R. File w/ File 143

Outlines and Abstracts of Presentations

Society of University Patent Administrators (SUPA)

1986 Summer Meeting

Seattle, Washington
June 24, 25 and 26, 1986

Re: SUPA Presentation -
Strategies for Protecting Intellectual Property
June 25, 1986

PTO Deposit Policy for Biological Materials

David J. Maki

It is well known that a U.S. patent grants the owner the right to exclude others from making, using and selling the claimed invention. In exchange for this patent grant, the public receives a disclosure sufficient to "enable" a person who is technically familiar with the field of the invention to "make and use the same" without undue experimentation.

In order to satisfy the enablement requirement of Section 112, applicants for patents in the biotechnology field were often required to make a deposit of the biological material in a recognized depository prior to or concurrent with the filing of the written specification. However, the Court of Appeals for the Federal Circuit decision in In Re Lundak, recently followed by the PTO Board of Patent Appeals and Interferences in In Re Old, has significantly changed the manner in which the Section 112 enablement requirement may be met. Prompted by the Lundak decision, the Patent and Trademark Office has recently released a policy statement directed toward the establishment of comprehensive uniform regulations governing the deposit of biological materials for patent purposes. The presentation will provide an overview of this policy statement, together with comments directed toward initiating compliance with the proposed guidelines.

The Case Study:

University Ownership of Faculty, Staff and Student Inventions

Spencer L. Blaylock

What are the University's rights and the inventor's rights?

How does the University obtain title?

Publication: What constitutes a publication that starts the statutory bar running and when can a publication be a reference against your application?

6/11/86

The Patentability of Algorithms
Donald S. Chisum

New and useful algorithms, including mathematical algorithms, should constitute subject matter eligible for patent protection. Yet, the current state of the law is that "mathematical" algorithms "as such" or "in the abstract" do not constitute patentable subject matter--at least not in theory. Use of the qualifier "in theory" is appropriate, because in fact a large number of patents are currently being obtained on what are essentially computer programming concepts. While the patents use claim language referring to "apparatus," "systems," "methods," and the like, they cover algorithms implemented on a computer to solve various problems, including problems pertaining to (1) the internal operation of the computer, (2) information processing, and (3) computer interfacing with "physical" processes, such as manufacturing.

The presentation attempts to demonstrate the weakness of the theoretical rule on the nonpatentability of algorithms. The presentation includes a review of the Supreme Court cases in this area and an examination of the policy implications of extending patent protection to new algorithms. Professor Chisum argues that the extension of patent protection to algorithms will not harm the creation and dissemination of knowledge in computer science and other areas of technology and will in fact provide much needed additional incentives for investment in computer software development.

The patent system is suitable for protection of basic software ideas, including algorithms, at the practical as well as at the theoretical level. In the past, many lawyers advising software developers (typically not patent lawyers!) have advised against usage of the patent system on the ground that it is too slow and expensive and a patent only provides a ticket to engage in expensive litigation. This type of advice may be based on

out-of-date information. First, with the time and expense of developing softare rising rapidly, patent procurement costing something in the range of $10,000 and taking about 12 to 24 months is not inordinate. Second, the trend of court decisions currently is toward stronger enforcement of patents and the provision of effective remedies, including preliminary injunctions and treble damages for willful infringement. See Chisum, Remedies for Patent Infringement, 13 AIPLA Q.J. 380 (1985). Indicative of this trend is the recent action of a federal judge in putting Eastman Kodak completely out of the instant photography business because of infringement of Polaroid patent rights. See Polaroid Corp. v. Eastman Kodak Co., 228 U.S.P.Q. 305 (D. Mass. 1985). While copyright may protect against "knock-off" copying of coding, and trade secret may protect against improper usage of confidential information, neither can protect against competition through reverse engineering and independent re-coding of a new software idea.

UTILITY PATENTS FOR NOVEL PLANT VARIETIES AND MATERIALS

I. Sources of Exclusive Rights in plants

A. Plant Patent Act of 1930 (35 U.S.C. §161-164)

B. Plant Variety Protection Act of 1970 (7 U.S.C. §2321 et. seq.)

C. Utility Patents (35 U.S.C. §101)

II. Diamond v. Chakrabarty, 447 U.S. 303 (1980)

III. Ex Parte Hibberd, 227 U.S.P.Q. 443 (P.T.O. Bd. Pat. App. & Int'f 1985)

A. Claims

B. PTO Arguments

C. Patentee's Arguments

D. Holding

IV. Remaining Issues

A. Must a patentee elect between PVPA protection and utility patent protection?

B. Must a patentee elect between Plant Patent protection and utility patent protection?

V. Possible advantages of utility patents for novel plant varieties and materials

A. Tuber-propagated plants and hybrid seed covered

B. Selling parts of the plant, in addition to the plant itself, would be an infringement

C. Claims for methods for cultivating or culturing the plant could be claimed in the same patent application

D. No compulsory licensing, or exemptions from infringement

Kim Smith
6/13/86

ABSTRACT

RE: SUPA Presentation
June 25, 1986

Special Concerns in Licensing
Unpatented Biological Materials
David J. Maki

Agreements covering the transfer of biological materials from universities to industry have often included only a limited number of restrictions, and, perhaps more frequently, have been of an informal nature. Arrangements of this type have been successful due, in part, to the development of a strong common business purpose between the university and the respective company, coupled with a desire to maintain an open exchange of ideas within a continuing relationship. Basic to any such successful arrangement with an industrial licensee is the recognition that biological materials are tangible, personal property. Therefore, whether licensed in conjunction with intellectual property rights, or the sole focus of the licensing arrangement, the transfer of biological materials should be covered by a separate agreement.

Biological materials are generally thought to include organisms, cell lines, hybridomas, or portions thereof, including DNA constructs, plasmids, transformed cells, and even useful proteins produced by the transformed cells. Unlike other forms of tangible personal property, biological materials are capable of reproduction, making control over the materials more difficult: (a) subsequent to the transfer of the biological materials; and (b) after the termination of the license agreement. The viable nature of the biological materials creates some special concerns when entering into a licensing arrangement. The presentation will focus on some of these concerns, while attempting to provide practical approaches to these problems.

SUPA PROGRAM

Wednesday, June 25, 1986

Afternoon Session - 3:45 - 5:00 PM

Interpreting Circular A-124 and Other Federal Regulations and Review of New or Proposed Legislation

Mr. Latker will address the regulations under PL 96-517 as set forth in OMB Circular A-124 and the new regulations which modify A-124 to comport with PL 98-620 addressing with particularity the changes which will come into effect under the new regulations. He will further discuss the current "rights in data" issues which have arisen with some Federal agencies as they may affect the technology transfer function and the dissemination and technology transfer of the National Technical Information Service.

Mr. Randall will present an historical perspective of the operation of the National Institutes of Health (NIH) under the former Institutional Patent Agreements and the subsequent experience of that Agency under PL 96-517 and OMB Circular A-124. He will also discuss the handling of requests made to NIH under the Freedom of Information Act and the NIH position relating to hybridoma technology.

Howard Bremer will discuss some pending legislation which can have a significant positive impact upon the University sector in its technology transfer efforts. In particular, attention will be focussed on H.R. 4899, Congressman Kastenmeier's Process Patent Bill, as well as concurrent efforts to amend the Tariff Act of 1930 in relation to the operation of the International Trade Commission, and the Administration approach to product liability reform under Amendment 1814 to S. 100.

S.F. EXAMINER 4-9-86.

NORMAN J. LATKER
FEDERAL TECHNOLOGY MANAGEMENT POLICY DIVISION
U. S. DEPARTMENT OF COMMERCE
JUNE 25, 1986

SUMMARY OF MAJOR PROVISIONS CONTAINED IN PUBLIC LAW 98-620

1. The new law repeals the Public Law 96-517 provision excepting inventions made by nonprofit organizations when operating Government-owned laboratory facilities. This provision for uniform treatment of all domestic nonprofit organizations regardless of where they perform their federally funded work and is particularly important to organizations that manage Department of Energy laboratories.

2. As part of the change affecting nonprofit contractors of Government-owned facilities, the new law includes a limit on the amount of royalties that the contract operators are entitled to retain after paying patent administrative expenses and a share of the royalties to the inventors. The limit is based on five percent of the annual budget of the laboratory, but includes an incentive provision rather than a simple cap to stimulate continued efforts to transfer technology if royalties ever reach the five percent figure. This provision ensures that Government shares in the results of the research expenditures in the event the contract operator of a Government laboratory makes a major discovery.

3. The new law includes the favorable reporting provisions that were developed in OMB Circular A-124. These provisions have been proven to work. Small business and nonprofit organizations should be assured of their continuance beyond February 1985 when OMB Circular A-124 is scheduled for sunset expiration.

4. The new law repeals certain conditions placed on licensing of inventions by nonprofit organizations. Among the conditions repealed is the five year cap on the grant of an exclusive license to an industrial concern (other than a small business). This provision has made the licensing and development of inventions that require Food and Drug Administration approval prior to marketing difficult to negotiate. Its repeal will remove a substantial barrier to industry participation in research projects at universities and other nonprofit organizations.

5. The new law expands the definition of "invention" in Public Law 96-517 to include - "any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et. seq.)." This assures nonprofit organization ownership of some inventions resulting from research in agriculture which were not previously covered by P. L. 96-517.

6. The new law allows agencies to limit patent ownership by small business or nonprofit organizations that are not located or do have a place of business in the United States. This will clarify that agencies can control the export of technology in cases where the performer is not a domestic organization.

GOVERNMENT INVENTIONS

I. Current statutes and regulations governing the disposition and administration of patent rights in inventions made by Government contractors, grantees, and employees:

Public Law 96-517 (35 USC 200-211)
OMB Circular A-124
Public Law 98-620
Executive Order 10096

How patent rights are disposed of and administered under current statutes and regulations.

II. Similarities and differences between the Institutional Patent Agreement and P.L. 96-517 and P.L. 98-620.

III. Implementation procedures.

IV. Freedom of information requests.

V. Hybridoma inventions.

VI. Disposition of patent rights in inventions arising under collaborative agreements between nonprofit organizations, commercial organizations, and the National Institutes of Health:

A. Inventions made by employees of the commercial collaborator.

B. Inventions made by employees of the National Institutes of Health.

C. Inventions made jointly by employees of the commercial collaborator and employees of the National Institutes of Health.

Leroy Randall

Edmund Regina

DESIGNING A MARKETING STRATEGY FOR UNIVERSITY TECHNOLOGIES

OVERVIEW

Later sessions will examine specific marketing tools such as market intelligence, promotion and selling as they might improve our technology transfer efforts. This session will consider the marketing concept and how it might apply to University Patenting and Technology Transfer. Our guiding idea is that marketing involves not simply a set of tools to be used at one or another stage in the process of technology transfer but rather that it represents an orientation affecting the entire process.

In responding to the presentations consider the following issues:

University Patent Administration/Technology Transfer as a Marketing activity

> How would we characterize what we do now? Do we see it as marketing? What if we defined it as primarily a marketing activity? How would we behave differently? What activities would we stress? Which would we downplay?

The University Patent/Technology Transfer Office as a Marketing Organization

> How would we structure our offices if we saw them as primarily marketing organizations? What staffing, workflow, reward changes would we make in our current organizations? How would such an organization fit into our parent institutions?

University Patenting as Providing Market Values

> What are the market values we provide? Patent rights? Knowledge? Licenses to each? Can we also provide specific solutions to problems for the firm? What values can we add to the bare bones of patent rights?

Marketing as an Orientation/Philosophy

> As marketers who would we serve primarily? How would we serve them? How would we address our present constituencies?

UNIVERSITY FRAMEWORK FOR TECHNOLOGY LICENSING

-- ESCAPING FROM THE MOUSETRAP (SYNDROME) --

I -- THE ROLE OF MARKETING IN UNIVERSITY TECHNOLOGY TRANSFER

A. Why is Marketing Relevant?

1. University Perspective

2. The Mousetrap Syndrome

B. Why Doesn't the "Better Mousetrap" Approach Work?

1. Must know there is another mousetrap.

   a. Technology Explosion -- a problem of threshhold

   b. Publishing & Conferences
      -- Low probability connection
      -- Limited demonstrated relevance

   c. Not the Mousetrap, but Rights to the Mousetrap
      -- Patent
      -- Patent Application
      -- Know-How
      -- Research Product

2. Must be convinced it is better

   a. Comparative Advantages

   b. Technical Information (Secrecy Agreements)

   c. Further Development

3. Must appreciate have a mouse problem in first place

   a. Mouse Problem

   b. Appreciation

4. Must be able to make a decision

   a. University Contacts -- scientists & lawyers

b. Decision Makers -- businessmen

C. What are the Key Tasks of a Marketing Program?

1. Communicate to Prospective Customers

2. Convince them of Comparative Advantages

3. Focus on qualified Customers

4. Identify Decision-Makers

II -- THE TARGETING PROCESS

A. The Need

1. "Technoniches"

2. Rifle vs. Shotgun

B. The Elements

1. Industry's Needs -- Market Research

a. General

b. Technology-specific

c. Company-specific

2. University Resources -- Research Analysis

a. Invention analysis

b. Research resource analysis

c. Excellence strategies

C. Computerization -- An Example

1. Technology Questionnaire (Attachment #1)

2. Invention Categorization (Attachment #2)

3. Levels of Disclosure

a. Non-Disclosing Paragraph

b. Non-Disclosing Summary

c. Disclosing Summary

d. Other
   -- Patent Application
   -- Proprietary Notes, Models, etc.
   -- Technology Package

4. DataBase Management

III -- ORGANIZATIONAL CONSIDERATIONS

A. Essential Functions

1. Disclosure Review
2. Sponsor Relations/Obligations
3. Patent Analysis/Administration
4. Marketing/Market Research
5. Licensing
6. Accounting/Reporting/Monitoring
7. System Administration

B. Minimum Office Configuration

1. Elements
   a. 1 Professional
   b. 1 Supporting Staff -- Boy Friday
   c. 1 PC
2. Cost

a. Payroll + Benefits (25%)	$94,000
b. Computer & Software (5 years)	$ 2,000
c. General & Administrative (travel, supplies, rent, etc.)	$14,000
d. Patenting Expenses	variable
e. TOTAL	$110,000 plus patent costs

3. Minimum Required Program

a. 8 - 12 marketable disclosures/year
   25 - 50 disclosures/year

b. License Issue Fees $10,000 - $25,000

c. Increases:
   -- loss from "Gross" due to distribution
   -- unrecovered patent expenses

C. First Growth -- Key Decision Point

1. Organize by Function

2. Organize by Market

3. Recommendation -- by Market (surprise?)

a. More precise targeting

b. Better internal coordination

c. "One-voice" external relationships

d. Better integration of market research

D. Ideal Office Configuration

1. Elements

a. 3 Licensing Specialists

b. 1 Market Research/Database Specialist

c. 1 Head Honcho

d. 3 Staff Support

e. One PC network

2. Costs

a. Payroll + Benefits (25%)	$370,000
b. Computer Net & Software (5 yrs)	$ 5,000
c. General & Administrative	$ 30,000
d. Unrecovered Patent Costs	$150,000
e. TOTAL	$555,000

3. Minimum Program

a. 15 - 30 marketable disclosures/year
   50 - 150 disclosures/year

b. License Issue Fees $20,000 - $100,000+

c. Modifications
   -- more needed if Net substantially less than Gross, due to distribution
   -- less needed to extent royalty stream becomes steady

CLOSING CONSIDERATIONS

(ATTACHMENT #1)

TECHNOLOGY QUESTIONNAIRE

(Please Type or Print)

PART ONE: ORGANIZATIONAL PROCEDURES

Name of Organization _____

Street Address _____

City, State, Zip _____

Main Telephone Number (____) _____ - _____

Person Completing This Questionnaire

Dr. Mr. Mrs. Ms. (Please Circle One) _____ (First Name) (Last Name)

Title _____

Address (if different from above) _____

_____

Phone (if not main number) (____) _____ - _____ (ext. _____)

What is your organization's level of interest in evaluating new technologies from outside sources and in licensing such technology for your own operations?

NONE _____ MINIMAL _____ MODERATE _____ HIGH _____

Does your organization have a central department responsible for reviewing invention disclosures from outside the organization?

NO _____ YES _____ DEPARTMENT NAME _____

Does your organization also review invention disclosures:

IN OTHER DIVISIONS OR DEPARTMENTS AT THIS LOCATION? _____

AT OTHER DIVISIONS/DEPARTMENTS AT OTHER LOCATIONS? _____

AT SUBSIDIARIES OR OTHER LEGALLY SEPARATE AFFILIATES? _____

[For each such separate department, division, subsidiary, etc., it would be greatly appreciated if copies of this questionnaire could be routed to the appropriate persons there, so that our records can be as complete as possible]

What is your organization's approach to receiving un-solicited disclosures of a non-confidential nature about new inventions?

NOT ACCEPTED _____ DISCOURAGED _____

ACCEPTED _____ ENCOURAGED _____

What is your organization's approach to reviewing inventions which have not been patented?

WILL NOT REVIEW _____ WILL REVIEW ONLY IF APPLICATION ON FILE _____

WILL REVIEW _____ WILL REVIEW SUBJECT TO CONDITIONS _____

[CONDITIONS: _____
_____
_____]

What is your organization's approach to signing a "secrecy agreement" or "confidentiality agreement" as a pre-condition to reviewing confidential technical data about an invention (e.g., to review a patent application to determine the exact nature of the invention)?

WILL NOT SIGN _____ WILL SIGN ON EXCEPTION BASIS ONLY AFTER HIGH-LEVEL APPROVAL _____

WILL SIGN IF FORM MEETS APPROVED STANDARDS _____ WILL SIGN MOST FORMS _____

TECHNOLOGY REVIEWERS [Please provide information on persons whom it would be appropriate for the University to contact regarding technologies available for licensing]

REVIEWER #1 [Check here and omit rest of REVIEWER #1 if same as person completing questionnaire _____]

Dr. Mr. Mrs. Ms. (Please Circle One) _____

Title _____

Address (if different from above) _____

_____

Phone (if different) (____) _____ - _____ (ext. _____)

REVIEWER #2

Dr. Mr. Mrs. Ms. _____

Title _____

Address (if different from above) _____

_____

Phone (if different) (____) _____ - _____ (ext. _____)

REVIEWER #3

Dr. Mr. Mrs. Ms. _____

Title _____

Address (if different from above) _____

_____

Phone (if different) (____) _____ - _____ (ext. _____)

REVIEWER #4

Dr. Mr. Mrs. Ms. _____

Title _____

Address (if different from above) _____

_____

Phone (if different) (____) _____ - _____ (ext. _____)

(ATTACHMENT #2)

PART TWO: AREAS OF TECHNICAL INTEREST

Instructions: For each category and/or subcategory where you wish to be informed of available inventions, please place in the left-hand column a number (1, 2, 3, or 4) according to which person (REVIEWER 1, REVIEWER 2, REVIEWER 3, or REVIEWER 4) we should contact regarding the invention.

____ 01000. FOOD
____ 01100. PRODUCTS
____ 01200. PROCESSES
____ 01999. OTHER

____ 02000. TEXTILES
____ 02100. PRODUCTS
____ 02200. PROCESSES
____ 02999. OTHER

____ 03000. WOOD PRODUCTS
____ 03100. PULP & PAPER
____ 03200. PROCESSING
____ 03999. OTHER

____ 04000. CHEMICALS
____ 04100. PRODUCTS
____ 04110. ORGANIC CHEMICALS
____ 04120. INORGANIC CHEMICALS
____ 04130. SPECIALTY CHEMICALS
____ 04140. PLASTICS, SYNTHETIC RESINS
____ 04150. SOAPS, DETERGENTS, COSMETICS
____ 04160. PAINTS, VARNISHES, ENAMELS
____ 04199. OTHER PRODUCTS
____ 04200. PROCESSES
____ 04210. MINING
____ 04220. REFINING
____ 04230. GASIFICATION
____ 04299. OTHER PROCESSES
____ 04999. OTHER CHEMICAL INVENTIONS

____ 05000. AGRICULTURAL PRODUCTS
____ 05100. CHEMICALS
____ 05110. FERTILIZERS/SUPPLEMENTS
____ 05120. PESTICIDES
____ 05130. HERBICIDES
____ 05140. GROWTH REGULATORS
____ 05199. OTHER CHEMICALS
____ 05200. AGRICULTURAL MACHINERY
____ 05300. DISEASE INHIBITORS
____ 05400. SOIL ANALYSIS & TREATMENT
____ 05500. BIOLOGICAL AGENTS

____ 05999. OTHER AGRICULTURAL PRODUCTS

____ 06000. VETERINARY PRODUCTS
____ 06100. FEED SUPPLEMENTS
____ 06200. HORMONES/GROWTH ENHANCERS
____ 06300. DIAGNOSTIC PRODUCTS
____ 06400. THERAPEUTIC DRUGS & PRODUCTS
____ 06500. VACCINES
____ 06600. HUSBANDRY PRODUCTS & PROCESSES
____ 06999. OTHER VETERINARY PRODUCTS

____ 07000. MARINE PRODUCTS & PROCESSES

____ 08000. STONE, GLASS, CLAY
____ 08100. STONE
____ 08200. GLASS
____ 08300. CLAY
____ 08400. CEMENT
____ 08500. CERAMICS
____ 08999. OTHER

____ 09000. METALS
____ 09100. PRODUCTS
____ 09110. METALLIC COMPOUNDS & ALLOYS
____ 09120. METAL/NON-METAL COMBINATIONS
____ 09199. OTHER PRODUCTS
____ 09200. PROCESSES
____ 09210. MINING & EXTRACTION
____ 09220. FORMING & ALLOYING
____ 09299. OTHER PROCESSES
____ 09999. OTHER METAL INVENTIONS

____ 10000. ENERGY
____ 10100. GENERATION
____ 10200. STORAGE
____ 10300. TRANSMISSION
____ 10400. PROCESS CONTROL
____ 10999. OTHER ENERGY INVENTIONS

____ 11000. ELECTRICAL & ELECTRONIC INSTRUMENTS

____ 12000. ELECTRICAL & ELECTRONIC EQUIPMENT

____ 13000. ELECTRONIC DATA PROCESSING
____ 13100. COMPUTERS & PERIPHERALS
____ 13200. SOFTWARE
____ 13999. OTHER

____ 14000. MAGNETISM & MAGNETIC PRODUCTS

____ 15000. SOLID STATE PHYSICS

____ 16000. MECHANICAL INSTRUMENTS

____ 17000. MECHANICAL MACHINERY & EQUIPMENT

____ 18000. TRANSPORTATION & LIFTING EQUIPMENT

____ 19000. POLLUTION CONTROL
____ 19100. EQUIPMENT
____ 19200. PROCESSES
____ 19999. OTHER

____ 20000. PHOTOGRAPHIC & OPTICAL INSTRUMENTS

____ 21000. LASERS

____ 22000. MEDICAL TECHNOLOGY

____ 22100. THERAPEUTICS
____ 22110. DRUGS
____ 22111. ANALGESIC/ANTI-ARTHRITIC
____ 22112. NEUROLOGIC/ANESTHETIC
____ 22113. ANTI-CANCER
____ 22114. CARDIOVASCULAR-RENAL
____ 22115. METABOLIC/HORMONAL/FERTILIZATION
____ 22116. GASTROINTESTINAL AGENTS
____ 22117. DERMATOLOGICAL & ANTI-ALLERGIC
____ 22118. ANTI-INFECTIVE (Microbial, Viral, Parasitic, fungal, immunological)
____ 22119. OTHER DRUGS
____ 22120. RADIOLOGY
____ 22130. DRUG DELIVERY & ENHANCEMENT
____ 22131. LIPOSOME ENCAPSULATED AGENTS
____ 22132. TRANSDERMAL
____ 22139. OTHER
____ 22140. INSTRUMENTS & DEVICES
____ 22141. ELECTRICAL
____ 22142. NON-ELECTRICAL
____ 22150. PROSTHETICS
____ 22199. OTHER MEDICAL/THERAPEUTIC INVENTIONS

____ 22200. DIAGNOSTICS
____ 22210. IN-VIVO
____ 22211. DEVICES
____ 22212. MARKERS
____ 22213. ANTIBODIES
____ 22214. CONTRAST MEDIA
____ 22219. OTHER IN-VIVO DIAGNOSTICS
____ 22220. NON-INVASIVE
____ 22221. RADIOLOGY
____ 22222. SONOGRAPHY
____ 22223. THERMOGRAPHY
____ 22224. NUCLEAR MAGNETIC RESONANCE
____ 22225. FIBER-OPTICS
____ 22229. OTHER NON-INVASIVE DIAGNOSTICS
____ 22230. IN-VITRO DEVICES
____ 22231. OPTICAL
____ 22232. RADIOLOGICAL
____ 22233. FLUOROMETRIC

22239. OTHER IN-VITRO DEVICES
22240. CLINICAL ASSAYS
22241. CHEMISTRY
22242. CYTOLOGY
22243. HEMATOLOGY
22244. HISTOLOGY
22245. IMMUNOLOGY
22246. MICROBIOLOGY
22247. SEROLOGY
22249. OTHER CLINICAL ASSAYS
22250. DIAGNOSTIC METHODS
22260. DNA/RNA PROBES
22270. MONOCLONAL ANTIBODIES
22280. REAGENTS
22299. OTHER DIAGNOSTICS

23000. LIPOSOMES & LATEX AGGLUTINATING AGENTS

24000. VACCINES

25000. GENERAL BIOTECHNOLOGY
25100. VECTORS, STRAINS & METHODS
25110. YEAST
25120. BACTERIAL & FUNGAL
25130. ANIMAL
25140. PLANT
25190. OTHER
25200. CLONED GENES
25210. PEPTIDE HORMONES & SMALL PEPTIDES
25220. ENZYMES
25230. CLONED ANTIGENS
25290. OTHER CLONED GENES
25300. HYBRIDOMAS (MONOCLONAL ANTIBODIES)
25310. REAGENTS & METHODS
25320. FUSION PARTNERS
25400. PURIFIED ANTIGENS
25500. VIRUSES
25600. GENERAL BIOCHEMICAL METHODS

26000. DENTAL PRODUCTS
26100. DEVICES
26200. DRUGS

99999. OTHER INVENTIONS NOT ELSEWHERE CLASSIFIED

Robert Goldsmith

THE ROLE OF THE "MARKET" IN THE TECHNOLOGY TRANSFER OFFICE FUNCTION

A. DEFINING THE MARKET FOR THE NEW TECHNOLOGY

1. Life sciences
2. Chemical/pharmaceutical
3. Diagnostic
4. Electronics/instrumentation
5. Physical sciences
6. Processes
7. Software

B. RELATIVE STRENGTH OF THE NEW ENTITY IN THE EXISTING MARKET

1. Totally new device, product, process or application

    a. laser
    b. new type of instrument
    c. plant variety
    d. waste water treatment process
    e. burn ointment

2. An improvement to an existing technology

    a. lower cost
    b. greater effectivity
    c. less side effects
    d. greater sensitivity-diagnostic or analytical instrument

C. LICENSING PRACTICES OF INDUSTRY IN THE SPECIFIC MARKET

1. Is the industry receptive to licensing?

    a. standard royalty rates
    b. non-exclusive licensing required or accepted anti-trust considerations
    c. only "world-wide" patents of interest

D. WHAT WILL THE ROYALTY RATE BE AND WHAT CAN THE RATE BE BASED UPON?

1. Rate

   a. chemical/pharmacuetical/agricultural
   b. instrumentation
   c. electronics

2. Base

   a. percent of selling price - retail - wholesale
   b. fixed dollar per unit sale - escalation
   c. throughput

E. SUMMATION OF POTENTIAL INCOME FROM LICENSING

1. Will income support protection of patent position under exclusive license?

2. Is non-exclusive feasible?

3. Can research support be obtained from licensee?

4. Is there institutional prestige involved?

F. CONSIDERATION OF ALTERNATE MODES OF TECHNOLOGY TRANSFER OTHER THAN BARE PATENT LICENSE

1. Equity position in new company formed outside of the institution

2. Equity position and assistance in forming a new company

3. Publish for institutional prestige

G. FINAL INPUT INTO THE ACCEPT / REJECT DECISION

Robert Goldsmith
RESEARCH CORPORATION
6/86

A PROFESSOR'S VIEW OF HI-TECH MARKETING STRATEGY

David C. Auth, Ph.D., P.E.

I. The Key Role of the Patent Administrator

1. It's more important for the patent administrator to sell the market to the campus than vice-versa.

2. The patent administrator looks for logical "fits" between the unique capabilities of the campus and the marketplace.

3. The patent administrator lobbies for incentives for inventors, arranges marriages, facilitates interdepartmental liaisons, and secures glory for the university when something of value has been given to the public.

II. The Key Role of the Inventor in Selling the Product

1. No one knows it better.

2. Maybe no one knows the competition better.

3. Probably no one understands the tradeoffs in the competition as well.

4. Probably no one can explain the product's features as well.

5. But, universities are stuffy about professors selling!

III. Product Champion

1. Who will be the product's champion?

2. Can it succeed without a champion?

3. Has any new technology ever succeeded without a champion?

4. Who is the one person not capable of suffering from the "not invented here" syndrome?

5. Who should be the most incentivized product champion?

IV. Is inventioneering out of place on campus?

1. If so, why bother to market?

SECONDARY SOURCES OF MARKET INFORMATION

A distinction is made between market data and marketing data. The presentation will focus on secondary sources of market data.

Secondary sources refers to published or unpublished information available at the outset of a technology project. Such information may be either internal or external to a licensing group.

Much of the useful secondary data is to be found outside the department and university. Virtually every question or problem confronting the licensing group can be illuminated to a certain extent by external secondary data. These data generally have been assembled/collected for purposes other than the question or problem at hand. This information is so ubiquitous that the principal challenge lies in knowing where to look in the face of so many possibilities.

A handout will be provided listing various sources of information, the general scope of the data included, and the contacts for these data bases and companies.

Floyd Grolle, Ph.D.
Manager, Market Research
Office of Technology Licensing
Stanford University

Converting Kodak Technology to New Businesses

Melvin R. Witmer

Abstract

In 1984 Eastman Kodak Company formed an internal venture board to review proposals for new business start-ups in areas outside of Kodak's existing lines of business.

In the last 2-1/2 years Eastman Technology, Inc. has formed a number of new businesses under Kodak's internal venture process.

Kodak's interest in new ventures fits its overall transition within its major businesses from a centrally managed, functionally organized company to one that is organized along business unit lines and is probing new areas involving a variety of entrepreneurial approaches.

Mel Witmer, Director of Market Assessment, New Opportunity Development, Eastman Kodak Company has worked with each of the new ventures formed by Eastman Technology, Inc., and will discuss his role in helping scientists and engineers within Kodak bring their ideas to market via Kodak's internal venture board.

Witmer will discuss the process developed in Kodak for encouraging internal entrepreneurs to evaluate their technology, conduct market research, estimate market size, determine production costs, and eventually prepare a business plan for review by the venture board.

6/19/86

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Packaging the Irresistible Technology

Philosophy of Technology Innovation

1.1 TIE Background
1.2 International Competitiveness
1.3 Time Horizons/Persistance
1.4 Value-added Technology Development
1.5 People, People, People

Packaging a Technology - Keep it Simple

Essential Information: Level I

1.1 Market Size
1.2 Market Leaders
1.3 Economic Advantages
1.4 Net Present Value Analysis
1.5 Identifying Licensing Interests
1.6 How To Find Out?

Essential Information: Level II

1.1 Target Licensee Identified
1.2 Find A Champion
1.3 Company Structure, Relationships
1.4 Complimentary Products/Processes
1.5 Rework Competitive Advantages
1.6 Sources - There is No Road Map

Non-essential Information, But Worth Considering

1.1 Second-tier Markets
1.2 Identifying Multiple Players

Example: Kirin Brewery Co., Ltd.

June Eva Peoples

CREATING COMMERCIALLY ATTRACTIVE

DESCRIPTIONS OF TECHNOLOGY

2:00 - 3:00 - THURSDAY JUNE 26, 1986

Presentation Abstract

This presentation reviews the reasons University Patent Administrators should want to make every effort to present their technologies in an attractive manner. Advice on how to package technologies so that the receiver will be encouraged to take the first steps toward a business partnership are offered. Examples of slide presentations, printed materials and trade fair exhibits will be demonstrated. In addition to the discussion of outer packaging, techniques for getting the unique and novel advantages of the technology out of the inventor are reviewed as well as suggesting efficient methods for preparing brief, yet interesting technology summaries. An awareness of the importance of personal touch that leads to a "win-win" deal will also be reviewed.

Some special tips on recognizing the "underdeveloped" technologies and applying creative techniques to bring the technology closer to commercial realization will also be presented by way of case history example.

All these techniques and advice are offered in a practical how-to manner that most University Patent Administrators will be able to apply upon returning to their university responsibilities.

J. Scott Stoelting,
Manager Venture Product Development
Merrell Dow Pharmaceuticals Inc.

C. Thomas Cross, Patent Administrator
University of Cincinnati,
Cincinnati, Ohio

Ray Snyder, Patent Licensing Consultant
Mt. Prospect,IL

File 143

AN INTELLECTUAL PROPERTY PROTECTION AND LICENSING

CASE STUDY

1986 SUPA SUMMER MEETING

UNIVERSITY OF WASHINGTON, SEATTLE, WASHINGTON

Any resemblance between the "facts" set forth in the following casestudy and actual facts pertaining to any invention are coincidental. These facts are the product of my imagination and do not describe any scientific facts or business relationships of which I am aware.

Marvin C. Guthrie
Director, Office of Technology Administration
Massachusetts General Hospital
Boston, Massachusetts

Introduction

You are the patent administrator for a Astudy University located in the United States. The size and location of Astudy University are not important in considering the facts that follow.

Astudy University's Intellectual Property Policy claims ownership and the right to license or otherwise dispose of all (1) discoveries and inventions patentable or unpatentable (2) copyrightable works including software, films, audiovisual or recording tapes, and drawings but excluding scholarly works such as books and scientific papers unless they are specifically prepared for the university as a part of the author's specified duties for the university, and (3) tangible results of research (sometimes called Tangible Research Property (TRP) which are produced or discovered by any full-or part-time member of the faculty, visiting scientist, employee of the university, graduate or undergraduate student or post-doctoral fellow in the course of his employment, or in the course of any research or other endeavor making substantial use of the university's resources including without limitation its

laboratories, hospitals, shops and other facilities, funds and other resources. TRP includes tapes, drawings, models and biological materials such as cell lines, microorganisms and various recombinant products. It is the university's policy to have "Participation Agreements" signed by (1) any individual who receives federal or industrial funds or participates in federally or industrially sponsored research, and (2) certain employees of the university such as computer programers and persons who work in its machine shops.

The university administration and faculty generally support its intellectual property program. Your office is adequately funded and you have ready access to intellectual property lawyers skilled in the chemical, mechanical, electrical, computer and biotechnology arts.

Fact Situation

On April 3, 1986 while perusing the Wall Street Journal you read that on April 1, 1986 Dr. Lucky Hyenergie of Astudy university reported orally to the National Cardiovascular Association Annual Meeting that teams from Astudy University have discovered a non invasive in vivo diagnostic method for detecting and locating blood clots and two methods of dissolving clots in vivo (1) by means of a clot dissolving enzyme and (2) by dissolving clots with laser energy.

Within the next week you ascertain that Dr. Hyenergie M.D., Ph.D. joined the university hospital's staff as a cardiologist and investigator in the cardiac research unit in January 1985. She came to Astudy University from Stanford University where she was a member of the medical faculty and obtained her Ph.D. in molecular biology. In December, 1984 she completed a one year post-doctoral fellowship in the Howard Hughes Medical Institute laboratories at Stanford where she worked on producing monoclonal antibodies to the major component of clotted human blood. She brought with her to Astudy University bone marrow cells from a patient Mrs. Sansclot who bled to death as a result of a rare blood condition. Her body produced an unknown enzyme that dissolved any blood clots her body formed. Dr. Hyenergie also brought a portion of a crude fraction prepared from Mrs. Sansclot's blood that was believed to contain the unidentified enzyme and antibodies also from Mrs. Sansclot's blood believed to be specific for the enzyme.

Upon arriving at Astudy University Dr. Hyenergie supported by an NIH Career Development Award began a collaboration with Dr. Nucell. Using Dr. Nucell's NIH grant funds and known techniques they attempted to fuse Mrs. Sansclot's bone marrow cells with a known tumor cell line in an effort to produce a hybrid cell line that would produce large quantities of the new clot dissolving enzyme.

Using departmental funds from several foundations Dr. Hyenergie continued her efforts to produce monoclonal antibodies to the major component of clotted blood. Her major collaborator, Dr. Fibrin, was supported by an American Heart Association Clinical Investigator award. After several months without producing any useable monoclonal antibodies Dr. Fibrin and a lab technician, C. Milestone jointly modified the antigen and the fusion technique being employed to produce the antibodies. The first fusion using the new fusion protocol and spleen cells from a mouse challenged with the new antigen yielded several clones-JF-1, JF-2 and JF-3-that produced monoclonal antibodies highly specific for the major component of human blood clots. On March 25, 1985, Dr. Hyenergie, who had lost useful hybridomal cell lines at Stanford when a power outage defrosted a freezer, deposited samples of the cell lines JF-1, JF-2 and JF-3 in a unrestricted collection at the ATCC in order to make sure she had a backup supply of the cell lines available.

Dr. Hyenergie took samples of the monoclonal antibodies MAB-1, MAB-2 and MAB-3 produced by JF-1, JF-2 and JF-3 to Dr. Chelate, a member of the University's Department of Chemistry. Dr. Chelate using a process invented by him and patented by the university in 1982 attached the paramagnetic ion magnesium (Mg) to the antibodies. The claims and specification of Dr. Chelate's patent as filed were limited to the production of X-ray imaging agents.

Dr. Chelate included theses new Mg labeled antibodies in a table of a review article describing the use of his process, attaching metal ions to protein molecules. The antibodies were identified as "monoclonal antibodies MAB-1, MAB-2, and MAB-3". No use for the complexes was mentioned in the article. The article was published April 31, 1985. Dr. Chelate was supported in full by an industrial sponsor, X-Ray Imaging, Inc. The university has granted to X-Ray Imaging the exclusive license under Dr. Chelate's patent.

Dr. Hyenergie took the Mg-labeled antibodies produced by Dr. Chelate to Dr. Spin, the head of the hospital's magnetic resonance imaging (MRI) group. Dr. Spin and the MRI group collaborated with Dr. Hyenergie in the development of a method of using MRI and the Mg-labeled antibodies to image blood clots in guinea pigs and dogs. In August 1985 Dr. Spin and Dr. Hyenergie began human clinical trials of Mg labeled MAB-1 and MAB-3 in the university hospital. The images obtained in human subjects were not as clear as the images obtained in laboratory animals, and were not of sufficient quality to be clinically useful. The research activities of Dr. Spin and the MRI group were funded by Body Imaging Corp., the manufacturer of the hospital's MRI equipment, and the American Cancer Society. The University's funding agreement with Body Imaging gives Body Imaging (i) an exclusive license to inventions pertaining to the design of MRI equipment, and (ii) non-exclusive licenses to

diagnostic methods which were first actually reduced to practice using the MRI equipment provided by Body Imaging.

In September 1985, Ima Author, an MIT graduate student doing the research for his Ph.D. dissertation in the MRI Unit rewrote a portion of the software for the hospital's MRI machine without the knowledge of Body Imaging Corp. Clinical trials using Author's rewritten software and the MRI group's imaging protocol which varies from known imaging protocols in the manner in which the imaging agent, the Mg labeled MAB-1 or MAB-3, is administered yielded clear images of blood clots in human subjects. The clinical trials were funded using NIH funds from a cardiovascular imaging grant to Dr. Roentgen, Chairman of the hospital's Radiology Department. Author was supported by a subcontract from MIT to Astudy under an NIH grant to MIT. These clinical trials served as the basis for part of Dr. Hyenergie's presentation on April 1, 1986.

Dr. Author's algorithm and its use in blood-clot MRI imaging is disclosed in his MIT Ph.D. dissertation which was approved at his dissertation defense on March 15, 1986. Copies of his dissertation were delivered to the MIT Libraries on April 1, 1986. The dissertation identifies the MRI imaging agent as Mg labeled monoclonal antibodies produced by cell lines which are identified by their ATCC accession numbers (Dr. Hyenergie described MAB-1 and MAB-3 in the same manner in her April 1, 1986 presentation). The exact manner in which imaging agents were administered to the patients is not set out in the dissertation.

While the MRI imaging agent was being developed, Dr. Hyenergie was pursuing her other objectives. In September 1984, her group finally purified and characterized the clot dissolving enzyme from Mrs. Sansclot's blood. Dr. Hyenergie named this enzyme "clotbusterase". Her group produced monoclonal antibodies to the clotbusterase and attempted to sequence the protein. Because of the small amount of clotbusterase available they were able to sequence only about 65% of the molecule.

At about the same time Dr. Hyenergie and Dr. Nucell using the cell fusion techniques developed by Milstein and Kohler to produce hybridoma cell lines for the production of monoclonal antibodies, produced a hybrid cell line that secreted a clot lysing enzyme. This enzyme which they named clotbusterase II appeared antigenically identical to the clotbusterase purified from Mrs. Sansclot's blood. Using this new hybrid cell line named "Implauseable", Dr. Hyenergie's group produced enough clotbusterase II to purify it and determine its amino acid sequence. A portion of the sequence of clotbusterase II was identical to the 65% sequence obtained from clotbusterase. Clotbusterase and clotbusterase II are identical in gel chromatography and HPLC. Manuscripts describing clotbusterase and clotbusterase II have been submitted and accepted for

publication during the summer of 1986. Dr. Hyenergie has now cloned the gene for clotbusterase II, and is attempting to obtain the human gene from a DNA library prepared from Mrs. Sansclot's bone marrow cells.

Once clotbusterase II became available in great enough quantities another group began exploring its therapeutic efficacy. Using the techniques already developed for the uses of urokinase and tissue plasminogen activator, Dr. Thrombe Licess began using the clotbusterase II to dissolve clots experimentally induced in laboratory animals. Lady luck was on the side of the Licess team. They rapidly established that clotbusterase II effectively lyses clots in vivo in animals. Human clinical trials of clotbusterase II were initiated in August 1985 under an IND filed by Astudy naming Drs. Hyenergie and Licess physician sponsors. These clinical trials served as the basis of part of Dr. Hyenergie's presentation on April 1.

In March 1986, Dr. Licess returned home to South Africa to receive an award in recognition of his contributions to clinical science. In his acceptance speech on March 15 before an audience of 800 scientists and their guests he discussed the success of the human clinical trials with clotbusterase II. He described clotbusterase II as a lytic enzyme produced by a hybrid cell that was a fusion product of a known malignant line and the bone marrow cells from a patient. He characterized clotbusterase II in some detail but did not disclose its sequence. When you discussed these events with Dr. Licess you suggested that it would have been helpful if he had informed you of his work prior to making his presentation. He smiled tolerantly but triumphantly and informed you that he is no fool. While visiting his family prior to his presentation he had his brother, a South African patent attorney, file a patent application in South Africa on March 14, 1986. The application claims the use of clotbuster for the in vivo lyses of animal and human blood clots. As he gave you a copy of the patent application he assured you that he had always intended to bring it to your attention but he had just been too busy. He said he will be happy to assign his rights to the University except for the one quarter interest he assigned to his brother as compensation for drafting and filing the application. As you thumb through the application on the way back to your office you notice that the sequence of clotbusterase II is not described and there is no reference to a deposit of the Implauseable cell line.

When you return to your office from your meeting with Dr. Licess you find Mr. Argon and Dr. Ruby, President and V.P. for Research of Entertainment Lasers, Inc. in your waiting room. They inform you that they read in the Wall Street Journal the report of Dr. Hyenergie's presentation on April 1. They have learned that Dr. Hyenergie gave credit for the laser destruction of blood clots to Dr. Zapum, a member of the medical faculty of Astudy University. They assure you that

this is just a social call, a formality as it were, and that the university will find them most beneficent in sharing the future success of Entertainment Lasers, Inc. Their beneficence, they hint, will be influenced of course by the cooperation of your office and the university with their attorneys as they patent and develop the laser treatment method developed by Dr. Zapum. When you explain to them that Dr. Zapum's research is subject to the university's patent policy they confidently explain that that can not be the case. They produce an exclusive 5 year consulting agreement signed by Dr. Zapum in 1983, one year before he joined your faculty. The agreement gives Entertainment Lasers, Inc. ownership of all inventions and improvements in the field of laser design or use conceived or reduced to practice by Dr. Zapum during the term of the agreement. They advise you that their prior agreement is not subject to university's patent policy and that Dr. Zapum has not signed the university's participation agreement. They also produce a copy of the company's purchase order used by the university to purchase the two lasers used by Dr. Zapum to conduct his research. The terms of the purchase order signed by the university's purchasing department state that any invention made using the equipment purchased via the purchase order shall be the property of and shall be assigned to Entertainment Lasers, Inc. They point out that Dr. Zapum also signed the purchase order the day after the purchasing department issued the purchase order and he specifically agreed to the invention clause. Argon and Ruby said that the price paid by the university was one fifth the usual market price of the equipment and that the company has maintained, repaired and up-dated the laser at no cost to the university. They request the cooperation of your office and the other faculty members working on the clot lyses project. As they depart they confide in you that they are considering changing the name of their company to Astudy Medical Lasers, Inc.

Upon further exploration you discover that Dr. Zapum's laser clot lyses project has been funded by grants from NIH and NSF. Entertainment Lasers, Inc. has filed a patent application in the name of Dr. Zapum and a company employee claiming a modification of the design of their lasers. The modification was necessary in order for the company's lasers to be useful in Dr. Zapum's work. Prior to Dr. Zapum's work the lasers had been used only in rock concert light shows. The application does not claim the use of the lasers to lyse blood clots but discloses an experiment in which animal blood clots are lysed in vitro. In addition you have learned that company's lasers are not useful for the in vivo lyses of blood clots unless the delivery of the laser energy to the blood clot is controlled by an amplification and pulsing device designed by a visiting professor, Dr. Foreign, on sabbatical from the Institut Pasteur. This device is driven by a software program written by a part-time employee of the university's machine shop where the device designed by Dr. Foreign was fabricated. The program was written on the employee's home computer and he has copyrighted it in his own name.

You call the University's patent attorneys together on April 9, 1986 and give them all of the above information and ask them to identify:

1. inventions the university can patent arising from:

   (a) the project to purify and sequence clotbusterase (you inform them that Dr. Hyenergie believes that clotbusterase and clotbusterase II can not be patented because they are "products of nature");

   (b) the projects to identify and locate blood clots;

   (c) the clotbusterase lyses of blood clots;

   (d) the laser lyses of blood clots; and

   (e) the molecular biology of clotbusterase project;

2. who among the individuals identified or others are the inventors of the inventions;

3. tangible results of research, patentable or unpatentable;

4. the subject matter that the university can copyright; and

5. the validity and strength, if any, of Entertainment Laser, Inc.'s claims to ownership of the inventions made by Dr. Zapum and the team using the Entertainment Lasers.

After meeting with your attorneys you return to your office and begin reading the correspondence and returning the telephone calls that have accumulated during the last week while you have been unravelling Dr. Hyenergie's activities. You discover the following:

1. A letter from X-Ray Imaging stating that they have learned from Dr. Chelate that his patented process was used to prepare the Mg labeled MRI contrast media described by Dr. Hyenergie on April 1. They want to meet with you as soon as possible to discuss their exclusive license to use this new invention.

2. Your secretary has scheduled you to meet with the President and vice presidents of Research and Marketing of Body Imaging next week. They want to discuss their license rights to the new clot imaging technology and discuss funding of future research and development of the new imaging agent.

3. Dr. Roentgen, Chairman of the Department of Radiology, the hospital's second largest clinical Department, has called insisting that he is entitled to be named as a co-inventor to the blood clot imaging inventions because he made the inventions possible by funding the clinical trials from his NIH funds and making time in the MRI machine schedules for the research team to reduce the invention to practice more rapidly than otherwise would be possible.

4. A letter from two monoclonal antibody companies asking for rights to produce the MAB-1 or MAB-3 monoclonal antibodies in commercial quantities and offering lucrative terms.

5. A telephone call from the Director of Licensing of a large pharmaceutical company that has a large X-ray and MRI contrast media line asking to meet with you.

6. Two genetic engineering companies asking to meet with you to discuss collaborating with Dr. Hyenergie in producing clotbusterase II by recombinant means.

7. A letter from the attorneys for Mrs. Sansclot's estate requesting a meeting to discuss an "equitable" sharing of the benefits derived by the university from the commercialization of products derived from her bone marrow. The letter is accompanied by a copy of the Hospital surgery permit signed by Mrs. Sansclot which states that removed tissues will be used for diagnostic purposes only.

8. The abstract submitted by Dr. Hyenergie and the other collaborators was accepted by the National Cardiovascular Association and mistakenly not printed with the other abstracts in the March issue of the association's journal.

9. An invention disclosure from Dr. Recluse, a member of Astudy University's School of Veterinary Medicine. The disclosure dated March 25, 1986 discloses the isolation and purification of a blood clot lysing enzyme from the blood of horses. Dr. Recluse using a well known animal model has shown that the enzyme he has discovered lyses blood clots <u>in vivo</u> in experimental animals. Based on the models well known high correlation with human blood clotting systems Dr. Recluse predicts that his new enzyme will also dissolve human blood clots <u>in vivo</u>. The invention disclosure form indicates that Dr. Recluse has been studying this clotting disease in animals since 1965 but was not successful in isolating the enzyme until early 1985. He has collected substantial data to

support his belief that this clotting ailment is responsible for the previously unexplained death of many wild and domesticated animals. When you compare the analytic data it appears that the enzyme isolated by Dr. Recluse and clotbusterase II are identical. Later studies will confirm that they are chemically identical.

You send all of the correspondence and the Recluse invention disclosure to your attorneys. You then sit back, take a little (or a lot if needed) of whatever helps you in moments like this and prepare a list of (i) inventions and copyrightable works you believe have been made, (ii) inventors (as you currently know them of each invention) and (iii) names of each institution or organization that might have a claim to ownership rights in each invention or a claim to share in any royalties you might obtain from each invention.

Bring your list to Seattle and see how your answers compare with those provided by the speakers.

How Japan Inc. is cashing in on free U.S. R&D

Technology transfer between federally funded labs and Japanese firms is flowing only one way — Eastward

It's a familiar scene. Japanese scientists tour U.S. laboratories to visit with their American counterparts and share information. In many cases, however, U.S. industrialists and government officials argue, the sharing is strictly one-sided. The Japanese, they contend, often walk off with innovative technology — for free — and offer little in return. "They recognized early that the U.S. is funding the entire world's basic research," says Norman Latker, director for federal technology management policy in the U.S. Department of Commerce's Office of Productivity, Technology and Innovation.

There is nothing illegal about this. Information on nonclassified research and development at national laboratories has been readily available. So it's no surprise that the Japanese and others have launched concerted efforts to cash in for free R&D. "They would be nuts to pay for research they can get for nothing," says one government official. "And the Japanese are anything but dumb."

What is perhaps more of a surprise is that few U.S. companies have followed suit. Some companies, such as Harris Corp. and Intel Corp., have technology transfer agreements with national laboratories, but U.S. industry in general has kept its distance from federal labs. One reason might be that U.S. companies want guarantees in the form of patents before they will invest heavily to adapt basic research for commercial applications. Until recently, this has been a difficult procedure.

Representatives of Japanese firms, however, point out that there is nothing illegal about picking up technology that is in the public domain. "It is a mistake to single out the Japanese for cleverly taking technology that is freely available to everybody on a nondiscriminatory basis," says H. William Tanaka, an attorney with the Washington, D.C., firm Tanaka-Walders-Rigter, which represents the Electronic Industry Association of Japan.

Furthermore, Tanaka contends, the technology transfer legislation goes against the current trend for companies from different countries to link up to share enormous R&D costs. "It is highly questionable whether this legislation will help American companies develop technology out of federally funded laboratories in the face of structural changes that are forcing companies and countries to pool their resources."

> U.S. companies want guarantees in the form of patents

Nevertheless, new legislation could change the often asymmetrical nature of technology transfer. At the very least, its proponents hope the Federal Technology Transfer Act of 1986 will give U.S. companies a beat on foreign competitors in making the most of U.S.-developed basic research. At best, supporters predict this new method of exploiting technological breakthroughs will give birth to creative Silicon Valley-like communities around many of the labs. "Our economic future depends on encouraging the efficient dissemination of skills and information within our communities," says Senator Patrick J. Leahy (D-Vt.).

Under the new law, national labs

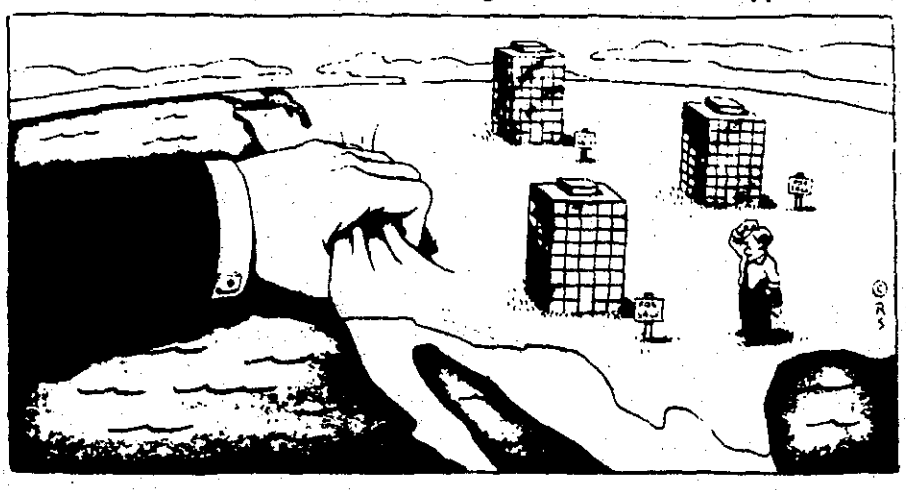
- Allows labs to enter into cooperative research agreements with industry, universities and others, and to negotiate patent licensing agreements
- Directs heads of agencies with large labs to institute cash award programs to reward scientific, engineering and technical personnel
- Requires agencies to give at least 15% of royalties received from licensing an invention to the inventor and distribute the balance of any royalties among its labs
- Creates the Federal Laboratory Consortium for Technology Transfer at the National Bureau of Standards.

Publish and perish

The need to make federal labs more responsive to national needs was outlined in a 1983 report by the Packard Panel, headed by David Packard, cofounder of Hewlett-Packard Co. and former deputy secretary of the Defense Department. "The national interest demands that the federal labo- will decide how best to disseminate internally developed technology. They can cut their own deals with interested companies and share the profits. "To improve technology transfer, the federal laboratories need clear authority to do cooperative research and they need to be able to exercise that authority at the laboratory level," states a Commerce Department report. Until recently, such information was routinely published and available to anyone — from the United States or abroad. Now, American companies will get first crack. The law:

ratories collaborate with universities and industry to ensure continued advances in scientific knowledge and its translation into useful technology," the report states.

Although the legislation encouraging such interaction was approved late



Rob Saunders

CRITICS CONTEND the Japanese are too aggressive in acquiring U.S. technology

last year, it will be some time before the provisions are routinely enforced, according to Latker. "We're now trying to implement the law," he says. "But first we have to change a significant cultural bias away from the idea of publishing everything."

It might seem naive to some that inventions funded by taxpayers were made equally available to everybody, but that policy reflects the democratic attitude that no individual or company should get preferential treatment. And federal researchers have felt uncomfortable coming down from their ivory towers and hooking up with private companies in commercial ventures. The financial incentives could help change these attitudes. "It [will be] interesting to see the response when the first researcher pulls up in a red Ferrari," says Joseph Allen, technology policy liaison in the Commerce's Office of Productivity, Technology and Innovation.

Lab officials are learning the benefits of licensing and cost-sharing arrangements from universities, which lately have expanded their ties with industry. Some particularly aggressive institutions like Stanford University and the University of Wisconsin reportedly have made more than $5 million a year in profits by licensing technology and sharing research costs.

By contrast, the U.S. Treasury made only $2 million on patents in 1985 even though it spent $18 billion — a third of all R&D spending — at about 400 federal labs. The labs do research on everything from thin film and optoelectronics technology to boll weevils, with the heaviest funding going to the relatively large labs for weapons, space science and energy research, medical programs, and physics experiments.

The labs, which employ a total of 185,000, including one-sixth of the country's scientists, have produced 28,000 patents. Only 5% of those patents have been licensed. "This statistic is a reflection both of the fact that many government patents have little or no commercial value and that agencies have made little effort to seek private sector users for even their most important commercial inventions," says E. Jonathan Soderstrom, director of technology applications for Oak Ridge National Laboratory at Martin Marietta Energy Systems in Tennessee.

It is difficult to track the evolution of basic research, so there are no clear-cut examples of U.S. technology that the Japanese have exploited for commercial products. But no one denies that there has been a concerted effort by aggressive foreign companies (and country-sponsored initiatives) to acquire technology from America. In 1983, for example, the Japan Economic Institute reports that the United States transferred to Japan six times as much electronics technology and almost eight times as much machine-tool technology as it acquired from Japan.

In all, 70% of Japan's worldwide technology imports that year came from the United States, according to Senator J.D. Rockefeller IV (D-W. Va.) "This asymmetry in the international flow of knowledge has real repercussions for our country's competitiveness in world markets," says Rockefeller. "If our cutting-edge technology is made fully available to our rival in international trade . . . we stand to lose not only foreign markets but also jobs and income at home."

SEMICONDUCTOR RESEARCH at Sandia Labs, where scientists no longer allow routine visits by foreign scientists.

Lab officials are learning the benefits of licensing

It's not that Rockefeller and others want to totally stop technology exchange programs with foreign countries. Rather, they want to guarantee that technology swaps are equal. "It's time we started bartering a little more," says Robert Stromberg, technology transfer officer at Sandia Laboratories in New Mexico. "We want a fair, equal exchange on a tough Yankee-trade basis." Stromberg cites, for example, that Sandia no longer allows routine visits by foreign scientists unless "we are sure they are as good as ours and that any exchange of technology goes both ways."

Allen of the Commerce Department points to the lopsided international scientist exchange programs as one of the most obvious inequities. "The Japanese have been able to place a lot of people in labs here," he says. "But we have a hard time placing them over there." At the National Institute of Health, for example, some 397 Japanese scientists were working in U.S. facilities in fiscal 1985, while only three U.S. NIH scientists were assigned to Japanese labs.

Even without their aggressive attempts to acquire U.S. technology, industry sources contend, the Japanese have a significant R&D advantage. Even though U.S. R&D spending has leveled off at about 2.7% of the gross national product, the Japanese project that, by 1990, R&D expenditures will rise to 3.2% of GNP.

"We're stagnating at 2.7%, much of it for the military, while they keep increasing spending for commercially exploitable R&D," says Ralph Thomson, senior vice president of the American Electronics Association. "Our one remaining competitive advantage was innovation, but we're wrong to believe the Japanese are just copiers. Their emphasis on commercial R&D has got them to the point where they are better than the U.S. in many products."

BETH KARLIN

The Washington Post
Thursday, October 16, 1986

PETER BEHR

Plugging the U.S. Knowledge Leak

The United States has quarreled with its trading partners over autos, TV sets, oranges, steel bars and semiconductors. Next comes a battle over knowledge.

The protection of American inventions, laboratory research and intellectual property from unfair exploitation has moved to the top of the Reagan administration's agenda for the next round of international trade negotiations.

It also has become a prime issue for leaders of universities and government labs, who argue that the basic research at their institutions constitutes America's best remaining competitive edge in world trade.

There are now suggestions that some of that research be put off limits to foreigners or that access be limited, at least temporarily. Call it a "buy American" approach to government-funded research and development.

Richard M. Cyert, president of Carnegie-Mellon University—one of the nation's centers of research on advanced industrial processes—says the competitive importance of the U.S. research establishment must be recognized.

"The United States, in my view, is in an analogous position to being on the frontier in colonial times. We really are fighting for our economic life. Unless we are able to do some things in universities to help in this, I think our whole way of life, our whole standard of living in this country is going to go down the drain."

Cyert said he would be willing to consider a proposal that would boost federal research support for American universities—with the requirement that the research work be restricted to U.S. citizens.

"I'd be interested in it, if we limited the period . . . . I'd be willing to go along with that for a little while. I'm sure it would be unpopular, in the sense that we like to think of ourselves as world citizens.

"It's obviously something I'm uncomfortable with. . . . But we want to have America get some temporary advantage from the research that we can do. . . . The notion that somehow you want to do something for your country should not be something that a university president is ashamed of," said Cyert.

Congress is not considering such a proposal. But it has approved and sent to President Reagan

See BEHR, E2, Col. 4

BEHR, From E1

legislation called the Federal Technology Transfer Act of 1986.

The bill's main purpose is to help American companies, universities and other institutions tap research in the nation's 700 federal laboratories. The labs would be authorized to enter into cooperative joint research arrangements aimed at speeding their technology into commercial use.

Foreign companies aren't prohibited from joining in such cooperative ventures, but preference is to be given to American firms that agree to manufacture in the United States.

Senate Majority Leader Robert J. Dole (R-Kan.), and Sen. John D. Rockefeller IV (D-W.Va.) added a section that is aimed at assuring that American companies get reciprocal access to foreign labs. In reviewing proposals by foreign companies, federal lab directors "may examine the willingness of the foreign government to open its own laboratories to U.S. firms," the legislation says.

Although the bill has strong congressional backing, there is some question whether Reagan will sign it.

Access to American research facilities—government and university—will become even more important in a competitive sense as these laboratories try to push their discoveries into the marketplace more rapidly.

University of Michigan has set up an "intellectual properties" office to help inventors obtain patents and to offer advice and aid in turning the inventions into products or commercial services. Like Carnegie-Mellon and most other major universities, Michigan is expanding its connections with American manufacturing companies.

In all of these area, universities must walk the narrow line between advancing the U.S. national interest and maintaining a tradition of open access to all. It is a microcosm of the free-trade, fair-trade dilemma confronting Congress and the administration.

Gilbert R. Whitaker, dean of the University of Michigan's Graduate School of Business Administration, notes that the school still looks actively for non-American MBA candidates.

"The Japanese send 10 to 15 students a year. Now we're getting increasing numbers of Koreans. They're obviously here to learn something about American culture and American business to take back with them. We're trying to learn similar things about their culture," he said.

Whitaker believes that the United States has more to gain through a continuing exchange of ideas, technology and expertise. "We'd like to get technology from elsewhere to put together with our knowledge. . . . We don't have a monopoly on brains."

Cyert agrees, with one qualification. "One of the great accomplishments of the United States has been the dissemination of its knowledge and technology around the world. . . .

"We want the bucket to leak. We do want the stuff out there. To the extent we can hold back a little bit, say by some restrictions on licensing, or on access to the most up-to-date [research], it would give us a little bit of a comparative advantage."

The search for that advantage promises to transform the way universities, company managers and politicians think about the American research establishment.

America, the 'Diminished Giant'

As Rivals Strengthen, U.S. Dominance in World Marketplace Fades

Fourth of a series

By Stuart Auerbach
Washington Post Staff Writer

The first made-in-Korea Hyundai automobile rolled into the United States 14 months ago, driven off a Japanese freighter at the port of Jacksonville, Fla.

To those who still regard Korea as the underdeveloped nation depicted in the sitcom M*A*S*H, instead of a budding industrial giant, what happened next was perhaps a surprise.

The low-priced Hyundai swept through this country, setting a record for first-year sales by an imported car—168,882 sold in 1986—and quickly became a name to be reckoned with in the world auto industry.

The Hyundai sailed on winds of change that have drastically transformed the economic shape of the globe—establishing an entirely new relationship between the United States and the rest of the world, making it vastly more difficult for U.S. industries to compete in crucial global markets.

The changes have been so sweeping and have taken place with such astonishing speed—over just 15 years—that they are only partly understood by the American public and policy-makers in government.

RUDE AWAKENINGS
THE CHALLENGE OF THE GLOBAL ECONOMY

But virtually all the experts agree that the era of overwhelming U.S. dominance of the international economy—an era that began after World War II when much of the rest of the world was devastated—is over.

"We have come to a divide," said University of California political scientist John Zysman. "The economic changes we are watching will reshape the international security system. They are fundamental shifts of the power relations among nations."

In the United States, these changes have contributed to serious economic dislocation: the closing of steel mills and auto plants, the conversion of the industrial heartland into the Rust Belt, a loss of millions of manufacturing jobs.

They have raised questions, as C. Fred Bergsten, director of the Institute for International Economics, wrote recently in Foreign Affairs magazine, as to whether

See COMPETE, A18, Col. 1

consulting agreements with third parties, to which the university is not privy and for which it disclaims all responsibility.

Government obligations - Nothing in this agreement shall be construed to restrict the right of university to transfer to the U.S. Government such rights as the Government may be entitled to under any agreement university may have or may hereafter enter with the Government, whether or not consistent with the provisions of this agreement.

Exclusivity - Funding for the research program will be exclusively by sponsor unless additional funds are made available to the university for its unrestricted use by the U.S. Government or private sources which are approved by sponsor. The university will consult with sponsor regarding the use of any equipment or facility in connection with the research program which has been acquired, in whole or in part, through U.S. Government funding. OMB Circular A-124 is referenced herein as establishing the U.S. Government patent policy applicable to any government funding of the research program.

Conflict of interest - It is understood that university is not now consulting with any other company or government agency on matters which conflict, or appear to conflict, with the subject matter of this agreement. It is agreed that if, subsequent to the execution of this agreement university finds that a conflict, or what may appear to be a conflict, develops because of a relationship created or intended to be created between consultant and any third party, university immediately notifies company who shall, notwithstanding paragraph _____ below, have the right, at its sole discretion, to terminate this agreement on 24 hours notice. Upon exercise of such right of termination company's only obligation to university shall be to reimburse them for services rendered to the date of termination.

REVIEW DRAFT

MASSACHUSETTS INSTITUTE OF TECHNOLOGY

OSP GUIDE

TO

RESEARCH AGREEMENTS

WITH

INDUSTRIAL SPONSORS

This Guide has been prepared by the Office of Sponsored Programs as a summary of the broad principles and specific contract provisions applicable to research agreements between MIT and industrial and commercial organizations. Questions and comments are invited. They may be addressed to the appropriate department or laboratory OSP respresentative or to any of the following:

OSP - George H. Dummer, ext. 3-2492
David J. Harrigan, ext. 3-2495
Carol E. Van Aken, ext. 3-1648

MIT Patent Office - Arthur A. Smith, ext. 3-6966

OSP GUIDE TO

RESEARCH AGREEMENTS WITH INDUSTRIAL SPONSORS

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PART I

INTRODUCTION

A. THE MIT-INDUSTRY RELATIONSHIP

MIT has for many years enjoyed a close relationship with business and industry. This relationship has, in large measure, flourished because it is not based on the view that the university is the central source of new knowledge, but on the conviction that new knowledge and discoveries occur throughout society, and that the movement of knowledge is never unidirectional.

Thus, industry can and does provide universities with important intellectual stimulation, as well as interpretations and reinterpretations of academic research results from a different and valuable perspective. In fact, one of the primary assets of MIT is its highly interactive relationship with industry, which keeps it informed of industrial needs and interests and provides important feedback on the results of MIT work.

This interaction is advanced by a variety of methods, including informal contacts between faculty members and industrial personnel; by the involvement of industrial representatives on the MIT Corporation and various departmental visiting committees; by discussions, seminars, and teaching programs, from the undergraduate level through continuing education for professionals; by MIT's industrial liaison activities; and by industrial sponsorship of MIT research activities, which is the subject of this Guide.

B. THE NATURE OF MIT RESEARCH

The primary purpose of Institute research is to advance the frontiers of science and technology and further the educational program. In the belief that instruction and research are interdependent and that both suffer when dealt with separately, the Institute has integrated these functions throughout the academic and administrative structure.

To achieve its purpose, Institute research should be of intellectual interest to members of the MIT faculty or senior research staff and responsibility for directing the research must reside in the MIT principal investigator. The research should have promise, if successful, of advancing knowledge or the state-of-the-art and provide thesis or dissertation opportunities for students.

Industrially sponsored research projects must be designed so as to maintain a balance between the Institute's pursuit of research as an integral part of the educational process and industry's search for useful knowledge to be applied toward the development of products, processes and services.

C. CONTRACT PRINCIPLES

The principles underlying MIT research contracts with industrial sponsors are set forth in detail in Part II of this Guide. The most important of these are the following:

1. Best efforts

Since state-of-the art research is by nature unpredictable and without guarantee of success, MIT research is conducted on a best efforts basis. Every effort is made, however, to organize research projects in a manner which is sensitive to the differing time constants of industrial sponsors.

The Institute receives no fee or profit on its research with which to cover business risk. For this reason, and because it is inconsistent with the best efforts principle, MIT cannot accept contract provisions which establish firm deadlines, impose penalties for failure to make progress, or provide for withholding of payment if the sponsor is not satisfied with the results.

2. Conflicting obligations

MIT does not knowingly enter research agreements which involve commitments and obligations which are in conflict with those accepted under other agreements. Special procedures for dealing with actual or potential conflicts may, in appropriate cases, be included in research agreements. MIT does not, however, accept blanket provisions which preclude the principal investigator from performing research for other sponsors in related areas.

3. Publications

To fulfill its objectives and meet statutory requirements relating to the Institute's status as a tax exempt educational institution, MIT research must serve a public rather than a private purpose, and the results must be disseminated on a non-discriminatory basis. The Institute cannot, therefore, undertake studies the results of which cannot be freely published.

MIT nonetheless recognizes the legitimate proprietary concerns of industrial sponsors. Where appropriate, publications can be deferred for a limited period of time, normally up to 30 days, in order to protect patent rights. Similarly, on those occasions where MIT has accepted a sponsor's proprietary information as necessary background data for a research project, the Sponsor may review proposed publications in order to identify any inadvertent disclosure of that data. Review procedures must, however, ensure that there is no delay in granting academic credit for a student thesis.

4. Patents

The Institute retains title to inventions resulting from sponsored research and licenses them in the public interest under an active patent management program in which licensing of industrial research sponsors is an important part. The basic aim of the MIT licensing policy is to promote the progress of science and technology, to assure that discoveries and inventions are utilized in ways most likely to benefit the public, and to provide adequate recognition to inventors as well as appropriate royalty revenues to the Institute.

Nonexclusive licenses are normally granted to the sponsor of the research which resulted in the invention. If necessary to the effective development of promising ideas, however, an exclusive license may be issued for a limited time period. In all cases, royalty income is shared between the inventors and the Institute.

5. Cost-reimbursement

MIT conducts research only on the basis of full cost-reimbursement and requires that such research be funded in advance since the Institute does not have a source of funds with which to finance work in process or the interest on funds borrowed for that purpose.

D. ESTABLISHING A SPONSORED RESEARCH PROGRAM

1. Preliminary Discussions

A sponsored research program is most frequently established (1) when an industrial sponsor wishes to support a research project which a member of the MIT faculty or senior research staff wishes to pursue and (2) the proposed research is approved by MIT as educationally appropriate and consistent with the Institute's research policy and tax exempt status.

Initial discussions between sponsor respresentatives and MIT faculty or senior research staff occur in a variety of ways. It should be understood, however, that no program can be established at MIT unless a research proposal has been submitted through regular MIT internal review procedures, and an acceptable grant or contract negotiated and signed by the authorized representatives of the parties.

2. Proposal Review and Submission

A faculty member or eligible member of the senior research staff must prepare a proposal describing the research to be done, identifying the individuals who will perform it, and setting forth a proposed budget.

The department head or laboratory director must be satisfied that (1) the project is appropriate for the department or laboratory to undertake as a part of its educational and research program, (2) senior staff are

available and willing to supervise the research, and (3) adequate space and facilities are available. The proposal must include a budget covering all applicable direct and indirect costs.

The proposal is reviewed by the Office of Sponsored Programs (OSP) with respect to financial, business and legal considerations, and is referred to appropriate MIT officers or committees for the resolution of any outstanding issues involving financial matters or research policy.

The appropriate Dean and the Provost, or Vice President for Research, as appropriate, must endorse the proposed project as suitable in relation to the entire Institute's program of research.

When the review process is completed, the Office of Sponsored Programs submits the proposal to the sponsor.

3. Grant/contract negotiations

All contracts and grants are negotiated by OSP. Where contract discussions are held between sponsor representatives and MIT faculty or staff, it should be understood that these are preliminary only and that OSP must review any proposed contractual agreement on behalf of the Institute, and either endorse it as conforming to MIT contract policy or negotiate necessary modifications.

When negotiations are completed, the contract can be signed only by the Director of OSP, or other Institute officer who has a specific delegation of authority from the Executive Committee of the MIT Corporation to sign contracts on the Institute's behalf.

4. Project administration

When negotiations are completed and the grant or contract signed, OSP establishes a project account, notifies the project supervisor and department and takes whatever other steps are necessary so that the project supervisor may begin the research and make appropriate charges to project funds.

The project supervisor and department or laboratory in which the research is performed are responsible for the conduct of the research and for the proper charging of the costs of conducting the project. Appropriate fiscal and technical reports are submitted to the sponsor.

The Office of Sponsored Programs reviews expenditures on an ongoing basis to assure compliance with the terms of the research agreement and Institute policy.

Any correspondence proposing modification of the terms or conditions of a contract or grant, including changes in the scope of work, or an increase or decrease in the total estimated cost must be forwarded via OSP. Renewals or extensions involving additional costs must also be reviewed through normal procedures in the same way as new proposals.

OSP GUIDE TO

RESEARCH AGREEMENTS WITH INDUSTRIAL SPONSORS

PART II

CONTRACT POLICY

This part describes the principal types of research agreements used by MIT and the policy considerations which determine the specific contract provisions appropriate to each under varying conditions and options. The contract provisions themselves are compiled in Part III.

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RESEARCH AGREEMENTS WITH INDUSTRIAL SPONSORS

PART II- CONTRACT POLICY

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MIT RESEARCH AGREEMENTS

The Institute performs industrially sponsored research under various forms of agreement, including principally the following:

1. Single Sponsor Standard Agreements

This is the traditional and most frequently used agreement, i.e., for research supported by a single sponsor for a one or two year period to be performed solely by MIT with minimal, if any, sponsor collaboration or interaction. The sponsor receives copies of publications and reports on the results of the research, patent and copyright licenses, and an opportunity for occasional informal discussion with the MIT investigators.

2. Single Sponsor Cooperative Agreements

The terms joint, cooperative and collaborative, as used to describe university-industry agreements, have been given a variety of different meanings. As used here, they refer to arrangements which involve a level of interaction which goes beyond that typical of standard agreements.

The interaction which occurs under cooperative arrangements may involve periodic briefings at MIT or at the sponsor's location, visits and/or participation in some phases of the research by sponsor's research and engineering staff, MIT access to the results of related research performed by the sponsor, access to sponsor's proprietary data (although this also occurs under standard agreements), and other forms of joint effort.

Patent provisions may also have to provide for joint inventions.

3. Long-term Institutional Agreements

This form of agreement is typically for a longer time period (i.e., five to ten years) and defines an area of research within which specific projects will be individually funded, with new projects to be selected from time to time.

The agreement is structured as an umbrella arrangement with a mechanism for the selection of projects acceptable to both parties. A steering, advisory, or policy committee and/or individual project committees including sponsor representatives may be established to evaluate the progress of the research and review new proposals. This may involve informal consultation or more structured review procedures. Whatever mechanism is established, MIT does not relinquish any of its corporate contractual authority and the MIT principal investigator is solely responsible for the conduct of the research itself.

In addition, the level of interaction between MIT investigators and the sponsor's research and engineering staff is often similar to that described under Section 2 above relating to cooperative agreements.

Proprietary considerations, principally those involving patent rights, take on more importance and the patent provisions are likely to be rather detailed. This, in turn, may result in a need for greater precision in the Statement of Work to avoid ambiguities and conflicts in relation to other MIT research, a

mechanism for determining where conflicts in patent rights might arise as new projects are selected, and a mechanism for ensuring that publications which might constitute invention disclosures are handled in a manner which does not defeat patent rights.

Funding provisions are also different from standard agreements since there is usually an over-all commitment and a mechanism for the funding of individual projects within that commitment. In addition, a portion of the funding or a supplementary amount may be provided for research projects to be selected at MIT's sole discretion and not subject to any contract restraints.

4. Multiple-sponsored Agreements

Research projects with multiple sponsors cover a broad spectrum.

A number of projects are funded by as many as thirty individual sponsors. They are conducted in roughly the same fashion as single sponsor projects under standard agreements, except that the funds are commingled in a common account to be used by the MIT Principal Investigator in conducting research projects of his or her choice within the broadly defined program goals. All sponsors receive the same publications and fiscal reports which result from the research. They do not necessarily receive any patent or copyright rights, although in some cases multiple sponsors are granted non-exclusive licenses. Some programs hold periodic conferences to present findings and provide an opportunity for interaction with the MIT investigators.

"Consortium" is a description normally applied to multiple sponsor arrangements which usually have more limited membership, frequently in the range of 8 to 12, many of the interactive characteristics of cooperative arrangements, as described in Section 2 above, and many features of long-term institutional agreements as set forth in Section 3 above, particularly with respect to project selection, evaluation and review.

The funding arrangements are usually peculiar to this type of arrangement since the over-all level is often determined as a function of the optimal size of the research program in the light of available staffing and physical resources, the appropriate size and membership for an effective consortium, and what constitutes an equitable and realistic fee structure. Fees may be based on company size measured in some manner, such as sales, and the funding level may vary as new members are added or withdraw.

The standard consortium agreement provides for MIT to retain title to all inventions with disposition of rights to take into account the equities of the participating members and the public interest. In some cases it may be desirable to be more specific. Normally non-exclusive, royalty-bearing licenses will be granted to the Members; under some circumstances, royalty-free licenses may be appropriate provided that the Members assist the Institute with the filing fees. Consortium members receive rights only to inventions made during their period of membership.

CONTRACT POLICY

The following sections discuss the policy considerations which determine the specific contract provisions appropriate to research agreements with industrial sponsors under varying conditions and options.

The contract provisions themselves are separately compiled in Part III with reference letters and numbers which correspond to the sections of Part II in which they are discussed. For example, the three patent provisions discussed in Section 1.4. of this Part II are identified in Part III as clauses 1.4.1., 1.4.2., and 1.4.3.

A. PARTIES TO THE AGREEMENT AND RECITALS

1. Parties

All MIT contracts with industrial sponsors begin by identifying the parties to the agreement by their entire legal names, as in Clause A.1.1. MIT is identified as the Massachusetts Institute of Technology for this purpose, but may be referred to thereafter for convenience as the "Institute", as "MIT", or as "Contractor" in the various clauses. Sponsors are identified by their correct legal names in the same manner, but are frequently referred to thereafter as "Sponsor" or by an abbreviated corporate name or initials. In some cases it may be important to specify whether the "Sponsor" refers only to the parent corporation or to subsidiaries and affiliates, however these may be defined, and this may be done in this section or in the definitions or other clauses in the agreement. This may be particularly important where the sponsor acquires certain patent rights.

2. Recitals

The Whereas clauses (recitals) are helpful in defining the general nature of the relationship between the parties and the purposes of each in entering the agreement. MIT's standard recital refers to the mutuality of interest between the sponsor and MIT and the Institute's purpose of furthering its instructional and research objectives in a manner consistent with its charter and its tax-exempt, non-profit status. See Clause A.2.1.

A wide variety of recitals may be used in order to reflect the nature and purposes of different types of agreements. A few sample recitals are set forth in the A.2. series of clauses.

B. THE RESEARCH EFFORT

1. Project Selection

Sponsored research projects are established on the basis set forth in Part I, i.e., proposals are initiated by MIT faculty and eligible research staff, approved under the Institute's internal review procedure, and submitted to a prospective sponsor for possible funding under a research grant or contract.

In some cases, however, the parties may agree on a broad field of research and negotiate an umbrella or institutional agreement covering research projects within that field to be established subsequently in the normal manner. Under some cooperative, long-term institutional, and consortium agreements, although the proposals are initiated and reviewed internally by MIT in the usual manner, they are submitted to a joint project committee for final selection. This approach is set forth in Clause B.1.1.

2. Statement of Work

The statement of work for each research project should be consistent with the approved research proposal and written in such a way that the general objectives of the research effort are clearly understood as well as the specific areas of investigation to be undertaken.

Where the Agreement covers unrestricted research under which patent and other property rights are not a factor, the statement of work is often quite brief and may simply consist of the title as set forth in Clause B.2.1.

Where, however, patent rights are involved, and the investigator or members of the research team work on other related projects, the statement of work may be crucial in terms of identifying any potential conflict in obligations and the rights of the parties. Therefore, an Appendix incorporating the proposal or other contract provision setting forth the statement of work is essential.

Under most agreements, the sponsor receives copies of all publications resulting from the research performed, as stated in Section H.1. If there are to be any other technical reports, such as an annual summary or final technical report, these must be specified in the Statement of Work, or added as an additional clause, such as B.2.2.

3. Conflicting Obligations

MIT does not knowingly enter research agreements which involve commitments and obligations which are in conflict with those accepted under other agreements. Consequently, as noted above, a properly detailed statement of work is necessary to ensure that the Institute's obligations under a research agreement are not in conflict with its obligations under other agreements supporting research by the same principal investigator and research team.

In cooperative, long-term institutional and other research agreements under which new projects may be selected from time to time, a procedural mechanism for dealing with actual or potential conflict in obligations is sometimes included in the contract. A sample clause is set forth as Clause B.3.1. It provides that MIT will review the participation of the principal investigator and other members of the research team on other related research projects to determine if conflicts may arise with respect to patent rights and, if so, will discuss with the sponsor appropriate steps to resolve them. MIT cannot, however, accept blanket provisions which

preclude the principal investigator from performing research for other sponsors in related areas.

4. Best Efforts

The Institute agrees to use its best efforts (1) to accomplish the research or studies described in the statement of work and (2) to do so within the total estimated cost and within the stated period of performance. It is understood, however, that if funds are exhausted before the project is completed, the principal investigator will, at the option of the sponsor, either submit a report on what has been accomplished to date, or will provide an estimate of further funds required to complete the work and will continue if such funds are provided by the Sponsor. If it is for any reason desirable to state this in the contract, the foregoing statement may be set forth in an additional clause, as in B.4.1.

C. RESPONSIBILITY FOR PROJECT SUPERVISION

1. Independent Contractor

MIT does not accept technical direction or joint supervision over the actual conduct of the research. The Institute conducts sponsored research as an independent contractor and not as an agent of the sponsor, a joint venturer, or as a partner as those terms may be defined for legal purposes. As noted in B. above, the sponsor may under some agreements participate in project selection. Once the project has been established, however, MIT alone is responsible for the actual conduct of the research and for the results, as stated in Clause C.1.1.

2. Principal Investigator

The Institute requires that a member of the MIT faculty or eligible research staff be designated as the principal investigator for each research project and that responsbility for directing the research reside with that individual. Clause C.2.1., or its equivalent, must be included in every agreement.

D. PERIOD OF PERFORMANCE AND TERMINATION

1. Period of Performance

The period of performance stated in each agreement is based on the principal investigator's best estimate of the time required to carry out the research project. As noted under the Statement of Work, MIT uses its best efforts to complete the work within the funds provided. A clause defining that period, such as Clause D.1.1. must be included in each agreement.

2. Termination

If the sponsor is not satisfied with the progress of the research, or for any other reason wishes to discontinue it, the sponsor may terminate the project at its convenience by giving sixty days prior written notice as set forth in Clause D.2.1. As set forth in the same clause, the Institute

reserves the right of termination if conditions beyond its control preclude the continuation of the program.

Upon receipt of notice, the Institute shall proceed in an orderly fashion to terminate any outstanding commitments and to phase-down the work. All costs associated with termination shall be reimbursable, including costs incurred prior to the receipt of notice of termination but which have not yet been reimbursed, and commitments existing at the time notice of termination is received which cannot be cancelled.

In the event of termination, the Institute shall provide the sponsor with a final report within ninety days after the effective date of termination of all costs incurred and all funds received. The report shall be accompanied by a check in the amount of any excess of funds advanced over costs incurred, or by a final invoice for amounts due.

The Institute will also provide the sponsor with a report summarizing the research results through the date of termination.

A clause which sets forth the termination procedure in more detail, such as D.2.2. may be substituted for the shorter D.2.1.

E. COSTS AND PAYMENT

1. Reimbursement of costs

All agreements must provide that the sponsor will reimburse MIT for the direct costs of performing the research as well as an allocable share of indirect costs, as set forth in Clause E.1.1.

The estimated direct cost of the Institute's research projects consists of the salaries and wages of project personnel, including associated employee benefits, and equipment, materials and services, travel and any other direct costs necessary for performance of the project.

In addition to the foregoing direct costs, the project costs include an allocable share of the Institute's indirect costs. Institute indirect costs cover maintenance of the physical plant and facilities, the libraries, the general and administrative services and other Institute support services.

Clause E.1.2. is added where it is desirable to spell out in more detail than in E.1.1. the composition of direct and indirect costs.

2. Budget flexibility

In performing the research, the Institute agrees not to exceed the total estimated cost unless it is increased by written authorization from the Sponsor. However, within that total cost, the costs accumulated under each of the various budget categories may change in order to adapt to the needs of the project as the research progresses. To maintain the needed flexibility, the Institute must reserve the right to shift funds between

budget categories at the discretion of the principal investigator. Where desirable to emphasize this, Clause E.2.1. may be used.

3. Payment

Interest costs incurred by the Institute in order to finance work-in-process are not included in the direct or indirect costs of its research program. The magnitude of the Institute's research program makes it impossible for the Institute to provide the working capital necessary to support the research from the time costs are actually incurred until invoices are submitted to sponsors and payment received. In addition, it would be an inappropriate diversion of the Institute's tuition and endowment income if they were used to finance the research program. Therefore, research agreements must provide funding in advance adequate to cover work-in-process as set forth in E.3.1.

4. Fiscal Reports

A final financial accounting of all costs incurred and all funds received by the Institute together with a check for the amount of the unexpended balance, if any, will be submitted to the Sponsor within ninety days after the completion of the project. Clause E.4.1. may be inserted if it is desirable.

In the event the sponsor wishes to receive interim reports of expenditures to support the funds advanced, monthly reports may be submitted to the Sponsor in the same format and with the same amount of detail as is provided by the Institute to the federal government. Because of the volume of research expenses which the Institute's accounting office must process, it is impossible to provide sponsors with copies of original receipts, vouchers and other source documents relating to the costs.

5. Financial Records and Audit

Financial records are maintained in accordance with generally accepted accounting practices and are available at the accounting office for inspection and audit by the sponsor for one year following completion of the project. If desirable to state this, Clause E.5.1. may be used.

F. FINANCIAL PENALTIES AND LIABILITIES

Unlike private research and consulting firms and commercial organizations, the Institute receives no fee or profit from its research with which to cover business risks, including financial loss or damages. Similarly, the Institute should not divert income provided for academic purposes in order to underwrite financial losses incurred in conducting the research program.

1. Financial Penalties

For these reasons, and because it would be inconsistent with a best efforts contract, MIT cannot accept contract provisions which establish firm deadlines, impose penalties for failure to make progress, or provide for withholding of payment if the sponsor is not satisfied with the results. The sponsor may, of course, terminate the program as described

below if dissatisfied with the progress of the research, or for any other reason.

2. Liability

Since MIT research contracts and agreements are written on a cost-reimbursement, best-efforts basis, they also require an understanding by the sponsor that MIT will not be held liable for loss or damage suffered by the sponsor as a consequence of acting on the research results.

G. USE OF THE INSTITUTE/SPONSOR NAME

Neither party may use the name of the other in news releases, publicity, advertising, or product promotion without the prior written approval of that party as stated in Clause G.1.1.

Advertising and news releases proposed by the sponsor are reviewed by the MIT News Office in conjunction with the MIT principal investigator. The News Office reviews the format and copy of advertising and the text of news releases primarily for factual accuracy and the appropriate characterization of MIT's role.

It has proven difficult to define in advance the kind of statements which MIT would find acceptable since such statements must be looked at in the total context of the particular news release.

H. PUBLICATION AND DISSEMINATION

1. Publication

The Institute's research activities are conducted as an integral part of the educational program and are intended to contribute to the advancement of knowledge. Much of it forms the basis for articles in professional journals, seminar reports, and presentations at professional society meetings. In addition, thesis and dissertation work performed by graduate students on research projects must be publishable if they are to receive degree credit.

The Institute cannot, therefore, undertake research or studies the result of which cannot be published without the Sponsor's prior approval.

Similarly, such publications, reports and theses reflect the professional judgment and the conclusions reached by the MIT principal investigator and research team, and the sponsor may not require that they be modified. Each agreement, therefore, must provide that MIT will be free to publish the results of the research. Under most agreements the only requirement is that the sponsor be provided with a copy prior to the date of publication, as set forth in clause H.1.1.

In addition, MIT insists on the right to publish significant results at any time during the course of the research. Any agreement to delay publication to the end of a contract must be approved in advance on an exceptional basis by the Office of the Provost.

2. Review for Patent Purposes

Under most research agreements, as described in Section I, which follows, the Institute reserves the sole right to determine the disposition of rights in inventions, including whether and in what countries to file patent applications. The sponsor, therefore, acquires rights, such as exclusive or non-exclusive licenses, only when MIT does in fact file for patents.

Under some agreements, however, the sponsor may make filing recommendations or obtain rights in inventions which MIT might not otherwise pursue, or in countries in which MIT might not otherwise file. Under these circumstances, the sponsor needs an opportunity to review potentially patentable inventions before patent rights are defeated by publication.

The normal means of doing this is to establish a procedure for identifying and disclosing inventions to the sponsor as they arise, or at periodic intervals, during the course of the research. This is the most effective method of protecting patent rights without any delay in publications. A clause describing such a procedure is set forth as I.5.1. under Patents.

In some cases, however, the sponsor is also given an opportunity to review manuscripts prior to publication in order to identify and take action on inventions which may not previously have been disclosed. Since the publication is usually submitted to the sponsor no later than its submission to the publisher there is normally ample time for such a review. Where this is not the case, however, the sponsor may be given an opportunity to review the manuscript for a period of up to 30 days prior to submission to the publisher. In the event that previously undisclosed and potentially patentable inventions are identified, the parties may agree to an extension of up to 60 days if necessary in order to take appropriate steps to preserve patent rights. This may, for example, be appropriate under consortia arrangements when more time is required to coordinate filing recommendations. In no event, however, may the total delay in submitting material for publication (1) exceed 90 days without the approval of the Provost's Office, or (2) delay the granting of academic credit to a student thesis. An appropriate clause is set forth in H.3.1.

3. Review for Sponsor Proprietary Data

A small number of research agreements which involve access to the sponsor's proprietary data (as discussed in H.5.c.) below, include the "Sponsor Proprietary Data" clause (H.5.3.).

In such agreements, MIT will agree to provide the sponsor with advance copies, normally up to 30 days prior to submission for publication, to permit the sponsor to identify any inadvertent disclosure of proprietary data and to request its deletion. The appropriate clause is H.4.1.

4. Confidentiality

MIT does not generate proprietary research results or maintain the confidentiality of research results. The following comments, however, are applicable:

a. Sponsor identity

MIT cannot accept research agreements which provide that the identity of the sponsor or the nature of the research must be kept confidential. The contract may, however, provide that acknowledgement of sponsorship be omitted from the publication itself as in Clause H.5.1.

b. Contract documents

MIT reserves the right to publish research agreements or summaries of their essential provisions, but does not normally publish financial details such as royalty rates, as set forth in Clause H.5.2.

c. Sponsor Proprietary Data

Although the Institute cannot generate proprietary research results, there are situations in which more meaningful, publishable research can be performed if the principal investigator has access to the sponsor's proprietary data.

In such cases, the contract may include a clause which defines the conditions under which such data will be accepted and states that MIT will use reasonable efforts to protect such data, but cannot accept liability for its inadvertent disclosure. The standard clause for protection of the sponsor's proprietary data is H.5.3.

I. PATENTS

Introduction: The Institute retains title to inventions resulting from sponsored research and licenses them in the public interest under an active patent management program in which licensing of industrial research sponsors is an important part. The Institute's licensing program includes a wide range of options, depending on the circumstances. The normal mechanism for the transfer of technology is a non-exclusive license. Where required for the effective development of innovations and inventions to the point of commercial availability, however, exclusive licenses for a limited term may be negotiated.

The MIT Policy of Retaining Title

MIT retains title to inventions resulting from sponsored research for the following reasons:

a. Achieving MIT's Patent Objectives

MIT believes that it can most effectively achieve the following objectives of Institute patent policy by retaining title to inventions resulting from MIT research, whether publicly or privately sponsored:

i. The Institute believes that a university by its nature has an obligation to serve the public interest by ensuring that inventions arising from university research are developed to the point of maximum utilization and availability to the public and will not be used to the detriment of the public interest by the unnecessary exclusion of any qualified user or by any other means.

ii. MIT policy is designed to give adequate recognition and incentive to inventors, by sharing the proceeds of royalty bearing licenses in view of their inventorship and as an incentive to spend the time and effort necessary to properly disclose the invention, participate in its evaluation, assist attorneys involved in filing patent applications, and advise potential or actual licensees.

iii. It is both appropriate and desirable that MIT share in the proceeds of any invention not only to help pay the costs of the patent program, but also to support selected MIT education and research programs in recognition of the Institute's investment in facilities and personnel without which such inventions would not have been possible.

b. Compatibility with Federal Policy

Roughly 80% of MIT sponsored research is funded by the Federal government. Inventions which are conceived in the performance of research sponsored by the Federal government are subject to Public Law 96-517, "The Patent and Trademark Amendments of 1980". Under that act, universities may elect to retain title to such inventions, subject to Federal march-in rights if they fail to pursue their commercialization in the public interest.

Since research sponsored by industry often results in the reduction to practice of inventions conceived under Federal sponsorship, providing title to industrial sponsors would create conflicts which can be avoided by MIT retaining title to all inventions regardless of sponsorship. A total separation of industrially supported research from Federally sponsored projects would minimize this problem but is neither feasible not desirable in the MIT environment. Close interaction actually offers broader opportunities for the development and licensing by industry of inventions conceived under Federal sponsorship.

c. Determining Equities

The mode of MIT research (i.e., multiple sponsorship, including Federal core support of major laboratories and programs, with both basic and applications oriented research support from industrial sponsors) makes the sorting out of patent rights particularly difficult where ownership and title are at issue. This is compounded by the fact that patent law is often vague as to what constitutes an invention resulting from the performance of a research project. It is MIT's experience that such conflicts can be minimized and the equities of the parties more effectively recognized through licensing mechanisms.

d. Licensing by Field

By retaining title, MIT can grant a license in the field of the sponsor's interest and pursue with other licensees those applications of no interest to the sponsor which might not otherwise be developed to the point of commercial availability.

e. MIT Patent Position

In areas in which MIT has a patent position and license program, retaining title to related inventions protects MIT's position and the public interest.

Licensing of Patents to Industrial Sponsors

1. The MIT Licensing Program

Although MIT conducts an active patent program and believes in the importance of patents in the effective transfer of technology, there are financial constraints on the number of patents which MIT can pursue and the number of countries in which it can file. Under most patent clauses, therefore, including those cited in the sections which follow, the Institute reserves the sole right to determine which patents it will pursue and in what countries.

Nonetheless, where the sponsor wishes to pursue patents on a broader basis, appropriate arrangements can usually be made, including the sharing of costs. Since the pursuit of patents is not the primary purpose of MIT research programs, however, this can be done only when compatible with the effective conduct of the research and the achievement of its educational objectives.

When MIT does file for and acquire patent rights, the licensing options available to industrial research sponsors are those summarized in the following sections.

2. When the Sponsor seeks no patent rights

In a number of agreements, the sponsors do not wish to acquire patent rights and their disposition is therefore left to MIT. In such cases, the clause set forth in 1.2.1. is used.

3. Non-exclusive licensing to the Sponsor

The majority of industrial sponsors support MIT research projects under agreements which include one of the following provisions:

a. Non-exclusive license (royalty-free)

The right most frequently granted to industrial research sponsors is an irrevocable, royalty-free, non-exclusive license to those inventions, conceived or reduced to practice in the performance of the research, on which patents issue. The appropriate clause is set forth as 1.3.1.

b. Non-exclusive licenses (royalty-bearing)

In special cases, primarily involving situations where the sponsor is dominant in the field, or is an association representing a group of companies dominant in the field, MIT may wish to negotiate royalty-bearing, nonexclusive licenses. See Clause 1.3.2.

Such licenses may also be royalty bearing in cases where the sponsor may request the pursuit by MIT of patents on which MIT might not otherwise file. This is more common under consortium agreements. See Clause 1.3.3.

4. Exclusive royalty bearing license to the Sponsor

Exclusive limited-term licenses are granted when necessary to the effective development of promising ideas and are considered by MIT to be an appropriate vehicle for the transfer of technology in the public interest. They may be negotiated, however, only after the research project has been defined and the related research and other commitments of the investigator and co-investigators reviewed for potential conflicts. Exclusive rights cannot, therefore, be granted on a blanket basis under long-term institutional agreements and other arrangements where individual projects are not identified at the outset.

Where a research sponsor is dominant in the field in which patentable inventions may arise, however, the granting of even a limited-term exclusive license may present problems which preclude it or require special provisions.

a. Exclusive rights at the outset or by option

There are two basic alternatives available depending on whether the right to exclusivity is given at the outset or whether the sponsor is given an option of acquiring an exclusive license within a stated number of months after the invention is disclosed.

Exclusivity at the outset is provided under Clause 1.4.1., and an option of acquiring an exclusive license is provided under Clause 1.4.2. Both clauses provide that title to inventions made or conceived in the performance of the research remain with the Institute and provide the sponsor, in any event, with an irrevocable, royalty-free non-exclusive license for the use of the invention (which includes the right to make, use and sell) for the full term of the patent.

b. Length of exclusivity and royalty rate

The foregoing two basic clauses refer to the negotiation of the length of exclusivity and the royalty rate after the invention, if any, is actually made. The rationale for this approach is that only after the making of the invention can its value and potential market be ascertained.

If there are compelling reasons, however, for specifying these in advance, the minimum length of exclusivity and the maximum royalty rate can usually be agreed and specified in either of the basic exclusivity clauses set forth above. In that case, the clause set forth in 1.4.3. may be used.

It is not uncommon for the period of exclusivity to be five to eight years from the date of execution of the license agreement or three to five years from the date of the first commercial sale, whichever occurs first. In addition, exclusivity can normally be extended by the length of time required for premarket clearance by the FDA and other regulatory agencies.

c. Sublicensing and performance criteria

An exclusive license gives the licensee the right to sublicense others at reasonable royalty rates. Sublicensing is not usually mandatory under limited-term exclusive licenses since MIT will thereafter have an opportunity to make the license available to others in the industry. It is MIT's policy, however, under limited-term, exclusive licenses to require (1) performance milestones and/or minimum annual payments as incentives for the licensee to develop the technology and ensure that it becomes available for the benefit of the public, or (2) other forms of assurance that the commercialization will be diligently pursued.

The initial period of exclusivity can be extended only under exceptional circumstances and with contractual assurances that licensing will be pursued as diligently as it would be by MIT, since the licensee would, in effect, be acting as the Institute's agent for the transfer of the technology. These contractual assurances would normally include mandatory sublicensing, performance milestones, arbitration procedures, etc.

d. Field of Use

Where appropriate, the license may be restricted to a particular field of use so that the Institute can license other fields in order to fully develop all the applications of the patent.

f. Other license terms and conditions

In addition to terms as to the length and terms of exclusivity, royalties, and due diligence or performance requirements, MIT licensing agreements contain provisions relating to sublicenses, reports and records, termination, arbitration, infringement, assignment, etc. A sponsor may wish to review a sample licensing agreement before entering the research agreement. It should be understood, however, that the terms and conditions of that licensing agreement, although standard in the majority of licenses, are subject to modification based on the specific nature of the invention and a variety of other factors which become know only at the time the license is negotiated.

5. When MIT elects not to file

Under some agreements, the sponsor may negotiate to acquire rights in inventions which MIT might not otherwise pursue, or in countries in which MIT does not choose to file.

In order for the sponsor to exercise such rights, procedures must be established so that the sponsor can review inventions and take steps to preserve patent rights before they are defeated by publication. This is normally done by prompt disclosure during the life of the project, or at

regular intervals, thereby minimizing any delay in publications. A clause to this effect is set forth at I.5.1. (A clause allowing the sponsor to review publications prior to submission may be used also, as described in H.3.1.)

In addition, a procedure must also be established so that the sponsor and MIT can agree on what filing will be done and by whom. Clause I.5.2., for example, provides that the invention will be disclosed promptly by MIT and that the sponsor will within a stated time period provide MIT with its non-binding filing recommendations. MIT will then make its decision and promptly notify sponsor whether and in what countries it intends to file. Where MIT elects not to proceed, the sponsor may then file in MIT's name but at its own expense and acquire a limited-term exclusive license at reduced royalty rates.

J. COPYRIGHTS

Introduction: MIT retains the ownership of, and copyright in, all copyrightable materials first produced or composed in the performance of MIT research agreements, except that a sponsor is normally entitled to ownership of the physical embodiments of all such materials which are stipulated in the contract as deliverables. The sponsor is also normally entitled to a copyright license in all such materials, as defined below.

MIT believes that by retaining such ownership it can most effectively achieve the objectives of its copyright policy which, in most respects, parallel the objectives of its patent policy as more fully outlined in Section I of this guide. These objectives include protecting the public interest, providing recognition to authors and their depatment and/or laboratory, and supporting MIT's education and research programs with royalty income. Further, retention of copyright ownership by MIT will help to minimize conflicts arising from prior or concurrent federal sponsorship.

In addition, MIT believes that the retention of copyright ownership will insure that the integrity of an author's work is protected in a way that will be of maximum benefit to the author, MIT, and the public at large.

Licensing of Copyrightable Materials to Industrial Sponsors

a. The right most frequently granted to industrial research sponsors is an irrevocable, royalty-free, non-exclusive license to all copyrightable materials (except copyrightable software, copyrightable genetic material, and supporting documentation), such right to include use, reproduction, translation, and the right to prepare derivative works.

b. The right most frequently granted to industrial research sponsors to copyrightable software, genetic material, and supporting documentation is an irrevocable, royalty-free, non-exclusive right to use, reproduce, translate and prepare derivative works of such copyrightable material for the sponsor's own internal use and for the use of its subsidiaries. Industrial sponsors, on request, may also receive a royalty-bearing, non-exclusive license, such license to enable the sponsor to distribute such copyrightable material and derivativeworks commercially, and to sublicense others, at reasonable royalty rates and on other terms and conditions to be negotiated.

c. In exceptional circumstances, industrial sponsors may negotiate a royalty-bearing, exclusive license to copyrightable software, genetic material, and supporting documentation.

K. MISCELLANEOUS PROVISIONS

MIT research agreements may also contain other clauses relating to the interpretation of the contract provisions, resolution of disputes, communication between the parties, and other contract matters, as follows:

K.1. Notices
K.2. Assignment
K.3. Governing Law
K.4. Governing Language
K.5. Force Majeure
K.6. Arbitration
K.7. Entire Agreement