

To: Allan Tenson
From: Norm Latker

See

Attachment

STATEMENT OF
OF
NORMAN J. LATKER
PATENT COUNSEL
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE before the
SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
HOUSE OF REPRESENTATIVES
MAY 26, 1977

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE.

MY NAME IS NORMAN LATKER. I AM PATENT COUNSEL FOR THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE. MY OFFICE IS ASSIGNED TO THE BUSINESS AND ADMINISTRATIVE LAW DIVISION OF THE OFFICE OF GENERAL COUNSEL, WHICH HAS THE INITIAL RESPONSIBILITY FOR MANAGING THE INVENTIVE RESULTS OF THE DEPARTMENT'S RESEARCH AND DEVELOPMENT BUDGET.

I VERY MUCH APPRECIATE YOUR INVITATION TO SPEAK TO THE OPERATION OF GOVERNMENT PATENT POLICY, AS I BELIEVE IT TO BE A FUNDAMENTAL CONCERN TO THE LARGER ISSUES OF:

MAINTAINING A FAVORABLE BALANCE OF PAYMENT AND TRADE FOR OUR RESEARCH INTENSIVE INDUSTRIES,

ENHANCING TECHNOLOGY TRANSFER, AND

QUESTIONS OF INDUSTRIAL CONCENTRATION AND CONSUMER PRICES.

IN MOST PART I HOPE TO UTILIZE THESE MOMENTS AS BEST I CAN TO SUGGEST THE IMPORTANCE OF PATENT PROTECTION IN BRINGING

TECHNOLOGY ARISING FROM GOVERNMENT SPONSORED RESEARCH AT UNIVERSITIES AND NON-PROFIT ORGANIZATIONS TO FRUITION. THIS IS AN AREA OF VITAL INTEREST TO HEW, SINCE THE DEPARTMENT IS THE LARGEST SINGLE SOURCE OF FUNDING FOR SUCH RESEARCH IN THE UNITED STATES, AND THE SUBSTANTIAL PORTION OF ITS RESEARCH BUDGET IS DEVOTED TO THIS CATEGORY OF RESEARCH.

THE MOST OBVIOUS PROBLEM AFFECTING ULTIMATE UTILIZATION OF INNOVATIONS RESULTING FROM DHEW FUNDED RESEARCH AT UNIVERSITIES AND OTHER NON-PROFIT ORGANIZATIONS IS THE FACT THAT THESE ORGANIZATIONS DO NOT ENGAGE IN THE DIRECT DEVELOPMENT AND MANUFACTURE OF COMMERCIAL EMBODIMENTS, AND IT IS INDUSTRY WHICH MUST BRING SUCH INNOVATION TO THE MARKETPLACE.

A FUNDAMENTAL PREMISE OF DHEW PATENT POLICY AND PRACTICE IS THE UNDERSTANDING THAT INHERENT TO THE TRANSFER OF THE INNOVATIVE RESULTS OF THE RESEARCH CONDUCTED IN UNIVERSITY LABORATORIES TO INDUSTRIAL DEVELOPERS IS A DECISION ON THE PART OF THE DEVELOPER THAT THE INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION BEING OFFERED FOR DEVELOPMENT ARE SUFFICIENT TO PROTECT ITS RISK INVESTMENT. OF COURSE, NOT ALL TRANSFERS OF POTENTIALLY MARKETABLE INNOVATIONS FROM SUCH LABORATORIES REQUIRE AN EXCHANGE OF INTELLECTUAL PROPERTY RIGHTS IN THE INNOVATION, BUT IT IS UNPREDICTABLE IN WHICH TRANSFERS THE



ENTREPRENEUR WILL DEMAND AN EXCHANGE TO GUARANTEE ITS COLLABORATIVE AID. NOTWITHSTANDING, WHERE SUBSTANTIAL RISK INVESTMENT IS INVOLVED, SUCH AS REQUIRED IN DEVELOPING CLINICAL DATA FOR PRE-MARKET CLEARANCE OF POTENTIAL THERAPEUTIC AGENTS AND MEDICAL DEVICES, WHICH IS RARELY UNDERTAKEN IN ITS ENTIRETY AT GOVERNMENT EXPENSE, THERE IS AN IDENTIFIED LIKELIHOOD THAT TRANSFER WILL NOT OCCUR IF THE ENTREPRENEUR IS NOT AFFORDED SOME PROPERTY PROTECTION IN THE INNOVATION OFFERED FOR DEVELOPMENT. THIS POINT WAS MADE WITH SOME FORCE TO DHEW AFTER A 1968 GAO INVESTIGATION AND REPORT ON "PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT-SPONSORED RESEARCH IN MEDICINAL CHEMISTRY."^{1/} THIS LIKELIHOOD SEEMS EVEN MORE PREDICTABLE WHEN CONSIDERING THE EXTRAORDINARY ESCALATION IN THE ESTIMATED AVERAGE COST OF SUCCESSFULLY DEVELOPING A NEW DRUG FROM \$534,000 IN 1962 TO 11.5 MILLION DOLLARS IN 1973 OR 24.4 MILLION DOLLARS WHEN INCLUDING THE COST OF RESEARCH ON PROJECTS WHICH DID NOT RESULT IN MARKETED DRUGS.^{2/} ECONOMIST DAVID SCHWARTZMAN, WHO DEVELOPED THESE STATISTICS, AND OTHERS WHO HAVE REVIEWED THEM FURTHER AGREE THAT RETURN ON SUCH R & D

1/ PROBLEM AREAS AFFECTING USEFULNESS OF RESULTS OF GOVERNMENT SPONSORED RESEARCH IN MEDICINAL CHEMISTRY, AUGUST 12, 1968, GAO REPORT B-164031(2).

2/ SCHERER, "THE ECONOMIC EFFECT OF MANDATORY PATENT LICENSING," P. 59, U. S. ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION, PUBLIC MEETING 1/12/77 AND SCHWARTZMAN, "INNOVATION IN THE PHARMACEUTICAL INDUSTRY," P. 66, 70 and 71.

INVESTMENT HAS FALLEN SHARPLY SINCE 1960 TO AS LOW AS POSSIBLY 3.3 PERCENT.^{3/} WHEN IT IS RECOGNIZED THAT COSTS TO SECOND ENTRANTS INTO THE MARKET AFTER PATENT EXPIRATION ARE A SMALL FRACTION OF THE ORIGINAL DEVELOPER'S COSTS, SINCE THE SECOND ENTRANT NEED NOT UNDERTAKE THE SAME R & D RISK, IT IS DIFFICULT TO DISAGREE WITH SCHWARTZMAN'S COMMENT THAT, "WITHOUT PATENTS THE RETURN FROM INVESTMENT IN PHARMACEUTICAL RESEARCH AND DEVELOPMENT WOULD FALL TO ZERO, AND PRIVATE COMPANIES WOULD NO LONGER ENGAGE IN RESEARCH AND DEVELOPMENT."^{4/} THIS HAS BEEN ILLUSTRATED BY THE IMMEDIATE MARKET ENTRY OF COMPETITORS UPON EXPIRATION OF PATENTS ON WIDELY SOLD ANTIBIOTICS, WHERE SUCH COMPETITION DOES NOT EMERGE UNDER SIMILAR CONDITIONS IN THE AIRCRAFT OR AUTOMOTIVE INDUSTRIES WHERE COST OF DUPLICATING THE ORIGINAL DEVELOPER ARE NEARER EQUIVALENT.

THE DEPARTMENT HAS VIEWED ITS ROLE IN THE NATION'S MEDICAL RESEARCH EFFORTS AS COMPLEMENTARY TO THE ACTIVITIES OF THE OTHER ELEMENTS WITHIN OUR SOCIETY, BOTH PUBLIC AND PRIVATE, THAT ALSO SUPPORT SUCH RESEARCH AND DEVELOPMENT. IT HAS SEEMED TO THE DEPARTMENT THAT THE INTERESTS OF THE AMERICAN PEOPLE ARE BEST SERVED WHEN THE VARIOUS ELEMENTS OF THIS MEDICAL RESEARCH STRUCTURE CAN INTERACT. THE MOST EFFECTIVE INTER-

3/ IBID P. 160, SCHWARTZMAN AND HENRY G. GRABOWSKI; DUKE UNIVERSITY.

4/ IBID P. 4, SCHWARTZMAN.

RELATIONSHIP RESULTS WHEN THE PARTICULAR CAPABILITIES OF THE VARIOUS ELEMENTS, FEDERAL AND NON-FEDERAL, CAN BE UTILIZED TO THE FULLEST EXTENT.^{5/} IT SEEMS CLEAR THAT THIS COLLABORATIVE RELATIONSHIP CAN ONLY EXIST IF EACH ELEMENT RECOGNIZES TO THE EXTENT FEASIBLE THE FUNDAMENTAL NEEDS OF THE OTHER ELEMENTS.

IN THIS SPIRIT DHEW HAS CONSCIOUSLY MADE EFFORTS TO CLOSE THE IDENTIFIED GAP BETWEEN THE FUNDAMENTAL INNOVATORS THE DEPARTMENT SUPPORTS AND THE PRIVATE INDUSTRIAL DEVELOPERS WHO MAY BE NECESSARY TO THE DELIVERY OF END-ITEMS TO THE MARKET PLACE. 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. THE MAIN THRUST OF DEPARTMENT PATENT POLICY AS APPLIED TO UNIVERSITIES HAS BEEN DIRECTED TOWARD:

1. ESTABLISHMENT OF PATENT MANAGEMENT FOCAL POINT IN THE INNOVATING ORGANIZATION TRAINED TO ELICIT TO ELICIT INVENTION REPORTS AND ESTABLISH RIGHTS IN MATTERS OF INTELLECTUAL PROPERTY ON A TIMELY BASIS FOR POSSIBLE

^{5/} TESTIMONY BY DR. JAMES A. SHANNON, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, BEFORE THE SUBCOMMITTEE ON PATENTS, TRADEMARKS, AND COPYRIGHTS OF THE SENATE COMMITTEE ON THE JUDICIARY, AUGUST 17, 1965.

LICENSING OF INDUSTRIAL DEVELOPERS. THIS HAS BEEN ACCOMPLISHED IN THE MAIN BY EXECUTION OF INSTITUTIONAL PATENT AGREEMENTS (IPA) WITH UNIVERSITIES WILLING TO CREATE AND MAINTAIN SUCH A FOCAL POINT. THE IPA PROVIDES AS AN INCENTIVE TO ESTABLISHMENT OF A PATENT FOCAL POINT, A FIRST OPTION TO OWN ALL FUTURE INVENTIONS ARISING FROM DHEW GRANT SUPPORTED RESEARCH. WE PRESENTLY HAVE 70 IPA, AND

2. ASSURANCE THAT THE INNOVATING GROUP HAS THE RIGHT TO CONVEY WHATEVER INTELLECTUAL PROPERTY RIGHTS ARE NECESSARY TO ACCOMPLISH A TRANSFER TO AN INDUSTRIAL DEVELOPER. (THIS IS ACCOMPLISHED IN THE MAIN THROUGH THE IPA HOLDERS' FIRST OPTION TO OWN HEW-FUNDED INVENTIONS AND OUR WAIVER PROGRAM, WHICH PROVIDES FOR OWNERSHIP IN PETITIONING UNIVERSITIES NOT HAVING AN IPA WHO COME FORTH WITH AN ACCEPTABLE DEVELOPMENT PROGRAM FOR AN IDENTIFIED INVENTION.)

DHEW HAS CAREFULLY CIRCUMSCRIBED THE CONDITIONS OF LICENSING WITHIN WHICH A UNIVERSITY PATENT MANAGEMENT FOCAL POINT OR SUCCESSFUL PETITIONER CAN FUNCTION. THESE CONDITIONS HAVE

BECOME WELL KNOWN TO INDUSTRIAL DEVELOPERS AND HAVE BEEN GRADUALLY ACCEPTED IN LICENSING ARRANGEMENTS BY A WIDENING CIRCLE OF SUCH DEVELOPERS. THIS COMPARES TO THE VIRTUAL BOYCOTT REPORTED BY GAO OF DEVELOPMENT OF NIH GENERATED DRUG LEADS BY INDUSTRY DURING THE 1962-1968 PERIOD COVERED BY THEIR REPORT. A MUCH MORE DETAILED DISCUSSION OF THE PHILOSOPHY BEHIND THE DEPARTMENT'S PATENT POLICY WAS MADE IN MY TESTIMONY BEFORE YOUR SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING AND ANALYSIS ON SEPTEMBER 29, 1976.

SINCE 1969 THROUGH THE FALL OF 1974 WE ESTIMATE THAT THE INTELLECTUAL PROPERTY RIGHTS TO 329 INNOVATIONS EITHER INITIALLY GENERATED, ENHANCED OR CORROBORATED IN PERFORMANCE OF DHEW-FUNDED RESEARCH WERE IN THE HANDS OF UNIVERSITIES' PATENT MANAGEMENT OR SUCCESSFUL UNIVERSITY PETITIONERS FOR THE PURPOSE OF SOLICITING FURTHER INDUSTRIAL DEVELOPMENT SUPPORT. WE WERE ADVISED THAT DURING THE 1969-1974 PERIOD THESE UNIVERSITIES HAD NEGOTIATED 44 NON-EXCLUSIVE AND 78 EXCLUSIVE LICENSES UNDER PATENT APPLICATIONS FILED ON THE 329 INNOVATIONS. WE UNDERSTAND THAT THE 122 LICENSES NEGOTIATED HAD GENERATED COMMITMENTS IN THE AREA OF 75 MILLION DOLLARS OF PRIVATE RISK CAPITAL. SINCE 1974 TO THE END OF FISCAL YEAR 1976 THE NUMBER OF INVENTIONS HELD BY UNIVERSITIES HAS SUBSTANTIALLY INCREASED TO 517.

I HAVE ATTACHED TO THESE COMMENTS 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 INVOLVES COMMITMENT OF RISK CAPITAL OF APPROXIMATELY 80 MILLION DOLLARS. AS YOU WILL NOTE, THERE ARE A NUMBER OF PHARMACEUTICAL PRODUCTS ON THIS LIST. WE KNEW OF NO COMPARABLE SITUATIONS AT THE TIME OF THE GAO REPORT OF 1968. I WOULD CONJECTURE THAT THIS NUMBER WILL INCREASE IN SUBSEQUENT YEARS DUE TO THE OPPORTUNITY OF THE PHARMACEUTICAL INDUSTRY TO CAPITALIZE ON POSITIVE LEADS FROM THE NON-PROFIT SECTOR WHICH COULD RESULT IN REDUCTION OF THE INDUSTRY'S ESCALATING R & D COSTS BY ELIMINATING A NUMBER OF BLIND LEADS. (THE ULTIMATE SAVING WOULD BE THE DIFFERENCE BETWEEN THE 11.5 AND 24.4 MILLION DOLLARS PER SUCCESSFUL DRUG DEVELOPMENT MENTIONED PREVIOUSLY.) THE RISE IN SUCCESSFUL DEVELOPMENT BY INDUSTRY OF UNIVERSITY GENERATED INVENTIONS IS ALSO CONSIDERED SIGNIFICANT WHEN NOTING THE STEADY DECLINE IN INTRODUCTION OF NEW DRUG ENTITIES IN THE UNITED STATES FROM 65 IN 1959 TO 15 IN 1975.^{6/} THIS SLIDE MIGHT ALSO BE ATTRIBUTED TO THE INCREASED COST OF DRUG DEVELOPMENT.

6/ PHARMACEUTICAL TIMES, APRIL 1976 (BASED ON DATA FROM PAUL de HAEN, INC.) AND HENRY G. GRABOWSKI, "DRUG REGULATION AND INNOVATION IN EMPIRICAL EVIDENCE AND POLICY OPTIONS," AMERICAN ENTERPRISE FOR PUBLIC POLICY RESEARCH, WASHINGTON, D. C.

IN THIS CONTEXT IT IS APPARENT THAT THE EXISTENCE OF A LICENSABLE PATENT RIGHT IS PROBABLY A PRIMARY FACTOR IN THE SUCCESSFUL TRANSFER OF A UNIVERSITY INNOVATION TO INDUSTRY AND THE MARKETPLACE, AND FAILURE TO PROTECT SUCH RIGHT MAY FATAALLY AFFECT A TRANSFER OF A MAJOR HEALTH INNOVATION.

I BELIEVE SOME MEMBERS OF THE COMMITTEE ARE AWARE OF THE SPECULATION THAT PRIVATE DEVELOPMENT AND MARKETING OF PENICILLIN WAS FORECLOSED FOR OVER 11 YEARS DUE TO THE LACK OF A PROPRIETARY POSITION NECESSARY TO THE PROTECTION OF THE LARGE RISK INVESTMENT INVOLVED.^{7/} IT WAS ONLY AFTER THE UNITED STATES GOVERNMENT UNDERTOOK THIS RISK UNDER THE PRESSURE OF WORLD WAR II THAT PENICILLIN'S CURATIVE POWERS WERE MADE AVAILABLE TO THOSE SUFFERING FROM INFECTION.

IN ADDITION TO INITIAL ADMINISTRATION OF THE IPA AND WAIVER PROGRAM DISCUSSED, THE DHEW PATENT BRANCH ACTS AS THE PATENT MANAGEMENT FOCAL POINT FOR ALL INNOVATIONS TO WHICH THE DEPARTMENT RETAINS TITLE. THE DEPARTMENT'S PATENT PORTFOLIO PRESENTLY CONSISTS OF APPROXIMATELY 400 PATENTS AND PATENT APPLICATIONS, WHICH IN THE MAIN ARE DERIVED FROM DHEW EMPLOYEE INVENTIONS. A LESSER NUMBER ARE ATTRIBUTABLE TO INVENTIONS MADE BY EMPLOYEES OF UNIVERSITIES OR COMMERCIAL CONCERNS FUNDED

7/ DAVID MASTERS, MIRACLE DRUG, THE HISTORY OF PENICILLIN, PUBLISHED BY GYRE & SPOTTI, WOODE, LONDON (1946), PP. 104-105 AND THE LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS, FORMAN, EDITOR, PUBLISHED BY CENTRAL BOOK CO., NEW YORK (1967).

BY DEEM GRANTS OR CONTRACTS WHICH THEY DID NOT CHOOSE TO
MANAGE OR WERE NOT PERMITTED TO MANAGE. SINCE 1969 WE HAVE
GRANTED 19 EXCLUSIVE LICENSES AND 90 NON-EXCLUSIVE LICENSES
UNDER OUR PATENT PORTFOLIO. UNFORTUNATELY, WE HAVE NO
STATISTICS ON THE AMOUNT OF RISK CAPITAL COMMITTED TO DEVELOP-
ING THESE INVENTIONS TO THE MARKETPLACE, THOUGH WE BELIEVE
IT TO BE SURELY MEASURED IN MILLIONS OF DOLLARS.



SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>Approximate Investment</u>
1. Walser	Johns Hopkins U.	Keto-Acid analogs of Amino Acids for treatment of uremia	Pfizer of Germany and Syntex of U.S.A	Millions - Clinical trials in process. Expected to be marketed in 6 mos. in Europe.
2. Wiktor	Wistar Institute ✓	Rabies Vaccine	Wyeth Laboratories	On the market - millions
3. Kamen et al	Case Western Res. ✓	Methotrexate Assay during Cancer Chemotherapy	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.
4. Lillehei/Kaster	U. of Minnesota ✓	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions.
5. Blackshear et al	U. of Minnesota ✓	Implantable Infusion Pump (Constant Infusion of Drugs for Treatment of Cancer, Diabetes, Pain, Morphine-addiction, etc.)	Metal Bellows Co.	Undergoing clinical trials. \$750,000.
6. DeLuca	U. of Wisconsin ✓	25-Hydroxycholecalciferol for treatment of Osteodystrophy with liver dysfunction	Upjohn Rousel-Uclaf (Hoechst) and Upjohn	Have applied for equivalent of NDA in France. Approximately \$5 million. About to apply for an NDA and an NADA. Will spend about \$10 million. ⊕
7. DeLuca	U. of Wisconsin ✓	1-Alpha Hydroxycholecalciferol for treatment of Osteodystrophy with Kidney Dysfunction	Leo Pharmaceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year. Approx. \$5,000,000.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>Approximate Investment</u>
8. DeLuca et al	U. of Wisconsin ✓	1, 25-Dehydroxyergocalciferol for Treatment of Osteodystrophy with Kidney and Liver Dysfunction and Senile Osteodystrophy	Hoffman-LaRoche Inc.	About to apply for NDA. Will spend about \$10 million.
9. Fox	Columbia U.	Silver Sulfadiazine used in Treatment of Burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. \$5,000,000
10. Heidelberger	U. of Wisconsin ✓	Use of F ₃ TDR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. \$5,000,000 NDA expected by end of 1977.
11. Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker	Pacesetter Systems Sylmar, California.	On market since Feb. 1975 - Approx. \$720,000
12. Holland	Tulane U.	Method of Reducing Intra-ocular Pressure in the Human Eyes (Glaucoma Treatment)	Cooper Labs., Bedford Hills, N.Y.	\$2,000,000 - Development leading to NDA is in process and on schedule
13. Pressman	U. of Miami ✓	Application of X-537A in the Cardiovascular System (for stimulation in cardiogenic shock, congestive heart failure, etc.)	Hoffman-LaRoche, Nutley, N.J.	\$500,000 to \$1,000,000 Clinical evaluations still in progress
14. Higley	Natl. Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C. R. Bard Inc., Murray Hill, N.J.	Over \$1,000,000. Market introduction expected imminently.
15. Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. \$330,000. Now on market.

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>Approximate Investment</u>
16. Plotkin	Wistar Institute	Rubella Vaccine	1) Wellcome Foundation 2) L'Institut Merieux 3) Swiss Serum and Vaccine Institute and others (Merck, an Italian firm, etc.)	Approx. millions - Now on market.
17. Schaffner/Mechlinski	Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb of U. S. A. and Dumex of Denmark	Millions - Clinical trials progressing favorably
18. Zweig	Syracuse U.	Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium	New Brunswick Scientific Co., Inc., of New Jersey	Millions - On the market since 1973
19. Lovelock	Yale U.	Gas Analysis Method and Device for the Qualitative and Quantitative Analysis of Classes of Organic Vapors	Richardson-Palo Alto, Calif.	On the market
20. Fried	U. of Chicago	Prostaglandins for possible Treatment of Bronchial Asthma, Duodenal Ulcers, Inflammatory Conditions, etc.	Richardson-Merrell, New York, N.Y. and ...	Several millions - In process of development and testing for marketing here and abroad
21. Leininger/Grotta et al	Battelle Memorial Institute	Preparation of Non-thrombogenic Surfaces and Materials	C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Louis Mo.; and American Hospital Supply Corp., Irvine, California.	\$107,754 - Some products being marketed and others being tested.

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SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>Approximate Investment</u>
22. Merrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides	Beckman Instruments, Fullerton, California	Being marketed since 1973.
23. Smith/Kozoman	Duke U.	Apparatus and Method for Rapid Harvesting of Roller Culture Supernatant Fluid	Bellco Glass, Inc. Vineland, New Jersey	Approximate \$500,000 - Being marketed since June 9, 1976
24. Zweng	Stanford U. ✓	Laser Photocoagulator	Coherent Radiation, Palo Alto, Cal.	Approximately \$500,000 Standard tool of ophthalmologists
25. Sweet et al	Stanford U. ✓	Cell Sorter	Becton-Dickinson, Rutherford, New Jersey	Approx. \$200,000. Import research tool
26. Boyd/Macovski	Stanford U. ✓	Computerized Axial Tomography	S.A.I. Cupertino, Cal.	Approx. \$300,000. Will be marketed soon.
27. Saxena	Cornell U. ✓	Method for Testing for Pregnancy	Carter-Wallace	Approx. 1/2 million On market
28. Calnek/Hitchner	Cornell U. ✓	Cell-free virus Preparation	Merck Supply	Data not available
29. Carlson	Iowa State ✓	Respiratory Augmentor with Electronic Monitor and Control	Bourns, Inc.	On market since 1966; sales now in millions
30. Leake/Rappoport	Harbor General Hospital ✓	Bone Induction in an Alloplastic Tray	Am. Hospital Supply	Data not available

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>State of Development</u>
31. Bradford/Williams	U. of Georgia ✓	Protein Assay Reagent and Method	Bio-Rad Labs, Inc; Quantimetrix Corp.	On the market since April 1977
32. Tenckhoff	U. of Washington ✓	Catheter Insertion Trocar	Sweden Freezer Mfg. Co; Cobe Labs; Physio-Control Corp;	On market
33. Leonard et al	U. of Illinois ✓	Fluorescent Derivatives of Cytosine-Containing Compounds	PL Biochemicals	On market
34. Secrist et al	U. of Illinois ✓	Fluorescent Derivatives of Adenine-Containing Compounds	PL Biochemicals	On market development
35. Asgar	U. of Michigan ✓	Partial Denture Alloy	Battelle Dev	On market
36. Carlson/Ward	U. of Washington ✓	Coherent Biological Cell Analyzer	3M Company	Marketing development in progress.
37. Charlson/Alhquist	U. of Washington ✓	Integrating Nephelometer and Photon-Counting Integrating Nephelometer	Battelle Develop-ment	On market
38. Thomas	U. of Washington ✓	Artery-Vein Shunt Applique	Battelle Develop-ment Corp.	Being marketed



SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>State of Development</u>
Holcomb	Yale University	Method and Apparatus for Stimulation of Body Tissue	Avery Labs, Inc.	On the market since 1973
Dugan	Temple University	Novel Compositions for Radiotracer Localization of Deep Vein Thrombi	Rand Research & Development Corp.	Licensed in 1977.
Roelofs	Cornell University	Codling Moth Pheromone	Zoecon Corp.	On market since 1972.
Whitby	Univ. of Minnesota	Particle Counter	Name not available	On market since 1969
Bacaner	Univ. of Minnesota	Method for Suppressing Ventricular Fibrillation	Burroughs Wellcome	On market
Whitby	Univ. of Minnesota	Aerosol Sampler	Not available	On market since 1969
Bradley	Univ. of Minnesota	Apparatus to Stimulate the Bladder	Two licenses, names not available	On market since 1972
6. BUTLER	Purdue Research Fdn.	Hydrophobic Noncovalent Binding of Proteins to Support Materials	Regis Chemical	On market since April 1977



<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>State of Development</u>
1. Rosenberg	Michigan State Univ.	Platinum Compounds as Anti-Tumor Agents	Possibly Adria, Bristol or Miles Labs.	On market in late 1977
2. Coller	Institute for Cancer Research	Process of Viral Diagnosis and Reagent (Radioimmunoassay)	Abbot Labs.	Licensed in 1977 (Canada) On market in U.S.A.
3. Kosikowski	Cornell University	Antibiotic Test Kit	Carter-Wallace Bacto Strip	On market
4. Kosikowski	Cornell University	Process for Milk Sterilization	De Laval Alpha Laval	On market
5. McLafferty	Cornell University	Pregnancy Test	Carter-Wallace	On market
6. Kattwinkel et al	Case Western Reserve	Device for Administering Pressure via Nasal Route	Sherwood Medical	On market since 1975
7. Neckers et al	(Univ. of New Mexico Wayne State University)	Polymer-based Photosensitizers	National Patent Development Corp.	Being sold for research purposes only at this time
8. Keith/Snipes	Penn. State Univ.	BHT Antiviral Agent	Key Pharmaceuticals	Development is at the IND stage
9. Najjar	Tufts University	Therapeutically Useful Polypeptides	Calbiochem	Being sold for research purposes only at this time
10. Story et al	Univ. of Georgia	Macrocyclic Compounds	(Chemical Samples Company Albany International)	Commercial marketing expected within the year
11. Mielke	Institutes of Medical Sciences	Template for Ivy Bleeding Time	Hemakit, Inc.	Being sold commercially

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>State of Development</u>
3. Murray/Somerset	State Univ. of N.Y.	Knee Joint Prosthesis	Howmedica, Inc.	On commercial market since 1976
9. Volz/Brownlee/Tyers	Penn. State Univ.	Rechargeable Cardiac Pacemaker	Intermedics, Inc.	Near market
0. Volz et al	Penn. State Univ.	Rechargeable Cardiac Pacemaker	Intermedics, Inc.	Being sold commercially
1. Travis/Pannell	Univ. of Georgia	Albumin Recovery Method	B. R. Squibb Calbiochem	Research quantities of albumin isolated by this method being sold to investigators.
62. Schaffner et al	Rutgers	Derivatives of Polyene Macrolide Antibiotics	E. R. Squibb	Nearing commercial market
63. Kupchan et al.	Univ. of Virginia	Ansa Macrolide Tumor Inhibitor	Bristol-Myers	In clinical development
64. Peterson	North Star Res. (Midwest Res.)	Blood Compatible Polymers for Blood Oxygenation Devices	Celanese Corp.	Development progressing to overcome serious barriers
65. Juni	Univ. of Michigan	Test Kit for the Genetic Detection of Microorganisms	Miles Labs	In process of development.
66. Schreiner	Univ. of Michigan	Pitch Synchronous Speech Band- with Compressor	Intermedics, Inc.	In process of development
67. Craig	Univ. of Michigan	Hydrophobic Polymer Composite Restorative	Sandoz, Inc. Dentsply, Intl	In process of development
68. Phillips et al	Colorado State	Therapy for Calf Diarrhea	Squibb & Sons Norden Labs.	NDA under review
69. Parlow	Harbor General Hospital	Male Contraception Method	Sandoz, Inc.	In process of development
70. Brooker et al	Univ. of Virginia	Complete Automation of Radioimmunoassay	Squibb & Sons	To be marketed in 1979
71. Stoner et al	Univ. of Virginia	A Material for Binding Amalgam to Teeth	Star Dental Co.	Under development

<u>Inventor</u>	<u>University</u>	<u>Invention</u>	<u>Licensee</u>	<u>State of Development</u>
Simmons, F. B.	Stanford Univ. ✓	Crib-o-gram Monomers for the Synthesis of Copolymers	Corp-Telesensory Systems, Inc.	Commercial production fall 1978 in part
Meindl/Hottinger	Stanford Univ. ✓	Arterial Flow Meter for the Study of Flow in A	Ultrasonic Diagnos- tics, Inc.	Being developed commercially in part
Butler/Kelly	Purdue University ✓	Phosphonate Monoesters as Specific Convenient Substrates.....	Regis Laboratories	Available for research purposes
Javid et al	Rockefeller Univ. ✓	Radioimmune Assay for Hemoglobin A _{1c}	Pfizer, Inc.	In commercial development

