Unit 20

TITLE: COMMERCIALIZATION STRATEGY WORKSHOP

PURPOSE: This unit presents a methodology for conducting a workshop in developing a commercialization strategy for a technology that is licensed to a firm.

OBJECTIVES: Upon completion of this unit, participants will:

- Have become more sensitized to the dynamics of developing a commercialization strategy
- Have addressed key concepts as they apply to management and decision-making approaches to a specific technology transfer opportunity
- Have identified laboratory or agency obstacles to transfer and opportunities for transfer activities
- Have participated in a practice marketing and license negotiation exercise.

NOTES TO WORKSHOP LEADER:

1. It is recommended that the workshop leader select a technology the laboratory has licensed or attempted to license as the subject of the workshop. Rather than using a prepared case study, this approach offers the advantage of familiarity with a technology that is relevant to laboratory research efforts. The course of events is known in detail, and the people who were involved may be available to participate.

2. The workshop format is relatively unstructured, focusing on the steps that need to be accomplished in developing a commercialization strategy and subsequently licensing a laboratory technology. The specific outcome is not as important as creating an awareness for the general procedures that must be accomplished. The workshop participants may make decisions that lead to a negative result (i.e., the technology is not licensed), or one that is different from the actual outcome. There is no right or wrong outcome. The participants benefit from the exercise by realizing that many outcomes are possible and that the outcome can be influenced by the pesonalities involved as well as laboratory policies.

3. The workshop uses role playing as the technique for working through the activities in developing the strategy and engaging in licensing negotiations. The workshop leader may elect to organize a group of knowledgeable individuals who will each play a defined role. The workshop attendees in this case will simply observe the process, make comments, and ask questions. The advantage of this approach is that the process can be presented efficiently within a specified time period. It requires prior coordination of the role players.

4. Another approach that was used in an experimental workshop conducted as part of the presentation of these instructional materials to Federal laboratory transfer personnel involves minimal role assignments. In this presentation, the workshop leader served as the moderator and as the inventor. The workshop participants played the other roles as a group or as individuals. Consequently, participants were free to select different roles in the various stages of the workshop. This approach is much more open-ended and allows the participants to raise and discuss issues and concerns that otherwise would not be revealed. The disadvantage is that the participants may not be knowledgeable about certain areas (e.g., patenting). This approach requires that the workshop leader have all of the necessary information, since it may be necessary to assume any of the roles on a temporary basis.

5. As an example of what might be expected to emerge from this workshop, a description of the workshop that was conducted during the prepration of these materials is presented. The instructions for each of the steps in the process are included, as well as excerpts from the proceedings.

Unit 20

COMMERCIALIZATION STRAGECY WORKSHOP

INTRODUCTION

A commercialization strategy developed by a laboratory serves as a plan of action for transferring a Federal technology to a private sector firm. This workshop is an educational exercise. Role playing is used to sensitize participants to the process of developing a commercialization strategy leading to a license, rather than providing specific skills training. The workshop also provides a method for identifying issues, impediments, and transfer opportunities within the context of each laboratory's particular procedures, regulations, and guidelines.

It should be noted that the focus on licensing is not intended to imply that this is the only effective transfer mechanism. Joint or cooperative agreements with the private sector are extremely important. However, licensing is a major transfer mechanism. A workshop approach for this subject provides an effective means of applying key instructional concepts, while allowing participants to explore issues and opportunities associated with licensing Federal lab technology within a realistic context.

Although excerpts of a workshop conducted with Federal laboratory transfer personnel are included in this unit, it is recommended that the workshop leader use an example of a technology that has some relevance to the operations of the individual laboratory. A Federal technology that has been licensed is ideal. Case study materials will need to be prepared, and a successful or unsuccessful example from the laboratory (or a similar laboratory) will be consistent with the culture, mission, and operations of the laboratory, as well as requiring less preparatory time by the workshop leader.

The case study approach is modified in the workshop and requires that the workshop leader (or moderator):

1. Feed necessary information into the process at appropriate points;

2. Guide the flow of the discussion to ensure that appropriate directions are being identified and pursued; and

3. Frame the issues and decisions to advance the overall workshop objectives.

ROLES AND RESPONSIBILITIES

The success of this type of workshop is heavily dependent on the performance of the workshop leader. Although this effort can be conducted by one person, it is recommended that the moderator have an assistant to present and discuss marketing information at the appropriate points as the workshop progresses. As a starting point, the moderator must be intimately familiar with all details of the case study, although he may not need to present all of this information. If the moderator does not have a working knowledge of licensing as a transfer mechanism, it is recommended that he be assisted by someone who does. Finally, the moderator must be able to guide the workshop while remaining flexible about how it gets there.

Moderator

It is the moderator's responsibility to guide the workshop towards its objective. The objective is to develop a commercialization strategy for licensing a Federal technology. The license may be exclusive or nonexclusive; it may be for a single application, multiple applications, or all applications of the technology. Although the preference is for a successful negotiation, the negotiation may or may not be successful, depending on the decisions the group makes as the workshop progresses. The outcome of the workshop may bear no relationship to the outcome of the case study on which the workshop is based.

It is the moderator's responsibility to guide the discussion through the activities needed to develop a commercialization strategy and to raise important issues that may be overlooked, while allowing the workshop to chart its own course.

Inventor

The inventor must be prepared to explain the technical aspects of the invention, the manner in which the invention was developed, and the

details associated with the circumstances surrounding the invention's conception. The inventor should also have some ideas regarding possible applications of the technology. This role is crucial because in addition to specifying the technology, and thus at least broadly determining the transfer opportunity, through the description of the technology, the inventor also creates a number of issues that must be resolved by the group in the course of discussion.

Legal Counsel

Parts of the workshop require counsel from an intellectual property attorney. If an attorney or licensing manager is not available (i.e., as an assistant or as a workshop participant), the moderator will need to seek the proper information prior to the workshop and be prepared to discuss these issues. This will most often be the case when an intellectual property attorney is not included among the workshop participants. A properly developed case study should contain enough detail on intellectual property aspects of the transfer process to resolve most issues that will surface during the workshop discussion.

Assistant to the Moderator

It is recommended that an assistant play the role of the marketing person. This individual is the source of information regarding potential markets for various applications of the subject technology. Although the marketing person can and should offer recommendations, he has no decision-making power. Like the moderator, he should also be intimately familiar with the underlying case study materials.

Workshop Participants

Workshop participants use the information supplied to them by the moderator, the inventor, the marketing person, and the legal counsel to carry the discussion, raise and resolve issues, develop the strategy, and perform the negotiation. Each participant has the flexibility to play a number of roles at any point in the proceedings. Possible roles should include that of a technology manager, a representative of an interested private sector company (or licensee), a laboratory director, a research program manager, and an agency official. The moderator may

choose to increase the number of possible roles, but this quickly becomes unwieldy. As a practical matter, since it is the technology manager's basic responsibility to facilitate a successful transfer, most participants spend the majority (but certainly not all) of their time in the technology manager role.

Rules and Guidelines

Since the workshop is relatively unstructured, there are only a few rules or guidelines:

1. Each participant should always identify what role he is playing before speaking.

2. The moderator must be prepared to exercise some degree of resolution-oriented control over the proceedings in order to keep the workshop moving toward the objective.

3. The moderator has the power to resolve any stalemate, in the event one should occur.

4. The moderator has the power to assign a specific role to a participant at any point in the discussion. For instance, since it is important that participants gain a sensitivity to private sector business motivations and behavior, the moderator at some point may need to assign a private sector role to some of the participants if there are no volunteers.

FORMAT AND STRUCTURE

The workshop is conducted according to the following format:

1. Introduction by the moderator
2. Identify the technology
3. Assess the technology's stage of development
4. Identify possible applications for the technology
5. Estimate the technology's commercial potential
6. Develop the commercialization strategy
7. Determine the value and price the technology
8. Choose company(ies) to approach
9. Negotiate with the company
10. Disclose the outcome of the case study on which the workshop was based (optional)

Steps 2 through 5 are required in developing any commercialization strategy. Steps 7 through 9 are particularly applicable if licensing

is the selected method for commercialization. Consequently, the workshop leader may prefer to conduct the exercise in separate sessions. The first session would end with Step 6 (develop the commercialization strategy). The second session would then focus on pricing, marketing, and negotiating the license.

It should be emphasized that the workshop discussion should by no means be limited to these subjects. Many other issues can and should be raised during the course of the workshop discussion, particularly issues related to laboratory and program management (e.g., procedures, reporting, conflicts of commitment, proper role of the technology manager). In many instances, some of the activities involved in developing a commercialization strategy cannot be accomplished until these issues are resolved.

(1) Introduction by the Moderator

The moderator's introductory remarks should include:

- Introduction of all workshop participants
- Description of objectives, rules, operation, and duration of the workshop
- Brief presentation of the workshop format
- Distribution of workshop materials, such as appropriate case study information (e.g. technical descriptions or diagrams, marketing data).

(2) Identify the Technology

The workshop leader explains that the objective of this portion of the workshop is to identify the technology and the circumstances under which it was developed. It is also important to limit disclosure in order to preserve the lab's ability to protect the invention should protection prove to be an essential element in the commercialization strategy. When licensing of a Federal laboratory technology is the goal, such protection will often take the form of a patent.

The workshop leader may assume the role of the inventor (which was the case in the workshop conducted with Federal transfer personnel). The participants as a group begin as the technology manager. The

technology managers should at a minimum obtain the following information from the inventor:

1. A detailed description of the technology, its function, and some possible applications

2. From the inventor's perspective, other substitutes or competing technologies

3. From the inventor's perspective, special advantages associated with his technology compared to other substitutes or competitors

4. In what research program or project was the inventor working as he began to develop the technology

5. Where and when did the idea for this technology occur to the inventor

6. Other participants in the development of the technology and their location

7. Where was the technology actually developed

8. What information the inventor has disclosed about the technology and to whom.

If some of these questions are not asked, the workshop leader (in his role as moderator) should prompt the participants to ask the questions. Other questions should be encouraged, especially those related to laboratory procedures, reporting, approval, and possible conflicts.

During this discussion, the technology manager or legal counsel should explain to the inventor the fundamentals of intellectual property protection and relevant details concerning patenting and disclosure issues (especially as they relate to the inventor's possible interest in publishing information concerning the technology).

(3) Assess the Technology's Stage of Development

This discussion should occur during the initial technology identification meeting between the technology manager and the inventor. The moderator explains that the purpose of this step is to discover the development status of the technology. From the laboratory perspective, this will be critical information in determining the commercialization strategy.

Since the workshop leader (in his role as inventor) has the answers to the questions that should be asked during this session, he has the capacity to guide the discussion towards these questions or to volunteer the answers should the workshop discussion not move in these directions on its own accord.

At a minimum, the technology manager should obtain the following information from the inventor:

1. How "developed" is the technology? For example, has it reached the prototype stage? Is the equipment used to create the technology readily available or was it created to develop the technology?

2. From the inventor's perspective, is further development needed before the technology is suitable for transfer? If so, how much? What are the additional time and equipment requirements?

3. Has the technology been sufficiently tested? Does sufficient documentation exist (logs, design, protocol, and so on) concerning the development of the technology?

4. Potential licensees may want the inventor to adapt the technology to applications or manufacturing processes specifically for their company. Is the inventor willing to do this, and under what conditions?

(4) Identify Possible Applications for the Technology

This item should also be covered during the initial meeting between the technology manager and the inventor. Its purpose is to prompt the inventor to rigorously work through possible commercial applications of the technology. Although the inventor's perspective on applications is obviously very important to the development of the commercialization strategy, other viewpoints from individuals with wide-ranging knowledge of markets and industries are extremely valuable and should be aggressively solicited before proceeding to the next step.

The technology manager should concentrate on getting the inventor to describe all the basic applications that he has considered. The discussion should then focus on special advantages or unique characteristics of the technology and the possible application of these advantages in other specific commercial endeavors.

The workshop leader (if he has assumed the role of inventor) should already know the most promising commercial applications for the technology. More detailed market information from the case study for these applications will be discussed in the next step. The inventor should adequately describe the promising applications in his discussion as the foundation for proceeding to the next step.

(5) Estimate the Technology's Commercial Potential

The workshop leader (in his role as moderator) should explain that the problem for the technology manager is to determine whether this technology has sufficient commercialization potential to justify further action. In order to do this, the technology manager has asked a qualified individual to gather and analyze some preliminary information describing the markets for the potential applications of the technology. This individual might be a staff member, a graduate student, or a professional marketing consultant. The workshop leader's assistant can play the role of the marketing person, if one is not available.

The assumption is then made that some period of time has passed and the preliminary marketing information has been collected and organized. As explained by the moderator, a meeting has been called by the technology manager to determine:

1. If the technology has sufficient commercialization potential to warrant further action
2. Whether or not to protect the technology
3. If protection is needed to facilitate transfer, what form this protection should take.

Participants in this meeting will include the technology manager, the inventor, and the marketing person. Advice from an attorney representing the laboratory will be communicated to the group by the moderator if an attorney is not available to participate in the workshop. If a patent or licensing attorney is present at the workshop, the workshop leader might consider recruiting this individual and providing him with sufficient information to play this role in the workshop.

The moderator opens the meeting by explaining its objectives and introducing the marketing person. The marketing person then presents his basic findings on the apparent commercial potential of applications provided from the previous step. This should include a brief description of competing technologies, products, or processes and the way in which they are produced; the possible competitive advantages of the subject technology; and the size, makeup, and characteristics of potential markets. The marketing person should offer his recommendations concerning which markets, if any, should be seriously considered at this point.

Based on all the information presented up to this point, workshop participants should then present and discuss their views on the commercial potential of the technology, the likelihood of a successful transfer, additional problems and opportunities associated with the transfer of this technology as they relate to the management and mission of their laboratory, and whether or not additional action is warranted. It should be noted that workshop participants have the flexibility to assume roles other than that of the technology manager (such as laboratory director, program manager, and agency official) and may choose to do so during this discussion.

Finally, the moderator calls for a decision from the group on whether or not the technology shows sufficient potential to warrant the preparation of a commercialization strategy. The moderator should anticipate this decision based on the information contained in his case study. Assuming the answer is "yes," the marketing person is then instructed to collect additional information required for the development of the commercialization strategy.

The final decision to protect the invention and in what form should be made at this stage. The discussion of this information should be based on the information supplied by the lab's attorney, the market information, and the technical nature of the technology and its competitive advantages.

Another meeting is then scheduled during which the additional requested information will be presented and a commercialization strategy will be developed.

Examples of the types of marketing information required for this step and excerpts of this particular discussion from the previous workshop are included at the end of this unit.

(6) Develop the Commercialization Strategy

This step involves a general strategy discussion, a detailed presentation of marketing information, and development of a specific commercialization strategy. Although organizations or individuals who are experienced at developing transfer and commercialization strategies might in some instances elect to forego the initial general discussion, for the purposes of this workshop it is important to work through the issues raised in the discussion.

The moderator explains that the purpose of this meeting is to decide on strategies for transferring and commercializing the technology. Among the issues that should be considered and resolved during this meeting are:

1. A discussion of laboratory, agency, and government objectives in transferring this technology

2. Does the technology appear to have enough viable applications to serve as the basis of a new business startup

3. If so, are the various objectives better served by licensing to a business startup or an existing business

4. If it is decided to attempt to license to an existing business, is a small firm or large firm most likely to successfully commercialize the technology, and why.

After the issues have been discussed, the marketing person is asked to present the information that has been gathered and analyzed since the last meeting. This presentation should typically include the following types of information:

1. Definitions of industries, markets, and market segments for which the technology appears to have viable commercial applications

2. Data on relevant market size--units sold, dollars, geographic area, projections, and trends

3. General industry data--number and size of companies in industry, competitive situation, average earnings,

projections and trends, major innovations, barriers to entry and exit (including typical capital requirements)

4. Company data--company listings for each industry, product lines, competitive advantages (companies and products), market share and volume, earnings, plans, performance projections, leading innovators, and so on.

Based on the conclusions reached in the opening discussion, the market information and any apparent special (competitive) advantages associated with various applications of the lab's technology, workshop participants should now devise a specific commercialization strategy. Participants should make a final determination regarding licensing to an existing business or to a startup and then discuss and decide which market(s) to pursue, generally what types and sizes of companies to approach, the anticipated value of the technology to the commercial operations of these types of companies, and generally how best to promote possible competitive advantages of the technology and its applications to these types of companies.

Roles necessary for this step include the moderator, inventor, technology manager, lab attorney, and marketing person. The moderator should be prepared to provide counsel from the attorney, especially regarding the value and use of any possible patents to the commercialization strategy. The marketing person should also be prepared to offer appropriate recommendations. The workshop participants should play the role of the technology manager and the additional roles of lab management and agency representation if needed.

Assuming that licensing has been selected as the appropriate transfer mechanism, the next step is determining the value and pricing the technology.

(7) Determine the Value and Price the Technology

The next step is to determine the value of the technology to the laboratory and to the potential licensee and to arrive at an initial price for the technology. The moderator should guide the proceedings toward a discussion of the relationship between value and price.

Roles in this discussion should include the moderator, inventor, marketing person, and technology manager. Legal counsel, especially as it relates to pricing of patents or copyrights, may also be included

through the moderator or through participation of an intellectual property attorney. Workshop participants have the option of including other roles such as laboratory management or agency representation.

It is suggested that the moderator prompt discussion of the following issues:

1. Dimensions of price such as royalty (determined on what basis), territory, and exclusivity. Participants should add other elements of price and suggest quantities or boundaries of each element that will be considered to arrive at the final price.

2. What tradeoffs are possible should the acquirer seek a different price structure than the lab seeks?

3. What are the benefits derived by the laboratory from a successful transfer other than price? How do they relate to price? What is most important to the labs?

4. Should the target price be revised considering the discussion related to laboratory benefits?

This session should end with an agreement by the participants on the value of the technology from the laboratory's perspective and the potential buyer's perspective and a target price that they will seek from potential licensees.

(8) Choose Company(ies) to Approach

The objective of this session is for the participants to discuss and decide: (a) which company(s) to approach; (b) who should be approached within each company; (c) how to approach these individuals (e.g., phone, mail, personal contact); and (d) how to most effectively promote the value of the technology relative to the operations and plans of the specific company.

The participants should use the information provided by the marketing person, the commercialization strategy, and their assessment of appropriate value and price as the basis for their discussion and decision. If the participants focus on the selection of a single market or company, the moderator should urge consideration of multiple markets or companies if this appears to be appropriate for the technology and its applications.

Roles in this session should include the moderator, inventor, marketing person, and technology manager.

Once the objectives of this session have been met, the participants are ready for the final session in which the licensing negotiation takes place.

(9) Negotiate With the Company

The purpose of this final segment is to provide the participants an opportunity to work through a negotiating session with a potential licensee. Roles should include the moderator, inventor, technology manager, an attorney representing the laboratory/government, and at least one representative of the company. The workshop leader plays the roles of the moderator and the inventor. Adequate knowledge of the government technology transfer process, its relevant legislation, the instructional materials, and the case study details are necessary to assume the role of the laboratory/government attorney. Workshop participants should play the role of the technology manager, company representative (which may include an attorney), and other appropriate roles.

The moderator states that although a number of companies are interested in the technology and its applications, this is the first negotiating session. In view of all the work leading up to this session, it is assumed that the negotiating team will keep its asking price (including terms) in mind. Additionally, it is assumed that the negotiating team is familiar with the company's operations, products, underlying technologies, and present and anticipated market performance.

The workshop leader should also stress that the session is intentionally unstructured. Whether the negotiating session will be successfully or unsuccessfully concluded will be up to the participants.

At this point, if no one has volunteered, the workshop leader should assign at least one participant the responsibility of playing the role of the company representative. Company representatives will have the responsibility of negotiating in the company's best interest.

After stating this session's objectives and setting the stage for the negotiations, the workshop leader (as the moderator) should start the session by stating who makes the first offer--the laboratory/government or the company.

During the course of the negotiations, it is the moderator's responsibility to raise issues that are likely to be confronted during the negotiating session between a government laboratory and a company--exclusivity, components and terms of price, sublicensing, government use of the technology, geographic area, etc. It should be mentioned that the moderator is free to raise issues that did not surface in the original case study. Although the moderator should use his knowledge of details of the actual case study negotiations to raise important issues, he should not try to influence the outcome of the workshop negotiating session.

(10) Disclose the Actual Outcome

The workshop leader may conclude the workshop by revealing the outcome and any undisclosed but relevant details of the actual case study on which the workshop was based.

DESCRIPTION OF WORKSHOP PROCEEDINGS

For illustrative purposes, the remainder of this unit presents a description of the proceedings of an actual workshop that was held in conjunction with the preparation of these instructional materials and that was attended by Federal employees interested in or practicing technology transfer. The participants' roles have been "scripted" in order to give the reader a "flavor" for what occured during the workshop, and excerpts from actual workshop discussions have been included.

This role-playing session involved various "scenes," each demonstrating a step in the transfer process:

1. Introduction
2. Identify the technology
3. Assess the stage of development
4. Identify possible applications for the technology
5. Estimate the technology's commercial potential

6. Develop the commercialization strategy
7. Determine the value and price the technology
8. Choose company(ies) to approach
9. Negotiate with the company
10. Disclose the actual outcome.

The case that was discussed was an actual transfer from a nonprofit resarch company to a private firm of a process for making hollow fiber membranes. The participants were provided some initial information on the technology and the circumstances of transfer so that they would be in a better position to play various roles. Many participants played the role of technology manager, and their comments are sometimes in conflict.

(1) Introduction

Participants: Moderator

MODERATOR: Explains that the purpose of this workshop is to develop a commercialization strategy for a laboratory technology. The session will involve "role playing" by several key participants, including an inventor, a technology transfer manager, a marketing person (representing the laboratory), a patent/licensing attorney representing the laboratory, and a representative of the firm.

(2) Identify the Technology

Participants: Technology Manager
Inventor
Moderator

TECHNOLOGY MANAGER: Asks the inventor to describe the technology.

INVENTOR: Describes the technology to the technology manager.

The technology is a process for making hollow fiber membranes. Membranes are thin barriers that separate two fluids and allow selective transport of solutes from one fluid to the other. They can be made of many different materials, including organic polymers, metals, ceramics, and some liquids.

Membrane separation occurs by the establishment of a driving force, such as pressure, concentration, or electrical potential, across

the membrane to force some solutes, solvents, or gases to pass through it, while restricting the passage of other substances.

There are several different membrane configurations, including flat sheet, spiral wound, hollow fiber, and emulsion. Spiral wound and hollow fiber configurations can be coated with ultrathin coatings to change the properties of the membrane.

Membranes are used for producing sterile, particle-free water for pharmaceutical products and ultrapure fluids for use in semiconductor and electronics products. They have many applications in the biotechnology and biomedical fields, in the processing of food and beverages, and in many other industrial applications.

Hollow fiber membranes are tube-like membranes (which look like spaghetti) that are hollow in the middle. The walls are semipermeable. They can be used individually, or grouped into a bundle that contains thousands of the fibers.

Hollow fiber membranes have several properties that give them advantages over other configurations for many uses. They have higher productivity per unit volume than other types of membranes, they are capable of operating unsupported in pressure applications, and the cost of producing the membrane on a square foot basis is low (however, fouling and plugging by particulate matter may present problems). Hollow fiber membranes can be made from almost any spinnable material. They are commonly made from many different types of polymers.

TECHNOLOGY MANAGER: Asks the inventor what he was working on when he developed this process.

INVENTOR: Admits that he really did not have authorization to work on the process when he started; but he thought he could do it, and he thought this process would allow the development of membranes with certain properties that would have significant advantages over membranes currently in use. He felt these membranes would be of use to the government in many different fields. He also thought it would allow him to do research in an exciting and important field.

TECHNOLOGY MANAGER: Asks the inventor if he has published any articles or presented any papers about this technology.

INVENTOR: Responds that he has not yet published any articles or presented any papers on the technology, but he has nearly completed an article that he intends to submit to several trade journals.

TECHNOLOGY MANAGER: Explains to the inventor that he will be able to publish about the technology, but the laboratory may hold up publications until the technology can be protected, if the lab decides to protect the technology. If the inventor publishes information on the technology before a patent is filed in the United States, the lab has one year to file for a U.S. patent; however, foreign patent laws are different, and publishing will prevent the lab from patenting in most foreign countries. Even if the lab decides to file for foreign patent rights, he will probably be allowed to publish once a patent application is filed in the United States. A treaty known as the Paris Convention for the Protection of Industrial Property allows applicants who first file patent applications in one of the 93 member countries 12 months to file for patents in other member countries. During the 12-month period, the applicant may publish the invention without fear of losing patent rights in the member countries. Since the United States and most of the countries where the lab is likely to want patent protection have signed this treaty, the inventor will probably be able to publish after the U.S. application is filed without forfeiting the ability to file for the desired foreign patents.

The following is an excerpt from the workshop proceedings.

MODERATOR: For the first set of meetings, there will be two parties present, the technology transfer agent and the inventor. Those are the only two people in the room. There are no lawyers, there are no administrators, no lab directors, just the two of us. And for these first three meetings, I'll be the inventor and you will be the technology manager. As a group that's the way you should be thinking. If you decide to be someone else, let me know.

TECHNOLOGY MANAGER: Who called this meeting?

INVENTOR: This meeting was called because. . .I called your office and said I have invented something in my laboratory and I don't know what to do with it. We need to talk about it. I don't have any idea about the process, I don't know anything about technology transfer. I've just done this in my lab and I think it's interesting. I think it may have some potential to be developed.

TECHNOLOGY MANAGER: First of all, in terms of development, what is the mission reason for development?

INVENTOR: Well, I have to admit this doesn't have much to do with a mission. We've really been kind of moonlighting in the laboratory on this. You know, funding has been hard to come by. We've been encouraged to seek outside sources of funds to do things that might ultimately create cooperative arrangements, industrial funding, and so forth. We thought that this was an area that had some potential. A couple of us had industry experience and knew something about what was going on in the industry, so we decided to take some of our free time in the laboratory and work on this, and our bosses don't even know about it. We don't think they'd object to it, it's not anti-mission, it just doesn't have anything to do with what we do on a day-to-day basis.

VOICE: Are you sure it's new?

INVENTOR: Well, it's new in terms of the existing literature. We've done literature searches on it. Obviously we're not patent lawyers and we haven't gone into that arena. We don't know if someone else in industry has done it and hasn't written about it, but in terms of what we've been able to go to the library and read about in terms of our own knowledge, this is new.

TECHNOLOGY MANAGER: Are we publishing it?

INVENTOR: Well, we haven't published it yet. We'd really like to publish it, and, as a matter of fact, we have a draft paper that we've written. We've talked to some friends of ours in one of the professional journals and they're prepared to publish it. We haven't submitted it yet and it doesn't have a publication date, but we think we can get one as soon as we like one.

TECHNOLOGY MANAGER: Have you filed?

INVENTOR: Have we filed what?

TECHNOLOGY MANAGER: Have you filed a patent application?

INVENTOR: No, we've done nothing but pick up the phone and ask you where we go from here.

TECHNOLOGY MANAGER: How many "we" are there?

INVENTOR: There are two "we," and the other just submitted his resignation and will only be here for another two weeks.

TECHNOLOGY MANAGER: Can you take the next half hour and sit down and talk about the technology. I'd like to understand it in as much detail as possible. I'd like you to describe everything that this does, including the parameters of temperature and structure which you tried to explain and which I'd like to understand. Out of our

discussion may come some possible application that you have not even thought about, so I'd like to have you educate me very thoroughly on this technology. Can you do that?

(3) Assess the Stage of Development

Participants: Technology Manager
Inventor
Moderator

MODERATOR: Indicates that the technology manager and the inventor must also discuss the laboratory's investment in the membrane process. Was it developed as a part of mission work, or was it done as a side interest? Is there a need for the lab to put additional development time and/or money into it. Would any additional investment be connected with mission work, or would it be because of the potential for commercialization, or both. If further development is needed, how should it be done? In-house with lab paying? With a company? Pros and cons of having a company participate in development with the lab are discussed.

TECHNOLOGY MANAGER: Wants to know how "developed" this technology is. Is equipment available to make hollow fiber membranes using this process? Is it just a prototype, or do you use equipment that is now on the market? If on the market, did you have to modify it in any way? Have any products been made using this process, or have you just made hollow fiber membranes to test for various properties?

INVENTOR: Discusses the development stage of this technology. It has been made and tested extensively in the lab, but it has not been used commercially. To develop the process, they adapted some equipment that was on the market; however, they had to design their own hollow fiber spinnerets, which they had made in a local machine shop. Equipment that needs only minor modifications to make hollow fiber membranes using this process is now available.

TECHNOLOGY MANAGER: Is further development needed before the technology can be transferred? Would it be useful to work with a company to do this?

INVENTOR: Believes that the technology has been tested sufficiently and probably could be transferred to a company now. However, he would be interested in working with a company to adapt the technology for their specific application and assist with getting their manufacturing processes going.

TECHNOLOGY MANAGER: Notes that the lab might consider encouraging potential licensees to allow the inventor to adapt the technology for their application and their manufacturing equipment.

(4) Identify Possible Applications for the Technology

Participants: Technology Manager
Inventor
Moderator

TECHNOLOGY MANAGER: Asks the inventor to suggest possible applications for the technology. He tries to get the inventor to think in terms of what the technology will do and what properties it has that would be useful in other applications.

INVENTOR: Responds to the technology manager's question about possible product applications. The most important areas for applications are: dialysis and hemodialysis, blood fractionation, water purification and desalination, and various industrial processes. The inventor believes that the best and most immediate application is for hemodialysis.

MODERATOR: Explains that the first problem for the technology manager is: can this technology be commercialized? To make this determination, some preliminary market information is needed. The technology manager could develop this market information, or use graduate students or an outside marketing organization to develop the necessary information. In this case, the technology manager will use a consultant to gather the data.

The technology manager calls a meeting to discuss the technology's commercial potential. The moderator explains to the audience that the participants in the next meeting, held at the laboratory, are the

technology manager, the inventor, the consultant who has gathered some preliminary market information, and the patent/licensing attorney for the laboratory.

The following is an excerpt from the workshop proceedings.

TECHNOLOGY MANAGER: Based on your literature search, have you done any kind of comparative advantages in terms of what your innovation would have over and above existing technology?

INVENTOR: Yes. There seems to be nothing else existing as a hollow fiber membrane at this point that is as flexible as this seems to be. It's much more flexible than those that are in use currently, and we think will have a longer useful life. The morphology of the fiber is something we can control now. We can perfect the pore size and therefore can affect what is separated and what flows through. And we can work at three times higher psi than anything else currently on the market that we're aware of.

TECHNOLOGY MANAGER: What about the cost of production of this method compared to whatever else has been used now in anything in ultrafiltration applications or hemodialysis or in any of those that you've looked at?

INVENTOR: We have not done any elaborate cost studies. However, the raw materials are not expensive. Although we have innovated during the course of it, there is nothing within that set of innovations that is expensive to do. Nor are the discrete elements very different from what would be done in a manufacturing process for existing fibers.

TECHNOLOGY MANAGER: But you don't have relative cost figures except to that extent?

INVENTOR: Correct.

TECHNOLOGY MANAGER: Why is the other inventor leaving in two weeks?

INVENTOR: The other gentleman is leaving in two weeks because he's been offered a teaching position in a university along with the ability to consult on the side. He's moving to Louisville, as a matter of fact.

TECHNOLOGY MANAGER: Have you thought about companies who might be interested in the primary potential use for this? Can you think of one or two companies that might be interested in this?

INVENTOR: Obviously there are some big companies out there that are in the fiber business, the Monsantos, the Du Ponts, that potentially might be interested in this, but we don't have any great experience with them. We don't know who to talk to. They're just generally in the business, so they might be interested. There are some

smaller companies in the gas separation business that might well be interested in this, but we haven't talked to anyone. There are the medical applications. There are a number of companies involved in dialysis, for example, that would be candidate companies.

TECHNOLOGY MANAGER: Who in the government right now is using the membrane type product that's similar to what you've developed?

INVENTOR: We know that NIH has been involved for a number of years in the development of a number of products or the development of technologies in dialysis therapy. Dialysis machines, the entire set of technologies leading up to dialysis treatment, has been an active area of treatment for the National Institute. There are probably some other agencies. Those are the only ones that we know about.

TECHNOLOGY MANAGER: Is there something new about the way in which you produce this?

INVENTOR: We feel, of course, that the result is new, and we think that the way in which we have achieved the spinning of the fiber and the coating of the fiber is new.

TECHNOLOGY MANAGER: I noticed that you did look at the permeability of the membrane to hemoglobin, so you must have thought seriously about considering using this in hemodialysis. Have you looked at any of the other medical applications? Have you talked to anybody else at NIH, any medical doctors or anyone? For instance, two things come to mind. Do blood proteins possibly go through the membrane or clog the membrane, other than hemoglobin, which is very heavy. You also mentioned something in the process which was a little fast when you presented it, about leachable items, about leachable parts of the compound. Are there things in there that would make it non-biocompatible, that would limit it's use in bio-engineering, or do you have any data?

INVENTOR: Based on the data that we have at this point, we think that there is nothing there that would inhibit us in that direction. Obviously we thought about hemoglobin dialysis because we know about that. That was the reason for the selection of hemoglobin. We have not tested it further, and it would obviously require some funded testing of all of those questions.

TECHNOLOGY MANAGER: Is there a chance that your colleague who is leaving in two weeks may go to someone else and request the same assistance?

INVENTOR: Well, I don't think that's going to occur. I think he's going to have a teaching position at a medical school. He'll be able to do some research.

TECHNOLOGY MANAGER: Yes, but do you have some kind of a legal agreement with him? Supposing we went ahead and decided to make a deal

with you, are we holding ourselves liable in the event that the lab countersues for actions against you or whatever?

INVENTOR: He's prepared to file whatever papers are necessary to say that the invention occurred here in this laboratory; and to whatever extent the government would be able to control me on the invention, they would be able to control him.

TECHNOLOGY MANAGER: Okay.

MODERATOR: Are you now satisfied that you have a handle on the nature of the technology, to the extent that you can get it in this first meeting?

TECHNOLOGY MANAGER: Do you have your draft journalism or sketches or lab books that you can leave with us xeroxed?

INVENTOR: Yes, I can give you what I have. Obviously it's at a fairly early stage. We have kept lab books on it, we have the data in a properly recorded form, and we have some very rough sketches.

TECHNOLOGY MANAGER: May I suggest to you that after our meeting, as soon as you get back to the lab, you make sure that you have a memorialization of this discussion and the disclosure that you made to me so that we can establish a document for use in any further patent discussions. Also, go back to your notebooks and be sure that you sign and date the notes properly so that if there are any documents which have to later be used in defense of prior knowledge of this material, you have established when you had this invention and that you've actually discussed it and reduced it to practice at least as a laboratory activity?

INVENTOR: Although we were not familiar with the outside forms that we need to fill out, we have kept excellent records internally. We do have all of the signed and dated material on the lab notebooks, and everything is currently in order on that side. We're ready to be protected.

MODERATOR: We've moved a little bit. Exactly where are we in the stage of development? How far are we from being ready to talk to somebody else, are we ready to bring in the lawyers, are we ready to talk to a company--do you have the data that you need to do that? Those are the sets of questions that will be relevant to assessing the stage of development. What others can you think of?

TECHNOLOGY MANAGER: In the case of the inventor, he should have a model or a sample of the product and a description of what a reasonable person would have to do to replicate it. Until he has that, and until we have that, we have nothing except claims on paper.

INVENTOR: I can show you a sample of the hollow fibers themselves. I can give that to you. We have rigged it in the laboratory. It's certainly not a replicable unit at this point, so I

can show you what I did, but there's nothing to pick up and take anywhere yet.

TECHNOLOGY MANAGER: Take a few pictures of your apparatus. We would like to make it into some kind of a record. And now we can start advertising claims.

INVENTOR: Can I keep working on this?

TECHNOLOGY MANAGER: Sure.

INVENTOR: Do I have to keep it a secret from now on?

TECHNOLOGY MANAGER: You've disclosed it. The new disclosure laws state you have to move on it within a year of disclosure.

TECHNOLOGY MANAGER: Is it possible that now we could begin to help by assessing the market to find potential users and investors.

MODERATOR: Not quite yet. You're right, but that's not where we want to focus yet. What we're interested in right now is what's the stage of this as a technology, and does it require more work, and how is that work going to proceed, and where do we take this from here in the laboratory?

TECHNOLOGY MANAGER: Did I understand you earlier that we have established that this is new enough to be patentable?

INVENTOR: I'm just a scientist. I don't know if it's patentable or not. I need some advice on that. What I know is that based on the literature that's out there, I don't see anything that accomplishes this, I don't see anything that's been done this way--it looks new to me and that's why I called you. But I don't know if it's patentable or not.

TECHNOLOGY MANAGER: We can do a patent search.

TECHNOLOGY MANAGER: In the next few days, sit down with your colleague and start thinking of all the characteristics of this product that you have produced. Do a little bit of brainstorming between yourselves on what possible applications this might have outside of the kidney dialysis area. Do some broad-range thinking as to how it might affect fabric that could be impregnated with dyes that could be using this material, or how hollow tubes could be used for light pipes for transmission of information, or what other applications this new material might possibly have; so that when you come back to us, we could think about the scope of the possible applications of this technology. You probably are well-advised not to discuss this very broadly with anybody else until we are pretty clear that we are going for, or are not going to go for, a patent disclosure; so at least you've got a running start on whatever searches are involved.

INVENTOR: What's the proper point to get a company involved? We've taken it to this point, but there is probably a lot of additional development work that will be needed to pursue any of the applications, the ones I know about or the ones I haven't thought about. Am I going to get the commitment from the agency or the lab to allow me to continue to work on it in-house? Am I going to sit down and develop a research budget? I'm going to need some equipment. I need access to a scanning electron microscope, and we don't have one here. To really get a handle on the morphology of these things, I need a scanning electron microscope. How do I go about getting those dollars and that support?

TECHNOLOGY MANAGER: The laboratory director knows all about the development, doesn't he?

INVENTOR: No, no. We haven't told the lab director.

TECHNOLOGY MANAGER: Don't you think it would be a good idea to talk to him?

INVENTOR: Well, we wanted to talk to you first. We wanted to make sure that we were within our rights and that we did everything right. We didn't want to get caught short on the part of putting all of this together from a patent standpoint. We've done this mostly at night and on weekends.

TECHNOLOGY MANAGER: Well, I think we ought to bring in the lab director now. You've got yourself protected. He's inside. I think perhaps we ought to see if we can get a buy-in by the lab director.

TECHNOLOGY MANAGER: In the meantime, we need to consult a patent attorney and ask if there are any disclosure forms that he has that you should have in front of you; you know, the forms that we usually use to transfer information into the patent process within our laboratory.

MODERATOR: Obviously there's been a limitation in the meeting that we're holding now in that you've asked the inventor to go back in the lab and to work on some things. You've asked him to think about other applications, get a little more serious about other applications. He's been focusing on one because he knew about that one. So, we're going to need some information for another meeting, and among the questions are, who needs to be involved in that next meeting, and what kind of information do we need to have gathered for that next meeting?

TECHNOLOGY MANAGER: Certainly we would want to get some market research done to see the level of utilization in terms of the population, the number of people that use such machines, etc. And the new entrance markets of those machines. We would try to do that to see if there is anything there.

MODERATOR: Okay.

TECHNOLOGY MANAGER: We'd better inform the president.

MODERATOR: Which president?

TECHNOLOGY MANAGER: What I'm saying is that at this point in time, you've done some things that, depending on who looks at it, could put your job in jeopardy. You've spent money, you've used lab equipment that was not authorized. So you've got to get the administrative side informed.

MODERATOR: So we've got to bring in the lab director.

TECHNOLOGY MANAGER: In no way do I think any of us are being given the power to give lab directors direction or guidance.

MODERATOR: In this case, I think the technology manager is trying to rescue the situation and trying to see that there is no disaster here. Something good that has happened in the laboratory remains good. The scientist who is kind of oblivious to all of this procedural stuff should be gently coaxed into the direction of getting this authorized and approved and into the system, obviously without stifling his creativity.

TECHNOLOGY MANAGER: Is not the technology manager receiving the delegation from the lab director to do these kinds of things? Once the inventor is talking to the technology manager he is essentially talking to the lab director, and so the lab director has to reduce this to a memorandum and seek the necessary approval.

MODERATOR: We certainly hope that that's the way it evolves. In this case, I think the point is that the scientist has been operating completely out of synch. And he's doing something that probably no one's going to be mad about because it's a good thing--he hasn't expended any real dollars just because he's burned the lights and stuff. But he's doing this for all the right reasons. Probably the system is going to rescue him and move him into the mainstream, and everything is going to be okay. He hasn't gone to the lab director or his boss himself, he's gone to the technology manager; and the technology manager needs to ensure that it gets moved into a proper set of agreements.

TECHNOLOGY MANAGER: The thing we're searching for, then, is a disclosure properly authenticated by the lab administration on one document. Is that correct?

MODERATOR: I think you're first seeking the disclosure, trying to tie it down. Secondly, you're seeking approval that this guy is not going to get fired for what he's done and that it's okay for him to continue doing what he's done in the lab because this is a good thing and we're glad he's done it. And next time, don't do it without letting us know about it.

TECHNOLOGY MANAGER: Is there an expenditure now of some funds to do the patent search?

MODERATOR: These are some of the things that you have to decide. Do you want a patent lawyer at your next meeting? Do you want the patent lawyer to meet with the scientist until the search is done?

INVENTOR: I'm not trying to exert any personal claims. I went to the technology manager to say "Look, I've done this in the laboratory, I've done this for the government. That's my only master." I didn't exactly go tell them I was going to do this. I sort of did it when I had time to do it and at night, but I'm not exerting any claims here.

TECHNOLOGY MANAGER: If this is not mission-related and is being done on your own time, then we as technology managers do not have a responsibility to help you. We can if we want, but we are tasked to do mission-related discoveries. And if you were in my lab I'd say, sorry Charlie, you're on your own. I'll give you any free advice I can, but as an official role I would not help you.

MODERATOR: For the purposes of continuing the exercise, let's say you are a creative technology manager and you've looked at the mission and you say well, it might not be exactly where we've set if off and it might be on this year's work statement, but it's related to the purpose and we want to keep it in the shop. So we're going to try to channel it in.

(5) Estimate the Technology's Commercial Potential

Participants: Technology Manager
Moderator
Inventor
Marketing person
Attorney

The technology manager opens the meeting by introducing a consultant who has helped him prepare some preliminary market information. This information, which is needed to determine the potential for commercialization, whether to protect, and how to protect, includes the following:

- How many other ways to make hollow fiber membranes are there?
- Why should a company use this process to make hollow fiber membranes (i.e., what makes this process better for some uses)?
- What types of products might the hollow fiber membrane technology be used to make?
- How many of these products are there?
- How many companies make these products?

The marketing person presents this information.

The technology manager discusses what he thinks the market information means (i.e., that there is commercial potential) and discusses with others in the group.

The group, led by the attorney, discusses reasons for patenting (and not patenting) the technology. The group decides that in this case, patenting is appropriate and will be necessary to encourage the companies to invest.

A decision to develop a commercialization strategy is made. The participants also decide that they need more market information to decide how best to commercialize the technology. They ask the consultant to collect additional market information, and he is given a month to gather the data. Another meeting is scheduled for a month later.

TECHNOLOGY MANAGER: Opens the meeting by telling attendees that the purpose of the meeting is to assess the commercial potential of a process for making hollow fiber membranes developed at the lab by the inventor. The technology manager believed there might be commercial potential, so he hired an outside consultant to gather some preliminary market information on the technology.

TECHNOLOGY MANAGER: Introduces the marketing consultant and asks him to present the information he has gathered.

The following is an excerpt from the workshop proceedings.

MARKETING PERSON: There are many companies that make hollow fiber membranes and a few that make hollow fiber membranes using polysulfone. The process developed at the lab works well using polysulfone.

- The process developed at the lab has some unique properties, particularly the ability to withstand high pressures, that differentiates it from others.

- There is potential for using this process for making hollow fiber membranes for hemodialysis, for desalination, for ultrapure water for use in semiconductor/electronics applications, for ethical drug/pharmaceutical applications, for food and beverage processing, and for various industrial separations.

- The most immediate market for hollow fiber membranes appears to be in the area of hemodialysis and hemofiltration.

- The dialyzer (or artificial kidney) is the most widely used medical application of membrane technology.
- The hemodialysis market is large, and the use of hollow fiber membranes is common and increasing.
- Hemodialysis is one of most mature market segments for membranes, but it is also one of the most enduring.

The data suggest that there probably is a market for this new process for making hollow fiber membranes.

TECHNOLOGY MANAGER: Decides that the technology has commercial potential. Based on information from the inventor verified by preliminary information from the marketing consultant, the technology manager decides to have the marketing consultant gather more information on the hemodialysis market.

TECHNOLOGY MANAGER: Brings up the subject of protection. He asks the attorney if patenting is appropriate in this case.

ATTORNEY: Begins by explaining that the legal protections for intellectual property offered by the government are used by business as a tool for leveraging or enhancing commerce. From the private sector perspective, they are appropriate and very useful in some cases, while in other cases they may prevent the most effective marketing of the product or process.

From the government perspective, patents are essentially the only form of protection that the government can obtain on its R&D. Based on discussions with the inventor, it appears that a rather broad claim can be successfully made on a patent application for this process for making hollow fiber membranes, and it appears that the market is substantial and will be around for a long time.

In this case it is unlikely that a firm would consider investing substantial financial resources in developing and commercializing technology for which they can't obtain some form of exclusivity. In view of all this and since the objective is to transfer this technology to the private sector and have it used, the lab should apply for a patent on this process.

TECHNOLOGY MANAGER: Agrees that the lab should file for a patent for the process. He asks the inventor and attorney to work together to prepare the U.S. patent application as soon as possible.

Discusses foreign patenting and decides that they need more information, particularly on foreign markets, before they make that decision.

Reminds the inventor that after the U.S. patent application is filed, the inventor is free to publish on the subject, and the lab is protected (both in the U.S. and in the foreign countries they might file for patent rights in).

MODERATOR: Explains to the audience that a month has passed. The technology manager, marketing consultant, inventor, and attorney are meeting to receive the new marketing information and to decide on a strategy for transfer. The moderator also explains that the attorney and inventor have been working hard on the patent application and expect to file it shortly.

The following is an excerpt from the workshop proceedings.

MODERATOR: A month has gone by since that initial meeting. The lab director has approved the project and the inventor is busy back in the lab, doing some more work and answering more questions.

The technology manager has begun to pull this together. He has organized the next meeting, invited a patent attorney, and asked a marketing person to provide some preliminary market information on the field.

You know that there are a lot of ways to do that. You could have hired a marketing consultant, you could have spent a lot of time in the library yourself, and you could have spent a lot of time on the phone yourself. And you could have gotten a grad student to do it. You may be so successful at such investigations that you have an extensive marketing capability internally. I will leave it to you to decide whether the person who does the reporting is a grad student, a consultant, or whatever.

It is a month later and we are getting together for the purpose of beginning to assess the commercial potential of the discovery, establishing what could happen from here, and deciding on a way to go. We are interested in why a company should use this process to make hollow fiber membranes. What kinds of products might the membrane technology be used to make? What companies out there are doing this sort of thing? How many products are there? We have asked our

marketing person to provide a preliminary report for us on that subject.

MARKETING PERSON: Having been briefed by the technology manager, what struck me as I was doing this work was that there appear to be some properties that may have substantial value in the marketplace. Especially noteworthy are the membrane's durability and the process ability to control microporosity.

When we took a look at the market, the first thing we found is that these membranes are embodied in technologies that are themselves embodied in technological products. I am going to run through the market applications very quickly. Reverse osmosis is not one of the biggest markets. Right now it is $53 million, but it has strong growth potential. As a rule, across the technologies and across the products, this is a very, very competitive market.

Ultra-filtration also has high growth potential and is $58 million at present. Hemo-dialysis is at $84 million. Its a large, mature market with pretty flat growth potential and looks like it is going to stay around that.

Gas separations is just $12 million. Micro-filtration as a process that uses membrances is at $169 million. In about 10 years, it looks like it is going to go to over $450 million. At about 10 percent a year it has strong growth potential. Now, as a technological market, what we have discovered is that it is very, very fragmented. It is very difficult to get a handle on it and there are numerous firms. Let's talk about technologies as they are used in products or processes.

The one single biggest membrane market is in hemo-dialysis, and as I said, that is about $84 million. It is projected to go to $86 in 1996, so that is a pretty flat market. It has also been an enduring market. The firms in the market have been around for a while, but if there is something that is going to change over the 10 years, it is that reuse of the membranes is going to capture about 75 percent of that market. Firms in this market are interested in durability.

Semi-conductors and electronics is the next biggest market right now at about $57 million, and that looks like it has pretty strong growth potential (one of the stronger ones). It looks like in about 10 years it will go to $171 million.

Use of membranes in purifying water for drugs and therapeutics is about $46 million, with moderate growth potential of about 7 and 7.5 percent a year, going to about $94 million. Potable and desalting processes will go from $35 million up to $90 million. Effluents, from $43 million up to $137 million, so that has some pretty strong growth potential. The biotechnology and bio-medical markets are moderate size right now at $55 million and are projected to go to $290 million in 10 years. But that is a very, very risky field at the moment.

Gas separations, especially in industrial applications, is pretty low right now at $12 million. There is not an awful lot of activity, but analysts look for pretty explosive growth based on present trends. It looks like they will go to $268 million. Electro-chemistry is another market. It is very small one right now, but looks like it has some good growth potential and will go from about $12 to $100 million in 1996.

TECHNOLOGY MANAGER: Two characteristics of the membrane that we discussed and assumed to have an advantage in were the control of the size of the pores to a very precise degree and an inexpensive manufacturing process that could be easily implemented.

Where these two factors are important is in driving down manufacturing costs and in controlling pore size over the range that we are interested in. I would now look to aggregate. In other words, if I am trying to sell to suppliers of those products or the manufacturers of those products, I would look at aggregating them. Can I sell the same type of membrane to the desalination people as to the toxic waste treatment group? What can I actually put in place that is going to influence those things?

I am a little nervous about the hemo-dialysis application because reuse is not necessarily good, especially in blood products when you have disease transmission and pore clogging, and there is a tendency toward disposables if you can drive the price down. But that is a tradeoff. In other words, whether you go to reuse depends on when you can really get the price down, and we may be able to influence that. But if you can really drive the price down, you are going for the disposable market, rather than recycle. The other thing is that you have manufacturing processes. You may be able to manufacture something for desalination which has the leechout product which you would not care about in desalination but would actually prohibit you from use in a human dialysis application.

So, those are the kinds of things that I would look at. The medical markets have approval requirements that drive up the cost a lot. We might want to develop the process for another market and then look at addressing the medical market.

MARKETING PERSON: Addressing the first part of your comment about polysulfone, it looks like the membrane would have value for hemo-dialysis, for desalinization, for the production of ultra-pure water for semi-conductors and other electronic applications, for drugs and pharmaceutical applications, and for food and beverage processes.

In terms of dialysis and hemo-dialysis, there is good news/bad news out there. The good news is that the renal care market looks pretty strong. Medicare is picking up a lot of those costs, and that looks pretty strong, but in the days of Gramm-Rudman, who knows?

So, that introduces some more uncertainty. It would be my recommendation that we look at that market. It is flat, but we seem to

have something that has some pretty strong competitive advantages. There should be some niches, something that we could carve out of that $84 million.

INVENTOR: I have got to interject my feelings about this. I have been back in the laboratory on this project. I have been looking at different things that we can do with it, and I think potentially we can do a lot of things. A couple of years downstream, we can apply what we have done to a number of different areas.

But the truth is that we are way ahead on things like dialysis. That is where we were doing the initial work. It was the application that we were looking to. If you want to get to the market quickly, if you want to get to someone funding us quickly, I can probably get you there more quickly, whether it is the biggest market or not.

The larger markets may be in desalinization, they may be in other things down the line. If you want me to get you a place in the laboratory where you can take a technology and sell it to a company where you can go to the market quickly with it, that is the one that I can get to first, and you need to know that.

TECHNOLOGY MANAGER: Well, I would recommend that we do that and try to get somebody to take a license on that field of use. Then we can go after the other parts of the market.

MARKETING PERSON: I am thinking about the microfiltration market again. I've been casting doubts on it, but it is mighty big. There basically are three companies that buy the membranes in that market and then sell to others. And it is a big three. The market is very difficult to get into, so these are the folks who you would be dealing with, if we decided to go in that direction.

They are Millipore, Pall, and Gelman.

QUESTION: Well, why don't we contact them? We can contact them and give them a description of the technology and call them in and see if they are interested.

INVENTOR: Well, in the case of the dialysis application, we are talking about a superior product that will enhance the quality of human life. That is the basic reason for continuing in that arena. I think that the other potential applications are ways that we can make money off of what we have done and have more funding for the laboratory so that we can do things that are mission oriented.

MARKETING PERSON: You've got a bird-in-the-hand on the dialysis and hemo-dialysis market because it looks good, but it is flat. But you have got something that is better than anything else.

And you have got a much riskier market that is hard to get to, but it could be much more lucrative in micro-filtration.

TECHNOLOGY MANAGER: Are these mutually exclusive?

MARKETING PERSON: No.

TECHNOLOGY MANAGER: Is there any reason, from your standpoint, that we could not aim initially for one of these niche markets, without compromising our ability to decide to enter another market later on?

MARKETING PERSON: In my estimate, we should figure on going after both. The only reason that we would back off is if we ran into some serious commitments on our own time and resources. But my recommendation is that we first concentrate on the dialysis-hemo-dialysis market.

TECHNOLOGY MANAGER: I agree, let's concentrate on the dialysis-hemo-dialysis market and see what we can do.

(6) Develop the Commercialization Strategy

Participants: Technology Manager
Marketing Person
Inventor

The purpose of this meeting is to decide on strategies for transferring and commercializing the technology. Should it be licensed to an existing firm, or could it be the basis for a new business? If it is decided to try to license to an existing business, is a small firm or a large firm most likely to successfully commercialize the technology and why? Participants need to bring out advantages and disadvantages of licensing to an existing or a new business. Advantages and disadvantages of licensing to large and small firms also need to be discussed.

The marketing consultant provides some background on the membrane industry in general (competitive situation, etc.) and on the hollow fiber membrane industry. Competing technologies, companies involved, annual sales of this or related technologies, and current and projected demand are determined. Reasons this technology is better than similar technologies already in use are also covered. Panel members also need to discuss and decide which types of companies to approach.

The next steps involve valuing and pricing the technology.

TECHNOLOGY MANAGER: Opens by saying that the purpose of the meeting is to decide how to transfer and commercialize the technology.

In this case, the technology could be licensed to an existing company, or to a startup company.

He then leads a discussion on the advantages and disadvantages of licensing to an existing company vs. a startup company. Advantages and disadvantages of licensing to small vs. larger firms may also be discussed.

Advantages of licensing to an existing company include:

- May already have manufacturing facilities that can be adapted to use this process
- May have marketing and distribution networks already in place
- May have more money to put into further development than a startup company
- Others?

Advantages of licensing to a startup company include:

- If someone is using the technology as the basis for a new business, he may be more inclined to work hard to commercialize it than an established, more diversified company.

TECHNOLOGY MANAGER: Asks the marketing consultant to present the information he has obtained on the membrane industry, hollow fiber membranes, and markets.

MARKETING PERSON: Data on the hemodialysis/dialysis/hemofiltration market:

U.S. Market - Hemodialysis

- U.S. market for hemodialysis equipment has grown rapidly since 1972, when Congress allowed Medicare to cover costs for anyone, regardless of age.
- Over $1.8 billion is spent each year by Medicare to keep people with End Stage Renal Disease (ESRD) alive.
- Hemodialyzers are used to treat:
  - Over 62,000 people in the United States
  - About 71,000 people in Europe
  - About 60,000 people in Japan
  - An estimated 35,000 people in the rest of the world

- A total of about 228,000 people worldwide

- If one estimates that 62,000 people in U.S. are treated each week at a cost of $20 per week, there is over $1.2 million spent each week on treatments in U.S. alone (or over $62 million annually).

- Total number of people receiving dialysis is increasing, but market is flat because prices of dialyzers are decreasing as a result of competition.

- Overall market is expected to stay relatively flat because of prices dropping, increases in kidney transplants, and medical advances in the treatment of conditions that lead to kidney failure, such as diabetes and hypertension.

  In addition, in the U.S., more and more dialyzers are being reused. U.S. Center for Disease Control says 65 percent of the kidney centers are reusing dialyzers. Dialyzers are generally reused about 12 times. In Japan, reuse is forbidden by law. Reuse in Europe is much less common than in U.S.

- As a result, probably need to find a market niche if we are to get into this market.

- In U.S., there are about 1,375 renal care facilities.

- In the approximately 700 renal care facilities that are associated with hospitals, over 16,600 kidney machines are used.

A dialyzer is the packaged bundle of membrane fibers that actually accomplishes the purification of the blood; hemodialysis equipment refers to the major equipment used for the treatments.

Hollow Fiber Membranes in the Hemodialysis Market

- Hollow fiber membranes are the most widely used membrane in the hemodialysis market.

  - Reusable hollow fiber units account for an estimated 75 percent of the membranes used in dialyzers in the United States in 1985.

  - Coil membranes (two percent) and plate membranes (23 percent) account for the rest of the membranes used in dialyzers.

  - By 1995, hollow fiber membrane units will probably account for 90 percent of the total market. Coil

membrane units will no longer be in use, and plate membrane units will not be as common.

Market Value

- Value of membranes for use in dialysis for 1986 (by type of membrane used) is:
  - hollow fiber - $63 million
  - plate - $19 million
  - coil - $2 million
  - total - $84 million
- Estimated value of membranes for use in dialysis - 1996 (by type of membrane used) is:
  - hollow fiber - $77 million
  - plate - $9 million
  - coil - 0
  - total - $86 million

Hemofiltration Market

- Hollow fiber membranes are also used in hemofiltration, which is essentially a different technique for accomplishing what hemodialysis accomplishes, though it also does some things better.
- Hemofiltration is often used for thinning blood during heart surgery and for such things as filtering blood in the case of drug overdoses.
- Hemofiltration, which was first used in the 1960s, hasn't grown much because the ability to control the balance of fluids is a delicate process. Hemodialysis is easier to control, so home use has grown.

Based on this information, it appears that the biggest growth market is overseas. Patenting in Europe and Japan should be considered.

The group decides that licensing to an existing company is probably the best way to get this technology into the commercial hemodialysis marketplace.

TECHNOLOGY MANAGER: Concludes the meeting by saying that the next steps are to value and price the technology and determine companies that might be interested in licensing the technology.

(7) Determine the Value and Price the Technology

Participants: Technology Manager
Marketing Person
Inventor

TECHNOLOGY MANAGER: Opens the meeting by explaining that its purpose is value and price of the technology. Addressing value first, he then raises questions regarding the way in which value manifests itself, the manner in which value is measured, and the relationship between value and price.

The group discusses these issues and develops a consensus concerning the value of the technology.

The technology manager then begins the next segment of the discussion by suggesting three dimensions of price that seem most appropriate to him for the present situation. These dimensions are royalty (based on what?), territory, and exclusivity.

MARKETING PERSON: Reviews his industry and company information on historical and projected product sales, geographic markets, competitive behavior, and industry culture and behavior, especially as it relates to propensity to innovate and to accept innovation and so on.

TECHNOLOGY MANAGER: Leads group through ensuing discussion and then helps develop a consensus concerning the recommended government position on the price of the technology.

In view of the consensus on the "asking" price, the technology manager then raises three additional issues:

1. What should the terms of trade be between the various elements of price if the potential licensee seeks a different price structure than the lab seeks?

2. What are the benefits derived by the laboratory from a successful transfer other than price? How do they relate to price? What is most important to the lab?

3. As a final check, should the target price be revised considering the above (2) discussion?

(8) Choose Company(ies) to Approach

Participants: Technology Manager
Marketing Person
Inventor
Moderator

During this portion of the meeting, the group must decide:

(a) Specifically which company(s) to approach

(b) Who best to approach within each company

(c) How to approach these individuals--phone, mail, personal entree, etc.

(d) How to most effectively promote the value of the technology relative to the operations and plans of the specific company.

TECHNOLOGY MANAGER: By way of group discussion, decides that a secrecy agreement will be required before the technology can be disclosed to anyone in sufficient detail. The technology manager with assistance from the attorney then develops a market relevant description of the technology that is also suitable for public disclosure.

After group discussion, the technology manager decides to try to license the technology to firms that have a relatively large share of the hemodialysis market. These firms will have marketing and distribution networks already in place.

The agreed upon objective is to grant an exclusive license for specified field(s) of use of the technology for a flat fee plus an escalating minimum annual royalty.

The technology manager explains that they must be able to convince a company that this process is a better way to make fibers for use in dialyzers than they are currently using.

The lab will seek to exclusively license the technology to one of these firms for use in blood purification. Justification for the exclusive license is based on the need for large expenditures to get started and the fact that companies won't be willing to invest that kind of money without exclusive rights to the technology in that field. As an aside, the technology manager explains that the legislation

requires that the labs justify the granting of exclusive licenses. One reason they may license exclusively is if it is necessary in order for a company to spend the money needed to bring the invention to practical application.

The technology manager then tells the meeting participants that he will keep them informed as to company responses as he talks with them. The group agrees to meet again to alter this strategy, if necessary.

MODERATOR: Explains that just as the technology manager is beginning the process of promoting the technology, the inventor calls to tell him that a former lab employee who he still keeps in contact with and who had worked with him in the early stages of development of the technology is now consulting with a company that would like some additional information on the process for making hollow fiber membranes. This company has developed a hemofiltration unit that is able to control a critical balance of fluids better than anything currently on the market. They requested and were given additional information on the lab's hollow fiber membrane process using polysulfone to make the fibers (patent application has been filed). This company approached the lab and is seeking to license the technology for use in therapeutic blood purification and blood treatment.

The following is an excerpt from the workshop proceedings.

MARKETING PERSON: The government spends $1.8 billion a year through Medicare on hemo-dialysis machines keeping people alive who have end-stage renal disease.

MARKETING PERSON: This looks promising because machine time and filters is a large part of the expenditure in dialysis treatment.

MARKETING PERSON: Additionally, there are 13 companies that are major players in commercial hemo-dialysis and dialysis and hemo-filtration in those membrane markets.

The majority of these companies are foreign.

TECHNOLOGY MANAGER: That could be a problem.

MARKETING PERSON: That is a problem, but also is an opportunity on the regulatory side. In my judgment, the domestic market has much more stringent regulatory requirements. There could be major delays.

Anyway, I have a list of those companies. Two of them look like they will have a strong interest in polysolfone. They have been playing with it themselves. The names are Frezenius and Amicon.

TECHNOLOGY MANAGER: Domestic?

MARKETING PERSON: Amicon is domestic and Frezenius is European.

MODERATOR: We have a consensus emerging today that says we want the lawyer to move as quickly as he can toward a patent application. We want the inventor to continue work in the laboratory, focusing first on hemo-dialysis application, not to the exclusion of anything else.

We want some contact between the technology manager and inventor with FDA to find out about approval processes. Finally, we have two strong licensing candidates--one is U.S. and the other is foreign.

MODERATOR: Is the cost of pursuing this patent going to have an impact on your office of significance. Is it going to have a high opportunity cost associated with it?

TECHNOLOGY MANAGER: Let's get back to filing patent applications on hollow fibers. Since 1974, we are paying anywhere from $800 to $1,200 to a patent law firm to prepare a patent application. We have gotten eight patent applications for the cost of one prepared in-house. Once again, you have got to go to the experts.

MODERATOR: So, you are saying that it is not going to bar you from doing other things?

TECHNOLOGY MANAGER: That is right.

MODERATOR: Fine, I just wanted to make sure.

TECHNOLOGY MANAGER: Forgive me, I think that I have been in the public sector for too long, but I must admit to a real gut reaction as we go next into the commercialization plan to consider that a government lab would look first at a company outside of the U.S. in an effort to avoid government regulations of a technology that was developed in a government lab.

That may be a very legitimate approach with respect to the private sector, but if Proximire got his hands on that one, that would be the last time that ever happened.

TECHNOLOGY MANAGER: If we decide now, as a matter of policy, that we are going to negotiate with the one American firm in the market, have we done something potentially for American competitiveness? The cooperation treaty filed with other 12 countries also furthers our competitiveness.

We have got the tools.

MODERATOR: That's an excellent point and a major concern. Let's get all the facts and ideas out on the table and then come back to it. I think we'll be in a better position to resolve this issue once we get all the information we need.

MARKETING PERSON: In that regard, the international market is $200 million. Frezenius has ten percent of that market, Amicon has five percent, so we're talking about $20 million and $10 million. Those are the two companies we had discussed approaching.

MODERATOR: How would we pursue the selection of a firm in this specific instance on this technology? Who would we want to go to and why?

MARKETING PERSON: Frezenius, which is a European firm, and Amicon, which is an American firm.

TECHNOLOGY MANAGER: They're the only two people supplying filters?

MARKETING PERSON: Polysulfone.

TECHNOLOGY MANAGER: Is there any reason we couldn't go to some that are using filters but not using polysulfone?

MARKETING PERSON: Not on the surface, no. We could decide to approach them.

TECHNOLOGY MANAGER: I want to make a particular question of propriety here, or law. We're a Federal agency. Our mission is to do X. This is a Z technology. This is potentially a private sector innovation. It's not going to be developed by the government for its own use enough so as to justify our mission.

TECHNOLOGY MANAGER: I think I disagree with both of those, as a matter of fact.

I think there's a possibility that we're going to have to go public because we can't turn up somebody else. The law clearly emphasizes that we are to deal with American firms to produce an economic advantage for the country on whose tax base we live at this point. As to whether we go to the world market or not, if I have to advertise now to get American firms or to be fair to those that can adequately pick up the technology, then I will do that.

But on the other side, I think if my market effort has turned up that there's only one or two firms that are American that can really exploit the technology, contact them and deal with them.

TECHNOLOGY MANAGER: How about this? Once we have this patent application in hand, we can then make this public, not necessarily in the Federal Register. That's probably not the best way. Let's

prepare a list of companies in the business of developing medical technology and those that are developing polymer technology and set up a workshop in which we invite a list of perhaps 15 or 20 such companies to come and hear about the technology. In the afternoon of that workshop, we will sit down with these companies, one-on-one, and discuss whatever interest they may have in further cooperation with us in the development of this technology.

This gives us an opportunity to introduce it to a number of potentially interested firms, including some small businesses, so we won't be charged with dealing only with one partner. We'll be able to find out their level of interest in subsequent conversations. This can help shape our response, whether we want to go to a cooperative venture, a licensing procedure, or some other mode of interaction.

TECHNOLOGY MANAGER: Here's another thought. I think one of the problems that we're facing is not just the magnitude of the number of labs and programs in the labs, but the number of industries we're talking about.

There's not, in the dialysis field, three or four or five. There are over 700 companies that work in some production area of dialysis material. There are over 7,000 biotechnology firms. There are over 100,000 food production firms of significant size in this country.

Try sending out 100,000 letters to food production firms. You can get the list, but it's going to take you a while to address them all.

It's going to take even longer to have them each come in for a one-on-one in the afternoon. You could spend 35 years of the government's civil service just having each one come in for one afternoon for one-on-one. You might get the technology out. Of course, it would be outdated by that time. The easiest and most expeditious way is if you are in the network, and you know pretty well who to trust in the entrepreneurial community and who not to trust. And if you don't know them, someone else who you know probably will know them. That's the most expeditious way to handle it. On the other hand, in government, and this is a real central dilemma, you have the CYA. The law was put outside of the procurement process so that you could act in government more like entrepreneurs.

But if you act more like entrepreneurs and somebody else gets upset--another firm--who all of a sudden after the fact sees this as a good product--they're going to go to their Congressman. Their Congressman, if they're on the oversight committee, is going to call a hearing, and then you're up there trying to cover your butt about why you went to that firm and not some other firm.

And if you are getting a perceived return in royalties or some type of cash stream, they can show passive conflict of interest in theory, even though it won't stick legally in my opinion.

So I think that one of the things that we really do need to address here is that most government employees are career employees and not part of the entrepreneurial network. That just happens to be the way it is.

But there are people who do know people in the network. Maybe what the government really needs is some type of broker or some type of brokerage system to connect the government labs to the network, either through a bridge which can be electronic in software, to consultants or a combination of the two.

The second thing is that we have to come up with a rational, reasonable method to cover our butt, because that's a real problem. Congressmen love publicity, and hearings are a great way to get publicity. That's just the way life is, because they've got to be elected.

I don't know if the Commerce Business Daily's the place to put it, or the Federal Register's the place to put it. Probably some type of agreed-upon open process needs to be developed. Not that you have to touch base with all 100,000 food firms, or 700 dialysis firms, or 3,000 to 5,000 biotechnology firms, but you have to show that you have provided access or availability.

MODERATOR: A good faith effort.

TECHNOLOGY MANAGER: Maybe we're thinking too much about the retail model of our technology transfer process.

Perhaps we might think in terms of using existing institutional arrangements that are already out there for other purposes, like the aggregated trade associations, or professional societies. Much as we have found that the FLC will probably become the central actor, it'll be the combined centralized thinking of the Federal technology transfer process that counts.

It's also reasonable to think that the private sector have similar networks that focus on Federal activities and university activities. Collectively, they have built quite an empire, if you will, in terms of lobbying and information clearing houses and so forth.

We've seen this happen in energy. We've seen the creation of these industry-specific R&D consortiums, think tanks, EPRI, things like that. There are logical private sector wholesalers who could be the focus of our technology transfer activities, rather than thinking in terms of small shop retailers that we have to deal with in each and every firm.

(9) Negotiate With the Company

Participants: Technology Manager
Inventor
Attorney
Industry person

The laboratory personnel involved in the negotiations agree to begin the negotiations by letting the potential licensee propose the terms of the license. The laboratory will then accept or propose other terms.

TECHNOLOGY MANAGER: Asks what the company is prepared to commit in resources to develop and exploit the technology and what the company anticipates it will realize in revenues and profits through development and marketing the technology.

COMPANY: Proposes a flat fee for the exclusive license of the technology.

TECHNOLOGY MANAGER: Counters with proposal for flat fee plus escalating minimum annual royalty. He then inquires as to which fields of use the company would like to license.

COMPANY: Says that it wants both domestic and international rights and that it wants the right to sublicense the technology.

TECHNOLOGY MANAGER: Asks why the firm seeks maximum exclusivity and sublicensing freedom, what plans it has for the technology in foreign markets, what prices it will seek from sublicensees, and what the laboratory will receive from such transactions?

TECHNOLOGY MANAGER: The government requests royalty-free use of any improvements they may make to the technology.

COMPANY: Wants to be paid for any such use.

COMPANY: Wants the license to be considered paid in full by the government after five years.

TECHNOLOGY MANAGER: The government's position is that it will be considered paid in full after 12 years.

(10) Disclose the Actual Outcome

Participants: Moderator

The moderator ends the session by describing what actually happened. This hollow fiber membrane process was actually developed in a not-for-profit research institute's laboratories by two chemists and a technician. The chemists had backgrounds in the textile industry. They had worked with the R&D group of a textile company, where they had gained experience in the spinning of rayon and nylon fibers, and one of the chemists was involved in the startup of a textile plant.

Having worked with the spinning of fibers and with membranes, the chemists believed they could make a hollow fiber membrane that had certain desirable properties that hollow fiber membranes on the market did not have. They believed the development of this type of membrane (with these properties) would lead to R&D contracts for the institute (i.e., work in this field for them). They developed this technology without the institute's approval.

The patent for this hollow fiber membrane process was filed in February 1976 and granted in September 1977. Two licenses have been granted to a European company. The company became aware of the technology through a consultant who was a co-inventor of the technology (and is no longer with the institute). The first license, granted in 1984, is an exclusive license for the field of therapeutic blood purification/blood treatment. The institute received a flat fee of $100,000 for this license. In March 1987, the same company was granted a nonexclusive license under this patent for the field of industrial ultrafiltration. For this license, the institute received a flat fee of $100,000 plus a royalty of one percent of net sales in excess of four million dollars by the company and/or its sublicensees.

Subsequently, right, title, and interest in this patent were sold as a part of a package of patents. This patent was valued at $350,000 at that time.