Training Staff in IP Management

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ABSTRACT

This chapter provides an overview of training opportunities that developing country institutions can explore to start to address problems related to a smooth implementation and execution of all intellectual property-related aspects (policy, management, procedures, and so forth). The chapter offers to institutions guidelines for evaluating training needs and reviews different kinds of training programs, identifying the pros and cons of each. IP management training is a long-term investment, but a cost-effective one, leading to better utilization of third-party IP resources, more effective internal IP management policies and procedures, and higher efficiency in regard to outlicensing and partnership development. The chapter emphasizes the importance of strategic and practical training programs related to participants' responsibilities within an organization. Finally, multidimensional case studies are provided to illustrate the myriad issues that may arise with respect to the management of intellectual property.

1. INTRODUCTION

Whether technology comprises new products and services, or improvements of existing ones, and whether it is simple or sophisticated, technology is an important contributor to socio-economic development. The processes by which knowledge and technology are transferred ensure that technologies can be applied in virtually all industry sectors. But technology and knowledge transfer capabilities in developing countries are not meeting local needs for socio-economic development and for driving progress in such critical industry sectors as health and agriculture. Despite an active research environment, developing countries have been less effective in exploiting research outputs, especially intellectual property. Institutions in developing countries face numerous problems in managing their own intellectual property.[1] These include a limited understanding of the IP system and how it can be applied in the public sector research environment, a low appreciation of the benefits that can be derived from managing institutional intellectual property, and inadequate human and financial resource capacity to invest in institutional IP management policies and resources.

In IP management, the importance of practical training events cannot be overemphasized. For this reason, we have included, at the end of this chapter, a few brief case studies that can be used for training purposes (Box 1 at the end of this chapter). These case studies will allow the participants to play roles (that is, role-play situations that arise in the day-to-day management of intellectual property) and, most importantly, will allow participants to see how their specific roles in real life affect (directly or indirectly) deal-making activities. Even for those who are not involved in deal-making, this practical approach is especially useful as it enables participants to view their respective tasks in broader contexts and thus better understand their roles and responsibilities, as well as their importance in the process.

Pefile S and A Krattiger. 2007. Training Staff in IP Management. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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2. A STRATEGY FOR IP MANAGEMENT CAPACITY BUILDING

2.1 *Analyze institutional goals*

Deciding upon a program to build IP management capacity begins with a thorough analysis of institutional goals, recent policy changes, and required adjustments in the institutional strategy, with respect to IP management. Institutional capacity in IP management means a range of things: including clear and transparent policies (conflict of interest, licensing, patent, and so forth); established procedures (for example, for incoming and outgoing materials, laboratory notebooks); and people at nearly every level of the organization being well informed on how the procedures work, and why. It is essential to identify weaknesses and strengths of the IP management system within an institution in order to take better advantage of existing organizational structures. This means identifying where the weakest links are. A training program then will assist staff in better understanding and helping the institution to achieve its goals.

2.2 *Identify training needs*

The next step is to identify the competencies required to accomplish the overall goals. This requires an analysis of the required proficiencies, existing deficiencies, and the causes of the deficiencies. In general, the training requirements of staff members are summarized in Table 1. In order to ascertain specific needs, the following question should be answered:

- What knowledge and skills are required for optimal operation of the IP office and therefore required among IP management staff?
- What IP-related knowledge and skills are required for the research staff?
- What are the communication gaps with respect to intellectual property both within the institution and with third parties?
- What are the particular elements of the IP policy that seem least well understood and implemented?
- What resources are required to bring knowledge and skills to the required levels?

Information on training needs can be gathered in various ways:

- **interviews.** one-on-one or group format; face-to-face or by phone; formal interviews and off-the-record discussions
- **focus groups.** conversations among teams of workers from across the organization
- **questionnaires and surveys.** anonymous or not
- **document analysis.** a study of policies, strategies, and management procedures (for example, employment agreements, grant documents, and other contracts)
- **observation**.

2.3 *Develop strategies to achieve training goals*

Ranking the training goals and determining how to meet the highest-priority training needs is difficult. A well-developed plan should have specific and realistic objectives, include measurable and achievable outcomes, schedule clear time frames for all activities, and should undergo regular monitoring and evaluation.[2] Of course, different people have different understandings, vested interests, and preferences, so a lot of soft negotiation will be required. It may be helpful to work with a third-party training provider who, if they understand the organization, can take a more objective view and assist in better designing the training program to meet institutional goals.

3. IP TRAINING PROGRAMS

Initially, individuals interested in IP training were limited to a small collection of course offerings available through staff members of organizations that, due to their practical experience in the field, were able to share their know-how. But intellectual property as a field of study is growing in importance as institutions value it more and more. In addition to the essential practical training offered by institutions such as the Centre for the Management of Intellectual Property in Health Research and Development (MIHR), formal training in IP management is also available from

Table 1: Generalized Training Needs of Different Staff Groups

Group	Training requirement (minimum)
Researchers	• maintaining good laboratory records • a basic understanding of the types of IP agreements, especially in the context of exchanging research material and information • the importance of confidentiality, especially with respect to publishing and delivering academic presentations • when to disclose intellectual property to the relevant office • institutional IP policy guidelines and procedures
Research managers and institution directors	• the importance of IP management and management functions • IP protection processes and procedures; the investments required to manage intellectual property effectively (include key decisions required at different stages of intellectual property and research development) • implementing IP policies, processes, and procedures • an appreciation of the role of technology in addressing socio-economic needs
IP managers	• overview of IP management from the generation of intellectual property to its exploitation and application • awareness building • understanding of science (some domain understanding of certain fields of science an added benefit)
Operations	finance • understanding of IP policy guidelines, namely, systems and processes to handle IP payments and receipts, for example, royalties; the administration of benefits to researchers and the institution human resources • IP policy guidelines and interface with other institutional policies such as, conditions of service, recruitment, conflicts of interest and commitment, contracting with clients, and so on legal services • IP policy guidelines • IP contracts and agreements • What is intellectual property; and the different forms of IP protection • IP negotiation grant and contract research • IP contracts and agreements, especially clauses regarding IP ownership • IP policy guidelines

MIHR.[3] The online version of this *Handbook* will list many other such programs and places.

IP training opportunities can be divided into two distinct disciplines: law and IP management, which includes deal making as the central focus.

3.1 *IP law*

Although most training programs begin by covering IP law, it is more appropriate to present this topic at the end of the course. A brief overview at the beginning might be appropriate, but placing emphasis on it at the beginning diverts attention from the more important issues, namely what an institution is doing with its intellectual property and with the intellectual property of third parties. Therefore, a training program really ought to begin with the central issue, which is deal making for most institutions.

IP law is concerned with statutory regimes for the legal protection of IP rights. IP law studies normally include:

- **patent law**. the study of patents for inventions, including international and regional treaties that form part of an international legal framework in patent law
- **copyright law**. the study of principles and standards of protection under national and international copyright and related rights treaties
- **trademark law**. the study of legal provisions relating to trademarks in national, international, and regional IP treaties
- **industrial design law**. the study of laws pertaining to the registration and protection of original and innovative designs. (In some countries, design patents go under different names, such as "utility model" in France and the law for "minor inventions" in Australia.)

Other training opportunities exist in areas such as:

- legal aspects of traditional knowledge and biodiversity
- legal aspects of electronic commerce

Many law faculties offer training for becoming a patent lawyer. Typically, patent lawyers are responsible primarily for preparing and prosecuting patent applications, conducting patent searches, patent infringement and litigation, and preparing and filing applications for patent and other IP protection. During the course of performing these duties, patent lawyers are required to communicate with counsel and guide clients on legal issues in this field.

3.2 *IP management*

On the other hand, IP management courses train individuals to become IP practitioners. An IP practitioner may not necessarily have formal education or training related to intellectual property but would have work experience and some informal training in the field. IP management is the convergence of basic IP law, business and research management, and institutional policy administration. IP practitioners need to know the IP field well enough to make appropriate strategic and management decisions about the protection and exploitation of institutional intellectual property. Furthermore, IP practitioners are expected to: develop institutional IP policy, advise on when, where, what, why, and how to protect intellectual property; identify useful intellectual property from their institutions; establish institutional systems and processes to manage intellectual property; assess the value of intellectual property; report on IP activities; and build awareness of the importance of intellectual property within the research community. Essentially, the IP practitioner serves as a bridge between science and the outside world. Such an individual should know, therefore, how to articulate issues effectively to different stakeholders and when to seek professional counsel for highly technical matters.

3.3 *IP law vs. IP management training*

Important issues to consider when deciding on which type of IP training program would be appropriate for staff members include:

- **training costs.** It is important that the institution receive value for its training investment.
- **duration of training.** Legal training in IP law takes several years; short courses in IP management take weeks or months.

- **institutional needs.** While it is not unheard of for IP lawyers to be involved in IP management activities, normally, these lawyers are focused on legal issues. Institutions can outsource legal functions to local law firms. Depending on the type and volume of work, institutions need to determine whether their IP managers require a legal qualification in addition to the scientific and research management background that most IP practitioners possess.
- **access to and availability of training opportunities.** Unless an institution organizes an internal IP training program, the institution often relies on the training schedules of other programs. Some training opportunities may take place at awkward times in the organization's business cycle. Furthermore, it can be exceedingly costly for developing country institutions to fund individuals to attend a one- or two-day training course overseas as is often the case with such IP training programs.
- **size of institution and volume of IP activity.** Large institutions with a significant, growing IP portfolio may need an IP lawyer in addition to an IP manager. For most institutions, however, an IP practitioner may be adequate.

3.4 *Training locations*

A growing number of IP training programs are available on the market. The list of programs below is by no means exhaustive; an Internet search of the topic will certainly yield many more results.

3.4.1 *IP law*

Degree programs or courses in IP law are offered by numerous universities in both developing and developed countries. The World Intellectual Property Organization (WIPO), along with the University of South Africa (UNISA) offer a distance-learning course in IP law.

3.4.2 *IP management*

Highly regarded IP management courses are offered by:

- MIHR[4]
- AUTM (The Association of University Technology Transfer Managers)[5]
- NTTC (National Technology Transfer Center)[6]
- WIPO Worldwide Academy[7]
- NIH (United States National Institutes of Health) Office of Technology Transfer[8]
- PIIPA (Public Interest Intellectual Property Advisors, Inc.)[9]

3.5 *Designing training programs*

A training strategy should begin with a clear mission and provide measurable training objectives through which progress can be monitored. The training program should facilitate the achievement of the institution's goals for promoting and commercializing products that emerge from research.

Training-program development can be broken down into ten essential steps as illustrated in Figure 1. Note that training is a continuous and iterative process.

3.6 *Elements of a good training program*

Given the many different types of training programs available, how does one distinguish good training opportunities from those with little value? Key considerations to bear in mind when planning an IP training program include:

- **relevance to practical issues.** For example, whereas for lawyers, the course may well center around the law, in most cases emphasis on legal aspects, especially patent law, for IP management practitioners is too strong. Rather, equal emphasis should be placed on deal making, which should run like a thread through training programs for technology transfer managers.
- **reputation of trainers and programs.** Over the years, certain programs have built a good track record and are often recommended by former course participants. It is useful to seek the views of past trainees and trainers about courses attended and the value derived from those course.
- **qualifications and experience of trainers.** Some training programs provide a biogra-

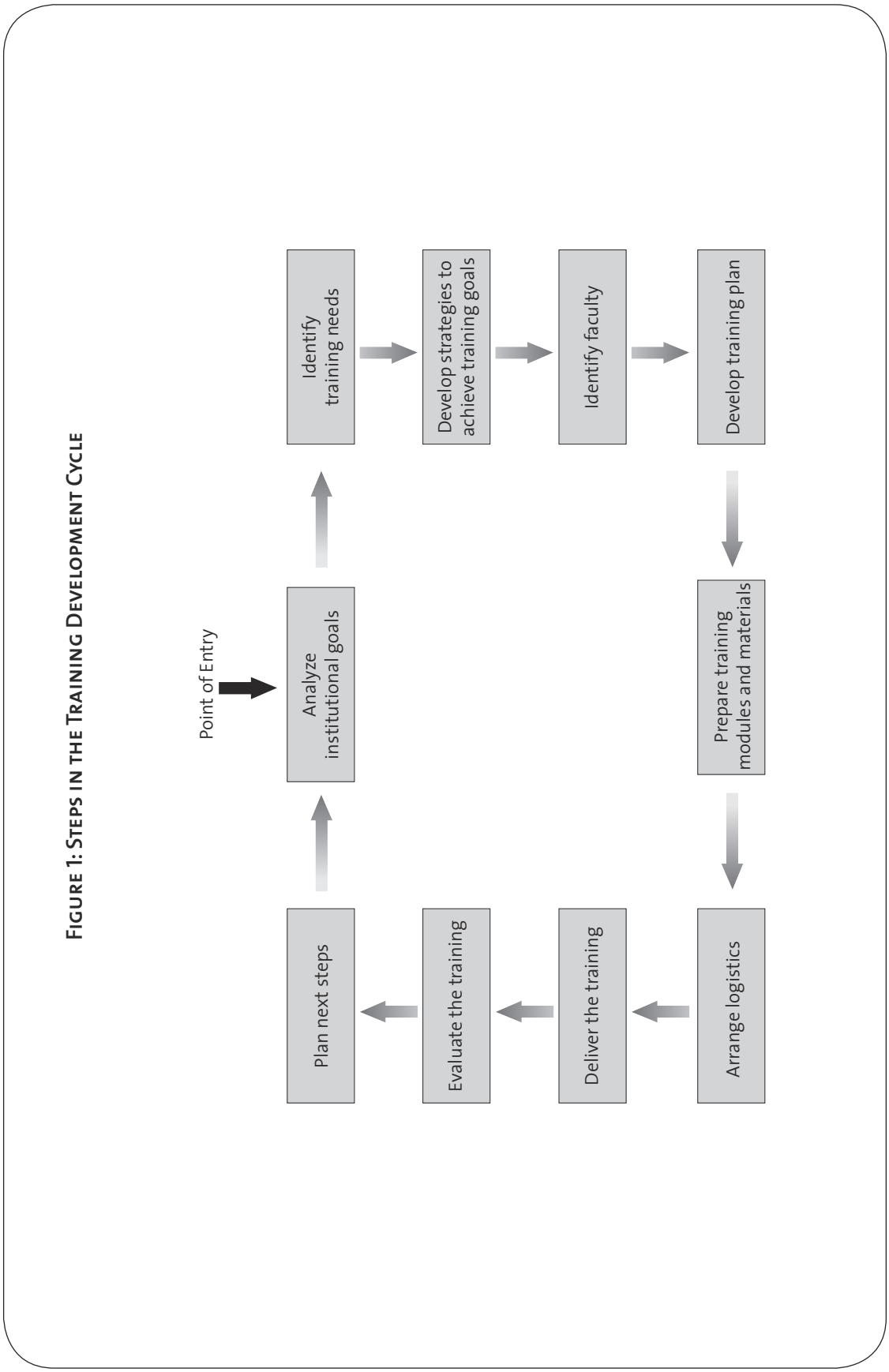


Figure 1: Steps in the Training Development Cycle

phy of trainers and presenters. The biographies provide useful information about the trainer's knowledge and expertise in the field, as well as experience in providing training to a given audience.

- **training topics and relevance.** It is possible to rapidly appraise the usefulness of the training opportunity by carefully examining the training subject matter. To maximize the benefit of the training opportunity, course content should be current, provide new knowledge, and show relevance to the training needs of the selected audience.
- **method of instruction.** To ensure effective learning, training should incorporate different methods of instruction. Lecturing is the most common form of instruction (although this may not be the most effective). Demonstrations, group discussions, role-playing, and simulations are other methods of instruction that can be used to maximize the training opportunity and maintain the audience's interest. Programs that use different instruction methods and a mix of student-teacher interactions tend to be the most effective and offer the greatest benefit to the trainee.
- **training environment.** The location and environment of the training site is of major importance to the trainee and the trainer. The training environment should not interfere negatively with the learning process. Venues and facilities need to be easily accessible and conducive to learning. Without a suitable setting, the training will be compromised.
- **training schedule and session plans.** A well-designed session plan will focus on topics that the audience needs to know. Session objectives should be clearly stated, the target audience identified, and the schedule should communicate the method and content of presentations and the time available for questions and discussion. A detailed analysis of the training schedule ahead of time will reveal whether or not the program is well planned and inform choices about which training programs to invest time and money in.
- **training material.** The merit of a course can be evaluated based on the quality and relevance of training material offered prior, during, and after the event. Pre-training material is important for introducing the topic and preparing the trainee. Post-training material should reinforce the training and provide trainees with reference material that will be useful for applying the new knowledge.
- **post-training support.** Support after the training event is important. In most cases, the real training takes place in the work environment, which is where the learning can be applied and utilized. Trainees may not always be certain of themselves; when it is possible for trainees to ask questions and reaffirm learning, the chances of applying the new learning successfully are greater.

Different forms of training programs exist, and some programs will be more valuable than others; if possible, trainees should experience a range of opportunities. Post-training reports should not only detail the outcomes of a given training program but also explain how the training experience will change work practice. The measures that management can use to monitor development should be clear. The institution paying for the training should be able to measure the outcomes of the training experience. Long-term outcomes should address the competency gaps identified in the needs analysis and should be evaluated using measurable indicators. Long-term outcome measures would include:

- increased research outputs
- more efficient resources utilized for IP management activities
- improved financial performance of the organization
- portfolio performance

Short-term outcome measures include:[10]

- improvements in skills performance
- improvements in the efficiency of conducting procedures and tasks

- showing an understanding and appreciation of performing tasks in a prescribed way

Table 2 introduces the different types of training and examines the pros and cons of each form. Box 2 presents an outline of a workshop plan.

4. CONCLUSIONS

The chapter provided an overview of training opportunities that can enable developing-country institutions—or indeed institutions anywhere in the world—to strengthen staff competencies and thus build internal IP management capacity. The chapter offers to institutions guidelines for evaluating training needs and reviews different kinds of training programs, identifying the pros and cons of each.

The adage "reading is learning, seeing is believing, and doing is knowing" is particularly appropriate in the context of training and capacity building. Accompanying this chapter are several case studies for short courses, each presenting a different challenging IP management scenario. Case studies give trainees opportunities to envision how a technology transfer project might be carried out.

Finally, a detailed workshop plan that provides comprehensive steps is important. Such an IP management training course so that it can then be successfully implemented, while engaging, educating, and motivating participants. ■

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1 CIPR. 2002. *Integrating Intellectual Property Rights and Development Policy*. DFiD:London. www.iprcommission.org/papers/pdfs/final_report/Ch7final.pdf.

2 OPM. 2006. *Guidelines for Conducting Diversity Training*. Office of Personnel Management: Washington, DC. www.opm.gov/hrd/lead/Policy/divers97.asp.

3 www.mihr.org.

4 *Ibid.*

5 www.autm.net.

6 www.nttc.edu/services/training.asp.

7 www.wipo.int/academy/en/index.html.

8 tttraining.od.nih.gov/.

9 www.piipa.org.

10 Boydell T and M Leary. 2001. *Identifying Training Needs*. Chartered Institute of Personnel and Development: London. pp. 8–10.

11 Although the case studies are based on real occurrences, the scenario has been adapted to protect the privacy of all organizations and individuals involved.

Table 2: Pros and Cons of Different Types of Training Programs

Type of training	Pros	Cons
Short courses	• trainee not absent from work for extended periods • training opportunity focused and aimed at professional development • can be inexpensive • teaching specifically targeted to adult learners • possible to be selective and choose only the most relevant training courses	• no formally recognized qualification • course content shallow • course coverage possibly unfocused • value of learning experience dependent on the extent to which the trainee can apply the new knowledge
Full-time courses	• often leads to a formal qualification • course content detailed and the learning intense • direct access to training material, lecturers, and other resources • better opportunity for trainee to build lasting networks • greater chances that trainee will complete course within the stipulated period	• trainee absent for a longer period • training might be costly • not all of the course content relevant to the institution's current needs
Part-time courses	• trainee not away for extended periods • learning in segmented modules enabling trainee to apply new knowledge in a more structured manner	• overall training period possibly longer than full-time course • overall cost of releasing trainee from work not necessarily cheaper • possibility that trainee may take longer to complete course due to flexibilities built into the course
Distance learning	• flexible learning schedule • trainee can be situated anywhere • training material is normally in a form that makes it readily available for future reference • trainee may not necessarily need time off work	• need for good time-management skills and the discipline to study • trainers and training resources less accessible • coursework coincident with full-time employment

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Table 2 (continued)

Type of training	Pros	Cons
Internship	• can be customized for the individual • practical experience • greater exposure for trainees through secondments to different organizations • training in depth and teacher/trainee exchange better, resulting in a potentially better cost benefit to the institution supporting the training • overall training experience typically varied with broader exposure	• may necessitate extended absence • can be costly • no formal qualification obtained
Internal training	• training customized and contextualized • greater control over course content • training intense and in depth • can be structured to cater to the different needs of different groupings within the research community • greater number of individuals can be exposed to a single training episode • assists with creating an internal culture of learning and understanding intellectual property • helps to develop institutional IP networks and systems • post-training assistance is normally available	• the institution must pay unless training is funded • for the duration of the course, productivity may be lower • institutions need to be involved in the planning and implementation of the event; in some cases, institution may need to assign staff member to assist with training arrangements

Box 1 : Case Studies for Use in Training

EYEBORN™ ORBITAL IMPLANT

Your local research and technology institute (RTI), in collaboration with a clinical research organization (CRO), a group of surgeons and the local university, have developed an orbital implant to replace eyes lost due to disease or injury. The Eyeborn™ implant is to be launched as a commercial product at the next International Ophthalmology Conference. The central aim of the project, supported by an angel investor, is to develop an improved and more cost-effective orbital implant. The hydroxyapatite material from which the implant is made, allows tissue and blood vessels to grow into the porous ceramic. Since the eye muscles are attached to the orbital implant, mobility of the implant is synchronized with that of the normal eye. Once a polymer prosthesis, or cap, with artwork of an iris and a pupil is placed over the implant, it is often difficult to discern a difference in the eyes in appearance and movement. This means patients who receive an implant appear to have normal ocular function. Presently, your product offers a more affordable, high-quality alternative to existing implants. It will benefit a larger percentage of the poor population, and, because of the lower cost, will be more accessible to government hospitals and clinics. Presently at government hospitals, patients that have lost an eye are given either a silicon eyeball or nothing at all.

Background

- A local patent has been granted for the eye orbital.
- There is a patent application for the orbital eye inserter.
- RTI owns the intellectual property.
- You have approached a local company to do the manufacturing.
- You would like to sell the product nationally and internationally.
- You would like to ensure that the product is available at an affordable price at all local public health facilities.
- You have a three-year window of opportunity to get your product on the market and to secure a sustainable market position.

Tasks

- Determine whether or not you will file international patents, stating where, how and why.
- Determine how benefits will be shared with the consortium of researchers.
- Identify any other forms of IP you may consider protecting.
- Summarize what commercialization vehicle you will use and why.
- Identify your key partners to help you get the product on the market.
- List agreements you require with your partners.
- Describe your business model for supplying private *and* public sector health facilities.

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Box 1 (continued)

THE SMART-LOCK SAFETY SYRINGE

The Smart-Lock Safety Syringe provides improved protection against needle stick injury and contamination. The device has an added benefit of being easier to use and providing more accurate measuring.

Background

- The Smart-lock Safety Syringe technology is a new disclosure by your institution's researchers.
- A prototype has been developed.
- The market for syringes in your country is highly competitive and saturated. While there are no Smart-Lock Safety Syringes on the market, there are many different other types of syringes available.
- You have been promised significant distribution opportunities for your product in francophone Africa, provided you establish a factory in one of the countries. Most countries in this region have weak IP protection systems.
- To manufacture the Smart-Lock Safety Syringe is a highly technical process; the know-how or the process resides with the small group of researchers at your institution.

Tasks

- Develop an IP protection strategy for the Smart-Lock Safety Syringe detailing:
  - whether or not you wish to protect your intellectual property (if not, go to the next task); if so:
    - where to protect the intellectual property (taking into consideration national, regional, and international patent systems)
    - when to start applying for IP protection

- Given your answers to the questions above, develop a business plan that details how you intend to exploit your intellectual property . In the summary of the plan, address the following issues:
  - partnerships and partnership agreement conditions
  - other agreements required
  - technology and knowledge transfer arrangements
  - your business model

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Box 1 (continued)

AVENGING MONTEZUMA'S REVENGE!

The purpose of this case study is to consider basic strategies related to the building of public–private partnerships, the pooling of resources, building on comparative advantages, and achieving the dual goals of social needs and commercial objectives. Specifically, trainees will be addressing the issues of licensing across public and private sectors that are attempting to meet needs in developed and developing countries.

In this case study, trainees are encouraged to develop creative ways in which public and private sectors can combine their resources, segment markets, and address the specific needs of different constituencies (developed and developing countries).

Background

Viajes BioTech Inc.[11] is a small biopharmaceutical company in North America, founded by Jose (Pepe) Herrera, a Mexican immigrant to the U.S. Prior to establishing the company, Pepe worked for his mother's travel agency while he was studying for his doctorate degree at the Autonomous University of Cancun, Mexico, and visited all corners of the world. During these times, he often had intestinal discomfort and returned with diarrheal diseases. His doctoral thesis focused on such diseases, and he collected many *Escherichia coli* specimens from around the world. After making good money during the dot-com boom, he set up Viajes BioTech Inc. in San Diego, United States, to build on his Ph.D. research with the primary purpose of alleviating the suffering of the many millions of travelers to the developing world.

The Research To-Date

E. coli heat-labile enterotoxin (LT) is composed of catalytic A and noncatalytic homo-pentameric B subunits and causes diarrheal disease in humans and animals. In order to produce a nontoxic LT for vaccine and adjuvant development, two novel derivatives of LT were constructed by a site-directed mutagenesis of A subunit; Ser63 to Tyr63 in LTS63Y and Glu110, Glu112 were deleted in LT delta 110/112. Mice immunized with the purified mutant LTs (mLTs) either intragastrically or intranasally elicited high titers of LT-specific serum and mucosal antibodies. These results indicate that substitution of Ser63 to Tyr63 or deletion of Glu110 and Glu112 eliminate the toxicity of LT and both mutants are immunogenic to LT itself. Therefore, both mLTs may be used to develop novel antidiarrheal vaccines against enterotoxigenic *E. coli*.

Note that the particular strain used in this research originated from a sample collected from a *campesino* at a clinic in Pepe's grandparents' hometown, Chulula, outside San Cristobal de las Casas in the State of Chiapas. Whenever he visited his family at Christmas and Easter, Pepe would spend a few days helping in a clinic in that village. Campesinos are generally poor farm laborers.

Business Model of Viajes BioTech Inc.

The company focuses on the development and commercialization of a vaccine for diarrheal diseases that occur predominantly in developing countries but that have a significant market in developed countries among travelers for both business and leisure.

Viajes Biotech Inc. counts some 50 highly trained staff and has laboratories able to produce nonGMP pilot lots of the vaccine but has no clinics or production facilities.

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Box 1 (continued)

The company owns the key intellectual property for the vaccine in the form of a single dominating patent (but a series of *continuations in part* are still at the patent office in the United States). Pepe still has another two months to file for (PCT Patent Cooperation Treaty) applications in foreign jurisdictions, having marked all possible boxes in the application. Money, however, is relatively tight, and it is not clear whether the expense is warranted.

Because the infections are extremely rare in most developed countries, it is difficult to test the vaccine in those countries. Thus Viajes BioTech Inc. is seeking a partner in the developing world to assist in the clinical trials. Pepe, having lived the first 25 years of his life in Mexico, also wants to find a way to extend the benefits of the vaccine to people in the developing world.

During his recent vacation trip over Christmas to the South African vineyards, Pepe visited a former fellow student of his, Koreen Ramessar, who works on muscular dystrophy at the Department of Human Genetics at the University of Cape Town medical school. Koreen heard of the advances her classmate had made with his vaccine and introduced him to the director of IIMR, the International Institute of Medical Research in Colombo, Sri Lanka. The current director, D.C. Mokhobo, is originally from Cape Town and was visiting her family over the festive season.

Pepe and Dr. Mokhobo of IIMR had dinner just before New Year's Eve and agreed, in principle, on a joint effort to develop the vaccine further whereby Viajes BioTech would focus on introducing the vaccine into developed countries, and IIMR, through appropriate partnerships, would focus on developing countries.

The International Institute of Medical Research, IIMR

IIMR is an autonomous international nonprofit organization headquartered in Colombo, Sri Lanka. It maintains a network of laboratories and research centers hosted by a series of leading research institutions across the developing world. The institute also carries out research, teaching and training in its facilities. The entity does not have its own clinics but arranges for clinical studies through collaborating centers in developing countries.

Tasks

General

To develop a framework agreement between a public (IIMR) and a private entity (Viajes BioTech Inc), sketching the outline of a business plan, with particular focus on the IP strategy, incorporating all the available tools, as appropriate.

The Teams

Pepe and Dr. Mokhobo each requested the relevant people in their institutions to work out the details on how the scheme could be made to work to benefit both parties. Two teams were created:

- One team represents the business development and marketing side of Viajes BioTech Inc.
- Another team represents the R&D program of IIMR and also includes the deputy director for International Cooperation.

The Specifics

First, meet in your own team for 60 minutes to determine the issues that need to be addressed. Specifically, think of the ***needs*** of your entity to ensure that the primary policy of the entity is

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Box 1 (continued)

respected in the deal. Also think of the needs of the other party. For example, Viajes BioTech must find a way of making a return on its investment. IIMD, on the other hand, does not sell things and will need to think of marketing alliances and licensing, as well as obtaining the funding to conduct the work.

Second, the teams meet together and compare ideas, issues, and approaches. Note that this is *not* primarily a negotiating exercise. Begin by developing the overall business plan for how the vaccine would be tested and commercialized, both in the developing and developed worlds. Then develop a coherent IP strategy that reinforces the business plan.

Remember that your bosses have made the policy decision, in principle, to get this venture going. Your task is to flesh out the framework for how it could work in practice. Hence the other party is not a hostile team but, essentially, in the same boat as you are. Also, you are not required to develop a detailed investment plan with cash flow and royalty rates; rather, the principles of the deal are to be developed.

The Assumptions

- The time required to develop the vaccine for clinical trials is 9 months.
- Clinical trials will take two years to complete if all goes well.
- The cost for clinical trials across five countries is estimated to be US$20 million.
- The cost of production for 1 million units is US$10 million. That cost could be reduced to US$5 million if produced in a high quality laboratory in India. Note that these costs do not include marketing and distribution costs, commissions, advertising, and so forth.
- The total market in the United States, Europe, and Japan for business and leisure travelers is estimated by Viajes BioTech Inc. to be approx. five million units per year in the first five years, increasing to 15 million units per year thereafter. Viajes BioTech Inc. estimates that travelers are willing to pay up to US$25 per shot/unit.
- The total market in the major cities in Asia, Africa, and Latin America is estimated to be at least 100 million units per year.
- Viajes BioTech Inc. already invested US$7.5 million in the vaccine. The next round of financing will be launched in three months and the company needs to show a sound business plan and potential for significant profits, if it is to convince its current and prospective new investors of putting up an additional US$30 million or so over the next three years.

The Report to Your Bosses

Specific issues you should address in your report (in the form of a slide presentation lasting no more than 10 minutes), should include:

- Who supplies the vaccine for clinical trials?
- In which countries outside the U.S.A. should Viajes BioTech Inc. file for patent protection? Remember that each such filing will cost some US$25,000 including translation and filing fees.
- What other form of IP protection should be sought? When, where, and why?
- Who is liable for untoward events with the vaccine in clinical trials?
- Who should own potential new intellectual property generated from the clinical trials conducted by IIMR?
- Means by which the vaccine could be (1) produced, (2) marketed, and (3) sold in the developing world.
- How will you deal with third-party technologies that may have to be licensed-in for the production of the vaccine?

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Box 1 (continued)

- Are there any issues of compensating Mexico for use of the *E. coli* strain that led to the vaccine? If so, what might they be and how could they be resolved?
- Prior review of the labeling of the vaccine for sale in any market. Include an explanation of why there should be review.

Additional Considerations

- Should your group require specific technical, strategic, and legal advice, it can be made available for a limited time. However, the external advisors will only respond to well-formulated and relatively specific questions.
- Invent whatever additional information you feel you may need, but be sure to specify such assumptions (amount of capital needed, types of IP protection sought and obtained, terms of the commercial licenses required, the way that regulatory issues are addressed, and so on). Make reasonable assumptions, given the milieu of your activities.

Box 2: Sample Workshop Plan

Objectives

- To provide quality training for sustainable knowledge and skills transfer in intellectual property management.
- To develop appropriate skills for identifying, protecting, developing, valuing, and commercializing research resources.
- To develop knowledge and skills in strategic IP management, focusing on the fundamentals of IP rights: licensing issues and negotiating joint venture agreements that seek to enhance the availability of research results for health products.

Workshop emphasis

The workshop will focus on providing participants basic/intermediate/ advanced [indicate which] level training in IP management.

Background

Many developing country institutions lack the human capital and capacity required to design and implement IP management systems that serve the IP management needs of academic institutions. Without meeting the need to provide training to personnel in IP management, the execution of IP management practices is less likely to succeed. The proposed capacity-building initiative will focus on developing learning experiences that have immediate relevance to the participant's occupation and experience, thus providing the basis for activities that lead to institutional IP management development.

Partners

Acknowledge the organizations collaborating on or sponsoring the training.

Workshop format

- Tutorial work and presentations
- Case studies and role-play
- Materials for reading and future reference

Training topics

- The fundamentals of intellectual property management. This component will provide the basic principles of intellectual property protection processes and an overview of IP regimes.
- IP strategies and methodologies. The purpose is to teach participants the approaches to negotiation, establishing agreements, licensing, technology transfer processes, and business development.
- Technology transfer management. An overview of technology management functions and strategies is provided.
- Commercialization. Provide instruction on how to develop a commercialization plan, include discussion of the key components of such a plan and guidance on aspects such as negotiation, deal structuring, and venture fund sourcing.

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Box 2 (continued)

Teaching and learning methods

The teaching techniques selected are designed to enable trainees to gain knowledge through traditional tutoring methods and from each other's experiences.

- *lectures*. knowledge transfer using conventional teaching techniques (direct instruction)
- *presentations*. "guest speakers" including IP professionals representing private and public sector industries
- *case studies*. interactive practical exercises that encourage participants to apply the knowledge they have acquired to solve complex intellectual property issues
- *role play*. exercises that expose trainees to strategies and approaches in operation in various IP management disciplines

Workshop content and curriculum

The teaching content of the workshop will be developed in consultation with key partners. The suggested agenda for a four-day workshop is presented below.

Day 1. Refresher on IP processes and regimes: An overview of IP processes

Day 2. IP management practices

- current practices and issues in IP management
- licensing fundamentals

Day 3. IP management strategies: Managing an IP portfolio

Day 4. Technology transfer strategies and commercialization

- fundamentals of technology transfer
- fundamentals of commercializing intellectual property

Training materials

- slide presentations
- case studies
- role-play supplies
- reading material
- CD of reference material and Web-based links

Accreditation

Participants will receive acknowledgement for full attendance of the training program.

Tutors

Tutors will include:

- three to four keynote speakers
- lecturers and presenters
- facilitators of interactive activities

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Box 2 (continued)

Who should attend

This training program is directed at professionals in health R&D interested in acquiring skills in IP management. The target audience includes:

- technology transfer office staff
- research managers and scientists
- senior management

Venue

Accommodation will be provided at preferential rates. Refreshments and meals will also be provided.

Costs

Participants will be required to pay their own travel costs. Participants will be required to make a single payment [or other payment plan] when registering for the workshop.

Entry limitations

Entrance will be granted to the first 20 applicants who complete registration.

Subsequent training and support

Post-workshop activities will include issues identified during the training-needs analysis and also take into account responses received following a workshop survey among participants.

Workshop evaluation

The assessment measures will be determined first by the specific objective of the workshop, and second, by the expectations of participants. Evaluation measures will include:

- relevance of the workshop to participants
- choice of tutors
- professional diversity of trainees
- duration of workshop
- balance between theory and application
- training techniques
- discussion and exchange
- documentation

Suggestions for further improvement will be sought from trainers, trainees, and observers.