CLEVELAND SPEECH - APRIL 16, 1977

I VERY MUCH APPRECIATE YOUR INVITATION, SINCE I BELIEVE YOU ARE WORKING IN AN AREA OF TECHNOLOGY OF GREAT IMPORTANCE TO THE PUBLIC, AND THIS IS AN OPPORTUNITY TO EXPLAIN THE IMPORTANCE OF PATENT PROTECTION IN BRINGING THAT TECHNOLOGY TO FRUITION, ESPECIALLY IN LIGHT OF THE PREMARKET CLEARANCE REQUIRED BY THE NEW MEDICAL DEVICE ACT.

THE ALLOCATION OF INVENTIONS ARISING FROM GOVERNMENT-SPONSORED RESEARCH AT UNIVERSITIES AND NONPROFIT ORGANIZATIONS IS AN AREA OF VITAL INTEREST TO HEW. THE DEPARTMENT IS BY FAR THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND PROBABLY THE WORLD.

IT IS A FUNDAMENTAL PREMISE OF HEW PATENT POLICY THAT A GUARANTEE OF SOME PATENT PROTECTION MAY BE NECESSARY TO AN INDUSTRIAL DEVELOPER IN ORDER TO ASSURE TRANSFER OF HEW-FUNDED UNIVERSITY GENERATED INVENTIONS TO SUCH DEVELOPER. THIS PREMISE SEEMS OBVIOUS, GIVEN THE FACT THAT COMMERCIALIZATION OF UNIVERSITY INVENTIONS MUST ULTIMATELY BE ACCOMPLISHED BY INDUSTRY, AND INHERENT TO THE COMMITMENT OF RISK CAPITAL IS A DECISION ON THE PART OF THE INDUSTRIAL DEVELOPER ON WHETHER THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING CONSIDERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS INTERESTS. CONVERSELY, FAILURE TO PROVIDE SUCH GUARANTEE IN CASES WHERE IT IS NECESSARY MAY FATALLY AFFECT UTILIZATION OR TRANSFER OF A MAJOR UNIVERSITY INNOVATION. THE CONTROVERSY OVER GOVERNMENT PATENT POLICY THAT SOME OF YOU MAY HAVE HEARD OF, AT LEAST IN THE RESEARCH AND DEVELOPMENT AGENCIES, SEEMS TO ME TO BE <u>NOT</u>, AS COMMONLY STATED, WHETHER THESE AGENCIES SHOULD TAKE "TITLE" OR "LICENSE" TO INVENTIVE RESULTS IT HAS FUNDED, BUT <u>WHEN AND TO</u> <u>WHAT EXTENT</u> A GUARANTEE OF PATENT PROTECTION SHOULD BE MADE. EVERY MAJOR RESEARCH AND DEVELOPMENT AGENCY SUPPORTING RESEARCH IN THE UNIVERSITY SECTOR BELIEVES IT SHOULD HAVE THE DISCRETION TO WAIVE OR LICENSE PATENT RIGHTS WHEN IT IS DEEMED APPROPRIATE TO ACHIEVE COMMERCIAL UTILIZATION.

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THE MORE MEANINGFUL PROBLEM IS SIMPLY THAT THE AGENCIES HAVE NOT UTILIZED THIS DISCRETION ON A UNIFORM BASIS IN SIMILAR FACT SITUATIONS.

IN A 1939 LETTER DR. EINSTEIN ADVISED PRESIDENT ROOSEVELT OF THE COMING OF THE ATOMIC AGE, AND SUGGESTED THAT THE GOVERNMENT AID UNIVERSITIES AND INDUSTRY TO COLLABORATIVELY BRING ABOUT A CHAIN REACTION. IN A FEW WORDS, DR. EINSTEIN IDENTIFIED AND ASSIGNED TO EACH ELEMENT OF THE COLLABORATIVE TEAM HE DEEMED NECESSARY TO THE COMPLETION OF THE DEVELOPMENT, THE DUTY WHICH EACH WOULD PERFORM BEST. THUS, HE SUGGESTED THAT THE UNIVERSITIES BE AIDED IN COMPLETING THEIR EXPERIMENTAL OR FUNDAMENTAL RESEARCH, THAT INDUSTRIAL LABORATORIES BE TAPPED FOR THEIR ABILITY TO BRING SUCH FUNDAMENTAL FINDINGS INTO PRACTICAL APPLICATION THROUGH THE USE OF THEIR EQUIPMENT, AND THE GOVERNMENT ACT AS THE CATALYST OR IMPRESARIO IN BRINGING THESE FACTORS TOGETHER. AS SIMPLE AS DR. EINSTEIN'S FORMULA FOR DELIVERY OF THE RESULTS OF FUNDAMENTAL RESEARCH INTO PRACTICAL USE APPEARS, THE CLOSING OF THE ENORMOUS GAP BETWEEN NEW FIELDS OF KNOWLEDGE AS DRAMATIC AS RADAR, COMPUTER MEMORY CORES, LASERS, ANTIBIOTICS, ETC., AND THEIR PRACTICAL IMPLEMENTATION BY INDUSTRY, WITH THE EXCEPTION OF THE FEW CASES WHERE THE GOVERNMENT HAS DETERMINED TO PROVIDE THE CONTINUED FUNDING TO INDUSTRY FOR DEVELOPMENT OF SUCH FINDINGS, HAS BEEN LEFT TO RANDOM AND HAPHAZARD EXECUTION.

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THE STAKE IN CLOSING THIS GAP IS VERY HIGH. IN 1975 APPROXIMATELY 3.2 OF THE 13 BILLION DOLLARS, OR ONE-QUARTER SPENT BY THE GOVERNMENT ON RESEARCH AND DEVELOPMENT OUTSIDE ITS OWN LABORATORIES, WENT IN THE FORM OF GRANTS AND CONTRACTS TO UNIVERSITIES.

ON SEPTEMBER 23, 1975, THE COMMITTEE ON GOVERNMENT PATENT POLICY RECOMMENDED, ON THE BASIS OF ITS UNIVERSITY SUBCOMMITTEE'S STUDY, THAT <u>ALL</u> AGENCIES OF THE EXECUTIVE BRANCH PROVIDE TO UNIVERSITIES A FIRST OPTION TO SUBSTANTIALLY ALL FUTURE INVENTIONS GENERATED WITH FEDERAL SUPPORT, SUBJECT TO STATUTORY PROHIBITION, AND PROVIDED THAT SUCH UNIVERSITY IS FOUND TO HAVE A TECHNOLOGY TRANSFER FUNCTION. THIS FIRST OPTION TO OWNERSHIP IS SUBJECT TO A NUMBER OF CONDITIONS, THE MOST IMPORTANT OF WHICH ARE THE STANDARD LICENSE TO THE GOVERNMENT, A LIMIT ON THE TERM OF ANY EXCLUSIVE LICENSE GRANTED, AUTHORITY TO WITHDRAW SPECIFIED PROJECTS FROM THE OPTION, A REQUIREMENT THAT ROYALTY INCOME BE UTILIZED FOR EDUCATIONAL OR RESEARCH PURPOSES, WITH THE EXCEPTION OF A REASONABLE SHARE TO THE INVENTOR, AND THE RIGHT OF THE AGENCY TO REGAIN OWNERSHIP DUE TO PUBLIC INTEREST CONSIDERATIONS OR THE UNIVERSITIES' FAILURE TO TAKE EFFECTIVE STEPS TO COMMERCIALIZE THE INVENTION.

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THE IMPLEMENTATION OF THE COMMITTEE'S RECOMMENDATION HAS BEEN CIRCULATED FOR PUBLIC COMMENT IN THE FORM OF A FEDERAL PROCUREMENT REGULATION AND IS NOW IN ITS FINAL STAGES OF REVIEW.

THE UNIVERSITY SUBCOMMITTEE REPORT IDENTIFIED SOME GENERAL PREMISES FROM WHICH IT PROCEEDED, ALL UNDERSTOOD BY DR. EINSTEIN IN 1939.

FIRST, A SYMPATHETIC AND ENCOURAGING FEDERAL CLIMATE IS VERY IMPORTANT TO TECHNOLOGICAL PROGRESS.

SECOND, THE UNIVERSITY COMMUNITY AND INDUSTRY, LEFT TO THEIR OWN INITIATIVES, WILL PROBABLY BE UNABLE TO GENERATE THIS ATMOSPHERE.

THIRD, THERE APPEARS TO BE AN ABSOLUTE NEED FOR INDUSTRIAL COLLABORATION WITH UNIVERSITIES IF THE RESULTS OF GOVERNMENT-SPONSORED UNIVERSITY RESEARCH ARE TO REACH THE PUBLIC. MUCH OF THE WORK PERFORMED UNDER GOVERNMENT-SPONSORED GRANTS AND CONTRACTS AT UNIVERSITIES IS BASIC, AS OPPOSED TO APPLIED RESEARCH. INVENTIONS ARISING OUT OF BASIC RESEARCH INVOLVE AT MOST COMPOSITIONS OF MATTER WITH NO CLEAR UTILITY, PROTOTYPE DEVICES, OR PROCESSES WHICH USUALLY REQUIRE MUCH ADDITIONAL DEVELOPMENT. UNIVERSITIES DO NOT UNDERTAKE DEVELOPMENT OF SUCH INVENTIONS, AS DEVELOPMENT LEADING TO COMMERCIAL MARKETING IS NOT ORDINARILY WITHIN THE SCOPE OF THEIR MISSIONS OR CAPABILITY. FURTHER, FINANCING OF THAT TYPE OF DEVELOPMENT WORK NEEDED IS NOT GENERALLY AVAILABLE FROM GOVERNMENT SOURCES. THERE ARE MANY MORE INVENTIVE IDEAS THAN FEDERAL RESOURCES FOR DEVELOPMENT PURPOSES. CONSEQUENTLY, DEVELOPMENT OF SUCH INVENTIONS WILL GENERALLY BE ACCOMPLISHED ONLY WHERE INDUSTRY HAS KNOWLEDGE OF THEM AND HAS AN INCENTIVE TO UTILIZE ITS RISK CAPITAL TO BRING THEM TO THE MARKETPLACE.

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LAST, THE DIFFICULTY OF COLLABORATION IS COMPOUNDED WHEN THOSE WHO NOW PERFORM ESSENTIAL PARTS OF A FUNCTION REFUSE TO MODIFY THEIR OPERATIONS TO MEET THE NEEDS OF THE WHOLE SYSTEM. ORDINARILY, THE PRINCIPALS CAN'T BE ORDERED TO COLLABORATE. THE PROBLEM PERCEIVED IS HOW TO PROVIDE THE MEANS FOR INDUCING THEM TO INTEGRATE VOLUNTARILY INTO A SYSTEM THAT PERFORMS A SOCIALLY DESIRABLE FUNCTION.

WITH THESE PREMISES IN MIND, THE UNIVERSITY SUBCOMMITTEE IDENTIFIED THE FOLLOWING AS THE PRIMARY PROBLEMS THAT NEEDED TO BE OVERCOME BEFORE OPTIMUM RESULTS IN TRANSFERRING TECHNOLOGY COULD BE ACHIEVED. FIRST, AND THOUGHT TO BE THE MOST IMPORTANT, WAS THE CONCLUSION THAT UNIVERSITIES DO NOT GENERALLY HAVE AN ADEQUATE MANAGEMENT CAPABILITY TO FACILITATE THE TIMELY IDENTIFICATION, PROTECTION AND THE TRANSFER OF THEIR INVENTIVE RESULTS TO INDUSTRIAL CONCERNS THAT MIGHT MAKE USE OF THEM.

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IT WAS PERCEIVED THAT THE MERE EXISTENCE OF A BODY OF RESEARCH PUBLICATIONS AND OTHER TECHNICAL INFORMATION WAS NOT ENOUGH TO RESULT IN SIGNIFICANT INDUSTRIAL INVOLVEMENT IN FURTHERING DEVELOPMENT.

SECOND, WAS THE "NOT-INVENTED-HERE" SYNDROME. INDUSTRIAL ORGANIZATIONS HAVE COMMERCIAL POSITIONS IN MOST AREAS OF THEIR RESEARCH. THERE IS AN IN-HOUSE INCENTIVE FOR SUCH ORGANIZATIONS TO FURTHER DEVELOP THE RESULTS OF THEIR OWN RESEARCH IN ORDER TO IMPROVE THEIR COMMERCIAL POSITION. THERE IS A LESSER INCENTIVE FOR INDUSTRY TO FURTHER DEVELOP THE RESULTS OF UNIVERSITY RESEARCH, SINCE SUCH RESEARCH WAS NOT UNDER INDUSTRY EVALUATION THROUGH ALL STAGES OF ITS DEVELOPMENT.

THIRD, WAS THE UNCERTAINTY OVER OWNERSHIP OF INVENTIONS MADE AT UNIVERSITIES THAT MAY BE COLLABORATIVELY DEVELOPED OR ARE INITIALLY GENERATED THROUGH A COLLABORATIVE RELATIONSHIP.

INDUSTRY REFUSAL TO COLLABORATE WITH UNIVERSITIES IN BRINGING HEW-FUNDED INVENTIONS TO THE MARKETPLACE, UNLESS PROVIDED SOME PATENT PROTECTION AS <u>QUID PRO QUO</u> FOR THE ADDITIONAL INVESTMENT AND DEVELOPMENT REQUIRED, WAS SUBSTANTIATED BY A HARBRIDGE HOUSE STUDY AND A 1968 GAO REPORT. INDUSTRY FELT DHEW PATENT PRACTICES AT THAT TIME FAILED TO TAKE INTO CONSIDERATION THE LARGE PRIVATE INVESTMENT NEEDED BEFORE UNTESTED CHEMICAL COMPOUNDS SYNTHESIZED WITH DEPARTMENT SUPPORT COULD BE MARKETED AS DRUGS. I BELIEVE THIS SAME RELUCTANCE TO COLLABORATE WITHOUT PATENT PROTECTION WILL OCCUR IN REGARD TO MEDICAL DEVICES WHICH REQUIRE PRE-MARKET CLEARANCE DUE TO THE INCREASE IN RISK CAPITAL REQUIRED TO GENERATE CLINICAL DATA NECESSARY FOR CLEARANCE.

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THE EXPERIENCES ALREADY NOTED IN UNIVERSITY DEALINGS WITH THE PHARMACEUTICAL INDUSTRY AND SOME MEDICAL DEVICE MANUFACTURERS INDICATED THAT THERE WILL BE THE SAME RELUCTANCE TO COLLABORATE WITH UNIVERSITIES IN BRINGING OTHER HIGH-RISK INVENTIONS TO THE MARKETPLACE IF SOME PATENT EXCLUSIVITY IS NOT FIRST PROVIDED TO THE DEVELOPER.

FOURTH, IS THE PROBLEM OF CONTAMINATION. "CONTAMINATION" MEANS THE POTENTIAL COMPROMISE OF INDUSTRY PROPRIETARY RIGHTS DUE TO EXPOSURE TO IDEAS, COMPOSITIONS, AND/OR TEST RESULTS ARISING FROM GOVERNMENT-SPONSORED UNIVERSITY RESEARCH. IF THE COMPANY INCORPORATES INTO ITS RESEARCH PROGRAM SOME OF THESE IDEAS, COMPOSITIONS OR TEST RESULTS AND THEN DEVELOPS A MARKETABLE PRODUCT PATENTABLY DISTINCT FROM ANY OF THE UNIVERSITY'S IDEAS, THE COMPANY FEARS THAT THE GOVERNMENT IS IN A POSITION TO ASSERT CLAIMS TO THEIR PRODUCT. TO OVERCOME THESE BARRIERS TO TECHNOLOGY TRANSFER, IT WAS DEEMED ESSENTIAL TO THE SUBCOMMITTEE THAT THE GOVERNMENT PERSUADE UNIVERSITIES TO PROVIDE A MANAGEMENT CAPABILITY WITHIN THE INSTITUTION THAT WILL SERVE AS A FOCAL POINT FOR IDENTIFICATION, RECEIPT AND PROMPT PROTECTION OF THE INVENTIVE RESULTS OF UNIVERSITY RESEARCH FOR LATER DISSEMINATION TO INDUSTRIAL CONCERNS. THE SUBCOMMITTEE FELT THAT THIS MIGHT BE ACCOMPLISHED BY GUARANTEEING TO UNIVERSITIES AT THE TIME OF FUNDING, PATENT RIGHTS IN GOVERNMENT-SUPPORTED INVENTIONS IN RETURN FOR ESTABLISHMENT OF SUCH A MANAGEMENT CAPABILITY.

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I BELIEVE THAT ONE OF THE PRIMARY BASES FOR THE RECOM-MENDATION WAS THE REALIZATION THAT A SUBSTANTIAL MAJORITY OF INVENTIVE IDEAS REQUIRES "ADVOCATES" IN ORDER TO REACH THE MARKETPLACE, AND THAT EXPERIENCE INDICATES THAT THE INVENTING ORGANIZATION, IF INTERESTED, IS A MORE LIKELY "ADVOCATE" THAN A LESS PROXIMATE AND NOT AS EQUALLY CONCERNED GOVERNMENT STAFF.

HISTORY IS REPLETE WITH EXAMPLES OF INVENTIONS NOW ACCEPTED AS PART OF OUR CULTURE, WHICH REACHED FRUITION ONLY DUE TO THE PERSEVERANCE OF AN ADVOCATE. IT IS SAID THAT THE INVENTOR OF XEROX, CHESTER CARLSON, CONTACTED OVER 100 CONCERNS BEFORE HE WAS ABLE TO OBTAIN A FINANCIAL COMMITMENT FOR DEVELOPMENT. SIMILARLY, SAMUEL B. MORSE ARGUED THROUGH FIVE YEARS BEFORE HE WAS ABLE TO OBTAIN \$30,000 FROM CONGRESS TO BUILD A TEST LINE FOR HIS TELEGRAPH BETWEEN WASHINGTON AND BALTIMORE. THERE IS NO EVIDENCE THAT A GOVERNMENT ORGANIZATION WOULD BE WILLING TO DUPLICATE THAT KIND OF ADVOCACY, NOR IS IT APPARENT THAT MANY ORGANIZATIONS OR PERSONS WOULD, ABSENT A PROPERTY RIGHT.

THE GUARANTEE OF PATENT RIGHTS TO THE UNIVERSITY CARRIES WITH IT THE RIGHT TO LICENSE COMMERCIAL CONCERNS, THUS CREATING THE INCENTIVE NECESSARY FOR DEVELOPMENT IN THOSE SITUATIONS WHERE COLLABORATION WOULD NOT OTHERWISE BE ACCOMPLISHED AND LESSENING OR ELIMINATING INDUSTRY FEAR OF CONTAMINATION. FURTHER, UNDER SUCH A POLICY, COLLABORATIVE ARRANGEMENTS COULD BE MADE WHEREIN INDUSTRY'S PARTICIPATION IS PROTECTED <u>BEFORE</u> IT IS EVEN CLEAR WHETHER OR NOT INVENTIONS WILL BE MADE. SUCH PRIOR ARRANGEMENTS SHOULD MINIMIZE THE PROBLEM OF THE "NOT-INVENTED-HERE" SYNDROME.

TO A LARGE EXTENT THE SEPTEMBER 23RD RECOMMENDATIONS ARE A RATIFICATION OF THE PRACTICES IMPLEMENTED BY DHEW SINCE 1969 AND THE NATIONAL SCIENCE FOUNDATION SINCE 1974. THE DHEW PRACTICES, IN TURN, WERE INITIATED IN PART THROUGH THE IMPETUS CREATED BY THE CRITICAL REMARKS FROM THE 1968 GAO STUDY MENTIONED PREVIOUSLY ON THE LACK OF TIMELINESS IN PROCESSING

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PETITIONS FOR WAIVERS OF IDENTIFIED INVENTIONS AND THE NEED TO CLARIFY THE USE OF INSTITUTIONAL PATENT AGREEMENTS WHICH GUARANTEE FUTURE INVENTION RIGHTS TO UNIVERSITIES WITH TECHNOLOGY TRANSFER CAPABILITIES.

IN OCTOBER 1974 THE DEPARTMENT COLLECTED SOME ROUGH STATISTICS ON MANAGEMENT OF PATENT RIGHTS LEFT TO UNIVERSITIES. THIS STUDY INDICATED THAT 167 PATENT APPLICATIONS WERE FILED SINCE 1969 BY INSTITUTIONS WHICH CHOSE TO EXERCISE THEIR FIRST OPTION TO INVENTION RIGHTS UNDER THEIR INSTITUTIONAL PATENT AGREEMENT. UNDER THE 167 PATENT APPLICATIONS FILED, THE UNIVERSITIES HAVE NEGOTIATED 29 NONEXCLUSIVE LICENSES AND 43 EXCLUSIVE LICENSES. SEVENTEEN JOINT-FUNDING ARRANGEMENTS WITH COMMERCIAL ORGANIZATIONS, INVOLVING ONLY THE POSSIBILITY OF RIGHTS TO FUTURE INVENTIONS, HAVE BEEN MADE. WE WERE ADVISED THAT ON THE BASIS OF ALL THE AGREEMENTS NOTED, APPROXIMATELY 24 MILLION DOLLARS OF RISK CAPITAL MAY BE COMMITTED TO THE DEVELOPMENT OR MAKING OF INVENTIONS EVOLVING WITH DHEW SUPPORT.

UNDER OUR DEFERRED DETERMINATION POLICY, WHICH IS APPLICABLE TO ALL UNIVERSITIES WHO HAVE NOT YET ESTABLISHED A TECHNOLOGY TRANSFER CAPABILITY, IT WAS DETERMINED THAT SINCE 1969, 178 PETITIONS FOR WAIVER OF AN IDENTIFIED INVENTION HAVE BEEN REVIEWED AS OF OCTOBER 1974. OF THESE 178, 162 PETITIONS WERE GRANTED. UNDER THE 162 GRANTED, THE INSTITUTIONS

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INVOLVED AND RESPONDING HAVE GRANTED 15 NONEXCLUSIVE LICENSES AND 35 EXCLUSIVE LICENSES. THESE LICENSES HAVE GENERATED A POSSIBLE COMMITMENT OF RISK CAPITAL OF AS MUCH AS 53 MILLION DOLLARS.

SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES INCREASED DRAMATICALLY FROM 329 TO 517. I HAVE SOME EXAMPLES OF INVENTIONS LICENSED BY UNIVERSITIES WHICH HAVE REACHED OR ARE NEAR REACHING THE MARKETPLACE SINCE OUR 1974 SURVEY. NOTEWORTHY IS THAT THIS INCOMPLETE LISTING OF SOME 17 INVENTIONS INVOLVES A COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 60 MILLION DOLLARS. MEDICAL DEVICES ON THE LIST ARE (READ FROM LIST).

WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT IN 1968.

MORE SIGNIFICANT THAN THE FIGURES ARE REPORTS FROM THE UNIVERSITY COMMUNITY THAT INDUSTRY INTEREST IN UNIVERSITY RESEARCH HAS SIGNIFCANTLY INCREASED IN RECENT YEARS. I BELIEVE THIS TO BE THE RESULT OF THE UNIVERSITY COMMUNITY'S ACTIVE SOLICITATION OF COLLABORATIVE ARRANGEMENTS, WHICH IN TURN WAS PARTLY MOTIVATED BY THE FLEXIBILITY PROVIDED BY OUR PATENT POLICY.

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SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

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Inventor	University	Invention	Licensee	Approximate Investment
Chas. Heidelberger	Wisconsin 🔸	Use of F3TDR for Herpes Infec- tions of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C,	Approx. \$5,000,000 NDA expected by end of 1977
Charles Fox	Columbia Univ.	Silver Sulfadiazine used in treatment of burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. \$5,000,000
R. Fischell	Johns Hopkins	. Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, Calif.	On market since Feb. 1975 - Approx, \$720,000
Monte Holland	Tulane Univ.	Method of Reducing Intraocular Pressure in the Human Eyes	Cooper Labs., Bed- ford Hills, N.Y.	\$2,000,000 - Development leading to DNA is in process and on schedule
Berton Pressman	Univ. of Miami	Application of X-537A if the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffmann-LaRoche, Nutley, N.J.	\$500,000 to \$1,000,000 Clinical evaluations still in progress
Willard Higley	Natl. Institu te of Scientific Research	Polycarbonate Dialysis Membranes	C.R. Bard, Inc., Murray Hill, N.J.	Over \$1,000,000. Market introduction expected imminently
Talbot/Harrison [.]	Johns Hopkins .	Ballistocardiograph apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. \$330,000. Now on market
Stanley Plotkin	Wisțar Institute	Rubella Vaccine	 Wellcome Foundation L'Institut Merieux Swiss Serum and Vaccine Institute (Merck an Italian) 	Approx. millions - Now on market - and others

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

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Inventor	University	Invention	<u>Licensee</u>	Approximate Investment
McKensie Walzer	Johns Hopkins	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfrimmer of Ger- many and Syntex of U.S.A.	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe
Tadeusz J. Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions
· Barton Kamen et al	Case Western Res.	Methotrexate Assay	Diamond Shamrock Corp.	Being test-marketed, Production scheduled for late 1977. Millions.
Lillehei/Kaster	Univ, of Minn- esota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world- wide market since 1971. Millions
Blackshear et al	Univ. of Minn- esota	Implantable Infusion Pump	Metal Bellows Co.	Undergoing clinical trials. \$750,000.
Deluca	Univ. of Wiscon sin	25-Hydroxycholecalciferol	Rousel-Uclaf (Hoechst)	Have applied for equiva- lent of NDA in France. Approximately \$5 million.
			Upjohn	About to apply for an NDA and an NADA. Will spend about \$10 million.
Deluca	Univ. of Wiscon. sin	1-Alpha Hydroxycholecalciferol	Leo Pharma. ceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. \$5,000,000.
Deluca et al	Univ, of Wis- consin	1, 25-Dehydroxyergocalciferol	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about \$10 million.

Inventor	University	Invention	Licensee	Approximate Investme
Josef Fried	Univ, of Chicago	Prostaglandins	Richardson-Merrell, New York, N.Y.	Several millions. In process of develo ment and testing fo marketing here and abroad.