Inventors and Inventions

Universities, inventors, and inventions—and by extension intellectual property—are all inextricably intertwined. Scientists are the central force behind the research, teaching, and extension missions of universities. And inventors can be considered the central force behind intellectual property, since they generate patentable inventions. Dealing with scientists, and inventors, at least from an IP management perspective, is not always straightforward or easy, but the technology transfer process and licensing are made easier if **scientists know some basics of IP management** and of patenting, and are somewhat familiar with best practices. This applies equally to high-flying attention-seekers and low-key geniuses.

A university research program must frequently make decisions about whether its researchers' discoveries should be protected. The process leading to this decision can place a tremendous strain on the relationship between the technology transfer office (TTO) and scientists. And it is one of the principal reasons why scientists should be given an opportunity, from the day they join a research institution, to learn the very basic concepts of IP management to better understand the process and the challenges faced by TTOs and TTO officers. How are decisions made as to when to patent, what to patent, and how to protect an invention? When it comes to new inventions, unclear and non-transparent procedures lead to tensions that can be costly in terms of money, time, missed opportunities, and relationships between scientists, heads of departments, and TTOs. So it is important that university leaders and administrators—and scientists—work in concert on policies and mechanisms that establish the procedures used for recording inventions, for invention disclosure, and for sharpening the interface between scientists and technology transfer and licensing offices.

Three conspicuous but usually neglected issues deserve special consideration up front. First, it is often difficult to know when an invention has actually been made. Training of scientists with respect to IP management and an institutional atmosphere that encourages inventions and invention disclosures are essential for making the most of scientific endeavors. Second, inventors need to have a clear understanding of their rights—and responsibilities—when it comes to their inventions. Unrealistic expectations that are either too high or too low will get in the way of optimally productive research and can be a source of conflicts with TTOs. Third, **inventions, per se, are not necessarily innovations, though they may become innovations**.[1]

The section's opening chapter by Mutschler and Graff[2] provides essential information that university scientists and inventors need to know in order to manage new and existing intellectual property and to deal with TTOs. University

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 8: Inventors and Inventions. In *Executive Guide to Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Krattiger A, RT Mahoney, L Nelsen et al.). *bio*Developments-International Institute (Ithaca, USA), MIHR (Oxford, UK), PIPRA (Davis, USA), and Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil). Available online at www.ipHandbook.org.

faculty and scientists anywhere need a working knowledge of what intellectual property is and what can be done with it so that they are able to make decisions about their laboratories' IP issues. These issues range from how to start and run a research program (from an IP management perspective), how to handle new inventions produced by that research, and how to manage the property of their collaborators. Graduate students and postdoctoral scientists should also acquire a basic understanding of intellectual property, since this knowledge will be valuable to them no matter what their future careers hold, whether in government, academia, non-governmental organizations, or industry.

Universities typically have—or should have—**institutional IP policies** that must be complied with by all personnel. In the United States, these IP policies must conform to the guidelines outlined by the Bayh-Dole Act of 1980. This act was intended, among other purposes, to promote private sector investment in federally funded research to facilitate the transfer of federally funded research to industry. For these reasons, university employees in the United States must sign agreements that state that all intellectual property generated under the university's aegis belongs to that university (though an inventor is typically given a share of the revenues that come from the sale of any intellectual property that he or she generates). One major exception to the policy of assigning IP rights to the university, however, is copyrighted material (books, papers, drawings, paintings, sculptures, and so forth).

A university's **IP office or TTO** is typically responsible for protecting and developing commercial applications (including out-licensing patents) for inventions developed at the university. Its functions typically include:

- determining the most effective way to protect inventions
- evaluating the commercial potential of inventions
- obtaining the appropriate protection for inventions
- locating suitable commercial-development partners and marketing inventions to them
- negotiating and managing IP licenses
- encouraging and assisting the formation of new companies around university-generated intellectual property (start-ups)

In addition to briefly reviewing the above, Mutschler and Graff familiarize scientists with issues they face on a daily basis:

- how to deal with confidential information
- how to deal with materials from third parties
- what constitutes a public disclosure of scientific finding
- how the patenting process works
- understanding the basics of intellectual property

If scientists read only one chapter in the entire *Handbook*, Chapter 8.1 is the one they should read. But on a daily basis, a scientist's responsibility goes further than having a basic understanding of IP management. For authoritative IP management, university faculty, staff, and students need, at a minimum, to appropriately document their research findings, use of intellectual property not owned by the university, dealings with collaborators outside the university, and places and times of public disclosures of research results. **Good record keeping** is not only important for preparing publications, reports, and grant proposals, it is also essential for preparing IP-protection documents and supporting IP rights. Universities must be very careful when they use materials and methods that do not belong to them, in order to avoid infringing on the property rights of others. In a worst case scenario, third-party materials may be used in research, which would mean the new intellectual property generated through use of that material would belong to that third party. Ownership would depend on how the material was obtained. Issues related to ownerships (material transfer agreement) are discussed elsewhere.[3] But irrespective of the terms of access, good record keeping in general and laboratory notebooks in particular are essential to possibly later disentangle ownership issues.

Scientists should be familiar with the **ins-and-outs of keeping a laboratory notebook to document research**. As a matter of institutional policy,

the contents of laboratory notebooks should be treated as confidential and valuable. Notebooks should be stored in a safe place and any loss or theft should be reported immediately. A laboratory notebook is owned by the institution where work is conducted (essentially by the employer of the scientist). Therefore, when a scientist leaves an institution permanently, he or she should be required to turn notebooks over to supervisors (though copies can generally be kept by departing scientists).

Thomson,[4] a scientist herself, shares the practical aspects of laboratory-notebook keeping and her chapter offers a sample policy. Crowell[5] examines the entire range of invention documentation. It cannot be overemphasized how important is good documentation of research. It is a critical component of best practices in IP management for the following reasons:

- Well-kept laboratory notebooks are one of the most important *sources of documentation*. A laboratory notebook should contain detailed records of every experiment that has been planned or executed (including the date it was performed), the reasons for performing it, the methodology used in performing it, the results of the experiment, and the significance of the results.
- Laboratory notebooks are important instruments of *institutional memory*. Laboratories invariably have high personnel turnovers: scientists move on, post docs move up, students graduate, and technicians are promoted.
- Consistent documentation is important to *determine patentability*, and may even be essential for determining inventorship, for drafting and prosecuting patent applications, and (if necessary) for protecting patents from third-party challenges such as prior-art challenges and (in the United States) patent-interference proceedings.

Once scientists think they may have patentable inventions, they should file an **invention disclosure** to their TTO. McGee[6] examines the entire invention-disclosure process from a practical and logistical point of view and stresses the importance of involving inventors throughout the protection and commercialization process. He discusses how IP professionals can best work with inventors to develop high-quality invention disclosures. An invention disclosure is a description of something novel and nonobvious that would allow anyone of ordinary skill in the corresponding art to reproduce the invention. It may be simple in scope and include most details in an attached draft of a scientific paper (McGee also notes, quite appropriately, that carefully kept laboratory notebooks can be used in place of an invention disclosure). Importantly, an invention disclosure irrefutably establishes the date and scope of an invention, as well as the identity of the inventor(s). Disclosures are essential for managing intellectual property, preserving IP assets, "harvesting" inventions and securing IP protection for those assets, and eventually translating the inventions into innovative products or services.

Thus, an invention disclosure is the beginning of what is sometimes a long but often rewarding process that can benefit the institutions where the disclosures are made, the society at large, and the inventors in particular. ■

All chapters refer to: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. 2007. A Krattiger, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez, and SP Kowalski (eds.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org. The online version contains for each chapter a detailed Editor's Summary, Implications, and Best Practices.

1 See, also in this *Executive Guide*, part 9: Evaluation and Valuation of Technologies.

2 Chapter 8.1 by M Mutschler and GD Graff titled Introduction to IP Issues in the University Setting: A Primer for Scientists, p. 747.

3 See, also in this *Executive Guide*, part 7: Contracts and Agreements to Support Partnerships.

4 Chapter 8.2 by JA Thomson titled How to Start–and Keep–a Laboratory Notebook: Policy and Practical Guidelines, p. 763.

5 Chapter 8.3 by WM Crowell titled Documentation of Inventions, p. 773.

6 Chapter 8.4 by DR McGee titled Invention Disclosures and the Role of Inventors, p. 779.

PROCESS FOR GOVERNMENT POLICYMAKERS

- ✔ People and institutions typically look after their possessions in a much more serious manner than if they have no stake in them. This is applicable to physical property and to intellectual property. For this reason, governments should consider enacting legislation or, as appropriate, implementing **policies that clearly spell out how public sector institutions can protect, own, and license inventions** made in their institutions. This equally applies to government research centers and to universities.

- ✔ Arguably, the minds of scientists operate differently from those of lawyers, politicians, bankers, and policymakers. Similarly, those engaged in managing the intellectual property in public sector institutions face different challenges than the scientist-inventors. These differences can be the source of much tension, but such tension can often be preempted if **scientists are given an opportunity to learn the basics of IP management**, including best practices, in terms of data and information management related to inventions. Public sector institutions should have the resources to offer limited, but essential, training to every scientist when they join an institution.

- ✔ Such training programs can be given as a series of short seminars or even half-day orientation courses. These are most effective if the institutions have clear IP policies that include matters related to ownership of inventions, the **duty to disclose inventions**, and **laboratory notebook keeping**. The latter is common practice in any private sector R&D center. Comprehensive research records are fundamental to best practices in science, IP management, and in the regulatory process.

FOR SENIOR MANAGEMENT

(UNIVERSITY PRESIDENT, R&D MANAGER, ETC.)

- ✔ People and institutions typically look after their possessions in a much more serious manner than if they have no stake in them. This is applicable to physical property and to intellectual property. For this reason, **work with your governments to implement policies** (or enact legislation, as appropriate) that clearly spell out how public sector institutions, including government research centers and universities, can protect, own, and license inventions developed at your institution.

- ✔ Arguably, the minds of scientists operate differently from those of lawyers, politicians, and university presidents (although many a president is a former scientist). Similarly, those engaged in managing intellectual property in public sector institutions face different challenges than do scientist-inventors. The differences can be a source of much tension, but such tension can be preempted if **scientists are given an opportunity to learn the basics of IP management**, including best practices, in terms of data and information management related to inventions. Public sector institutions and companies alike should offer and require limited, but essential, training to every scientist, student researcher, and technician when he or she joins a research program.

- ✔ Such training programs can be provided as a series of short seminars or even half-day orientation courses. And they are most effective if the institutions have clear IP policies that include matters related to ownership of inventions, the **duty to disclose inventions**, and **laboratory notebook keeping**. The latter is common practice in any private sector R&D center. Comprehensive research records are fundamental to best practices in science, IP management, and in the regulatory process.

- ✔ University faculty, staff, and students do not have to become IP experts. The IP management training programs is best offered by the technology transfer personnel that will be interacting with scientists rather than by lawyers and outside consultants can be useful facilitators. Part of the aim of such training is **team building** that encourages communication between the scientists, technology transfer personnel, and senior management. It is part of creating a culture of IP awareness.

- ✔ Many scientists at public institutions often do not (initially, at least) appreciate the importance of laboratory notebooks and documentation protocols. For private sector R&D centers, this is done as a matter of routine. Some argue that good laboratory notebook practices lead to better science. **Laboratory notebooks** surely lead to better invention disclosures, prevent fraud, clarify inventorship, facilitate patent applications, and ultimately, pay off for individuals and institutions in the long term.

- ✔ If an invention is protected, then much can be gained if inventors are actively involved in all phases of the protection and marketing of their inventions. Inventors not only have intimate knowledge of their inventions; they may also have useful leads and contacts in companies or have ideas about how an invention could be incorporated into existing products or services. The practice of occasional seminars by technology transfer personnel for scientists is a practice that will **strengthen the interest and involvement of scientists** in this process.

FOR SCIENTISTS

- ✔ **IP management is an important element in facilitating the translation of research** into useful products or services that benefit your community and country.

- ✔ Encourage your technology transfer office (TTO) to organize **occasional seminars on the basics of IP management**. Ideally, your institution should provide an IP management primer when you join the institution that will help you understand the basic elements of IP protection and smooth the interface with your TTO. Even if you have taken such primers or seminars before, attend those offered by your new employer and encourage those in your group to do so as well. This will facilitate communication with your TTO staff and answer your questions about IP management.

- ✔ One potentially controversial issue faced by many TTOs involves keeping **laboratory notebooks**. For private sector R&D centers, this is done as a matter of routine. Make it a habit to use laboratory notebooks, as doing so can lead to better science and easier invention disclosures and can facilitate patent applications.

- ✔ **Good practices in laboratory notebook keeping** should include the signing of each page by a supervising scientist, occasional spot checks, and the setting aside of time for recording experiments and results. This applies to research assistants, students, post docs, and everyone else working in a laboratory.

- ✔ **Good record keeping** is important. It includes linking research proposals with material transfer agreements, publications, invention disclosures, and so forth. It promotes both scientific goals (it facilitates the writing of publications and grant proposals) and legal goals (good records make it easier to obtain and defend patents).

- ✔ Good record keeping goes beyond publications and IP management. Especially in institutions dealing with the **development of products** and clinical trials in health, or biosafety research in agriculture, record keeping may be essential for providing regulators the necessary evidence that good laboratory practices have been followed and may underpin regulatory filings. In many cases, experiments conducted years before regulatory filings can become valuable for those filings and, unless laboratory detailed notebooks were kept, experiments may have to be repeated at great cost and may also delay filings.

- ✔ Invention disclosures are the first step in protecting intellectual property. **Disclose early and often**. Rather than wait until your scientific paper is accepted, make it a habit every few months to think what might be disclosed and what should be disclosed, and then disclose it. But expect only a small portion of your invention disclosures to lead to patent applications.

- ✔ **Recognize when you actually have an invention**. Often, it is much earlier than you think. By filing an invention disclosure with your TTO, you are initiating a dialogue. Even if the TTO does not immediately file a patent based on your first invention disclosure, it is a process that has started, and follow-up invention disclosures will be much easier.

- ✔ Ideally, you should **invite your TTO liaison to visit your laboratory occasionally** and discuss with you and your research team what you have been doing. Discussions with technology transfer experts, especially patent attorneys, can help you to identify inventions.

FOR TECHNOLOGY TRANSFER OFFICERS

- ✔ Arguably, the minds of scientists operate differently from those of bankers, politicians, and licensing executives. Similarly, those engaged in managing intellectual property in public sector institutions face different challenges than do scientist-inventors. The differences can be a source of much tension, but such tension can be preempted if **scientists are given an opportunity to learn the basics of IP management**, including best practices, in terms of data and information management related to inventions. Public sector institutions and companies alike should offer and require limited, but essential, training to every scientist, student researcher, and technician when he or she joins a research program.

- ✔ Such training programs can be provided as a series of short seminars or even half-day orientation courses. And they are most effective if the institutions have clear IP policies that include matters related to ownership of inventions, the **duty to disclose inventions**, and **laboratory notebook keeping**. The latter is common practice in any private sector R&D center. Comprehensive research records are fundamental to good research practices in science, IP management, and regulatory areas.

- ✔ University faculty, staff, and students do not have to become patenting experts. Keep any such training programs simple and practice oriented. Generally, the intricacies of patenting legislation is not what motivates a scientist; rather, it is a vision of how his or her invention can eventually make a difference in people's lives. The IP management training programs should thus be practical and offered by technology transfer personnel that will be interacting with scientists rather than by lawyers. Contractors can be useful as facilitators. Part of the aim of such training is **team building** that encourages communication between your office and the scientists in your institution. It is part of creating a culture of IP awareness.

- ✔ It is good practice to **include senior management as participants** in the training sessions. This is especially useful when the training program includes case studies.

- ✔ Prepare simple brochures and Web sites that encourage scientists to contact you with their questions and inventions. Similarly, make an effort to attend seminars given by the researchers in your organization. It is a great way to show your interest in their activities and to build a good understanding of what the researchers actually do. Overall it helps to **get scientists involved in all phases of protecting and marketing their inventions.**