBJECT MATTER IS DEFINED BY CHAPTER 10, SECTIONS 100-104 OF THE UNITED STATES CODE, TITLE 35, AND AS INTERPRETED BY HUNDREDS OF COURT CASES. I ASSUME THAT THE NIH ACTION WAS INITIALLY OUT OF A CONCERN THAT AN INVENTOR MIGHT LOSE PATENT RIGHTS THROUGH PREMATURE PUBLICATION OCCASIONED BY PEER REVIEW PANELS, THEREBY JEOPARDIZING EFFECTIVE TECHNOLOGY TRANSFER.