

## Monitoring, Enforcement, and Resolving Disputes

Intellectual property is not a static asset. It is dynamic, requiring ongoing attention and management practices that will allow an institution to protect its value and maximize its utilization. Treating intellectual property as such is a fundamental best practice, regardless of whether an institution is public or private, whether located in a developed or developing country or whether its mission is directed toward commercial or public interests. Intellectual property, if it is to be an asset, cannot be simply be shelved and left alone, or even licensed and then left alone. Intellectual assets, with patents, as a particularly cogent example, must constantly be managed, monitored, maintained, and policed as part of a continual “cultivation” of IP rights.

The larger the IP portfolio, the greater the likelihood that disputes of one sort or another will arise. Few disputes end up in litigation, as there are many options and strategies for resolving disputes. Particularly in the context of partnerships between entities in developing and developed countries, litigation would be a complicated, time consuming, expensive, and risk-laden process. As Part 7 on contracts and Part 11 on licensing demonstrated, good contracts and good licensing practices anticipate that disputes arise with partnerships and licenses. But the best way to avoid disputes is to manage agreements in a manner that leads to effective resolution of disputes.

Feindt<sup>1</sup> details how the Office of Technology Transfer (OTT) of the National Institutes of Health (NIH) administers its technology licenses. Licensing is an important part of NIH’s operation and an important part of any technology transfer endeavor anywhere. The portfolio of licenses at OTT includes over 1,400 active technology licenses, 750 of which generate about US\$100 million in revenues.<sup>2</sup> These licenses represent five types of technology licenses:

1. Commercial evaluation licenses (also known as options), which enable companies to provisionally evaluate whether a new technology suits their needs
2. Patent commercialization licenses, which provide access to rights in patented or patent-pending technology. These licenses can be either:
  - a. Exclusive, providing a single licensee with the right to practice the patent
  - b. Nonexclusive, providing patent rights to, potentially, multiple licensees
3. Nonexclusive patent licenses for internal use, which provide access to tools or processes, useful for research purposes
4. Biological materials licenses, which provide access to nonpatented biological materials
5. Software licenses, which provide access to nonpatented software

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Although the above licenses differ as to the types of technology licensed, the specific terms of the license, and the reporting obligations, one aspect remains consistent: every license is written with well-defined financial terms and clearly delineated reporting obligations.

As a licensor, the NIH OTT administers, monitors, and enforces its technology licenses. It accomplishes this by monitoring licensee compliance with royalty payments and reporting obligations throughout the term of the license. Typically this is not a confrontational relationship. Instead, the NIH OTT seeks to build cooperative relationships with its licensees that, in turn, facilitate problem-solving discussions, resolve outstanding issues, and identify possible opportunities for advancing commercialization of products and/or services pursuant to the technology license.

In practical terms, OTT maintains licensee contact lists (people within the licensee organization) as they are important when royalty payments or issues of noncompliance need to be addressed. Such a list, and a certain level of personal rapport, greatly facilitate communication and save much time. Another essential operational procedure is maintenance of a well-organized filing system, possibly with archival, working, and computer files. A computer filing system can be structured as a searchable database for license administration, with integrated interactive modules organizing data on contracts, inventions, patents and license applications, royalties, receipts, and reporting. (Such a database is available for download free of charge from the online version of the *Handbook*.)<sup>3</sup> Many of the best practices listed and discussed by Feindt relate to licensees' reporting obligations, to amendments to license agreements, and to sanctions for noncompliance. Amendments reflect mutually agreeable changes in the expectations of licensor and licensee that occur with the passage of time and changing circumstances; they might involve term extensions, royalty adjustments, or changes in the field of use. Sanctions, on the other hand, are unilateral actions by the licensor that are triggered by licensee noncompliance (and may include a threat of license termination and even legal action in order to enforce lapsed financial obligations).

A different type of dispute is that of patent infringement. Patent infringement is, at least conceptually, analogous to trespass in that it is an invasion and/or misappropriation of another party's exclusive property right. Hence, identifying and taking action to remedy infringement is an essential part of IP asset management. There are four main categories of patent infringement:

1. *Literal infringement*, in which each and every element of a patent claim is found in the alleged infringing product or process
2. *Doctrine of equivalents infringement*, in which the alleged infringing product or process is substantially the same as the patented product or process
3. *Contributory infringement*, in which a party contributes to infringement of a patent by selling a component that has no use other than as part of a patented product
4. *Inducement to infringement*, in which a party actively and knowingly aids and abets another who is directly infringing a patent

Maintaining the integrity and value of public sector intellectual property is, as Haeussler<sup>4</sup> points out, a strategic process, which will vary somewhat depending on the category of infringement. First, it is important for a patent applicant, public or private, to consider claim structure and scope when drafting and filing patent applications. Unless the claims of a patent are sufficiently broad so as to confer clear economic potential, prospective licensees will be reluctant to enter into commercialization agreements or partnerships. Second, it is important to stay vigilant, establishing surveillance protocols **for possible infringement of patents**. For example, inventors should be contacted, on a regular basis, and asked if they know of anyone who is, or might be, infringing their patents; in addition, technology transfer staff members should regularly review key media related to the technology in order to watch for potential infringers. Surveillance is not only sound business practice but is essential for maintaining and preserving patent rights. For example, lack of enforcement can lead to a loss of patent rights.<sup>5</sup>

Patent infringement can also lead to a lawsuit. And litigation is expensive, risky, uncertain and often protracted. With good negotiation, a settlement through modified license terms often can be amicably reached. If litigation becomes inevitable, then a series of questions need to be addressed including whether to use in-house or external counsel, whether to file suit based on patent infringement or breach of contract, and where to file the lawsuit. Importantly, credible communication that the IP owner is serious about protecting its IP assets will go a long way to bringing infringers to the table to discuss the issues and to negotiate. Haeussler concludes that early communication with potential infringers, and good license and licensee diligence, are the foundations for policing and maintaining intellectual property, irrespective of whether the intellectual property is owned by a public or a private entity. Feindt, in his chapter, illustrates the importance of early communication with infringers using examples from NIH.

Due to the costs—and risks—associated with litigation, alternative dispute resolution procedures, such as mediation and arbitration, should under many scenarios be attempted first. These forms of dispute resolution do not work through formal legal systems, but are instead set up by the parties involved. They are established by dispute resolution clauses articulated when a partnership is set up or a license granted—before any problems have arisen. The goal is to have an already agreed-upon system when difficulties arise.

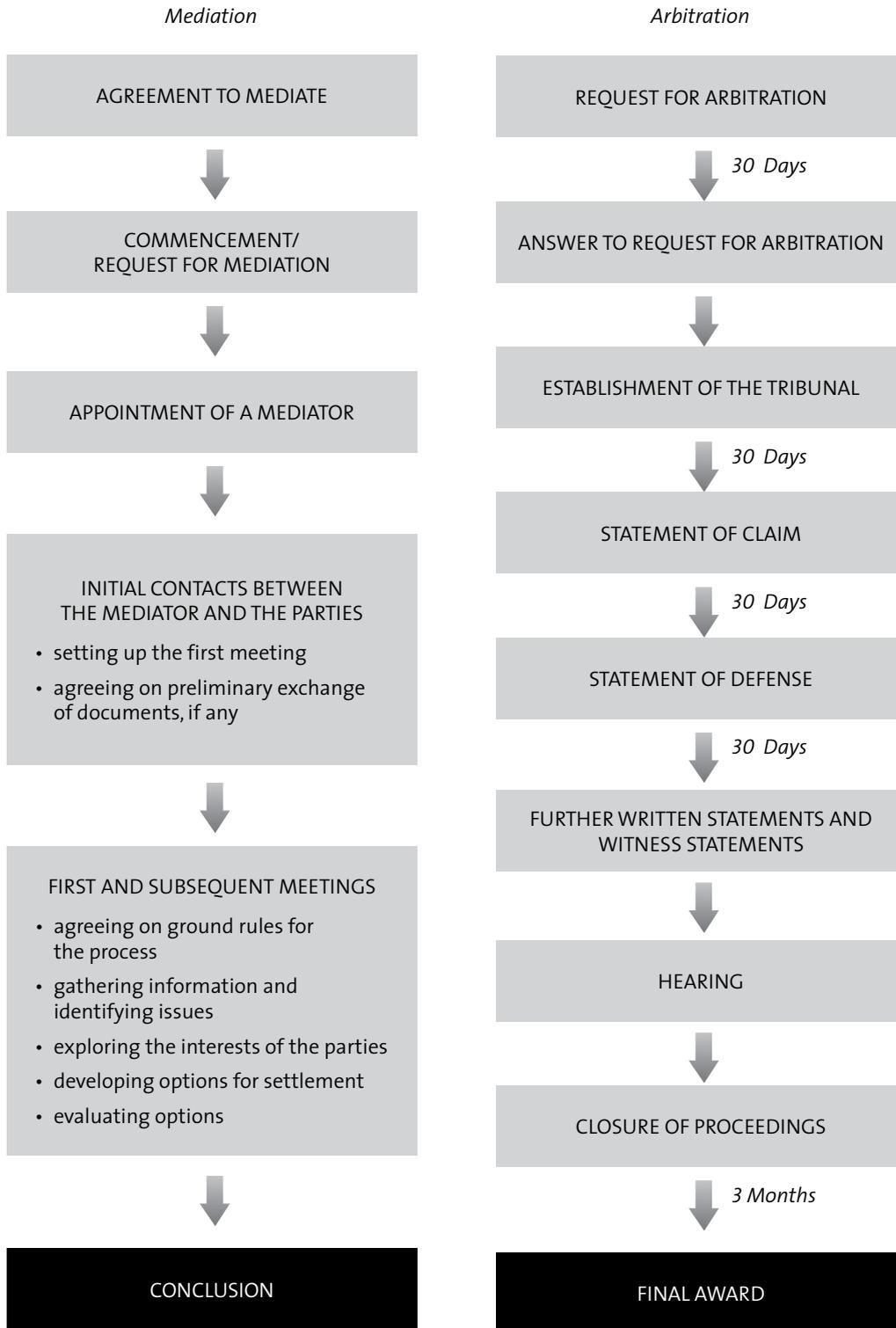
There are several elements unique to arbitration and mediation that can help parties resolve disputes as Min discusses in detail.<sup>6</sup> Figure 1 shows the two processes side-by-side. For arbitration, the parties have the power to decide on the number of arbitrators, the type of arbitration (ad hoc or institutional), the place of arbitration, the language of arbitral proceedings, and the applicable substantive law. Unlike judges, whose powers are defined by national laws, an arbitral tribunal's powers are limited to those conferred by the parties. Mediation involves the same kinds of choices, although unlike a judge or an arbitrator, whose mandate is to issue a binding decision or award, a mediator does not have the power to

impose a settlement on the parties. Instead, the mediator serves as a catalyst for party negotiations. The advantages of arbitration and mediation include the following:

- Through arbitration or mediation, the parties can, using a single procedure, resolve disputes involving intellectual property in a number of countries.
- In both arbitration and mediation, parties may resolve a transnational dispute on neutral territory.
- Arbitration and mediation are based on the consent of the parties.
- Parties can select arbitrators or mediators.
- Parties to arbitration or mediation can keep the proceedings and any results confidential.
- The protracted nature of litigation, which pushes parties into multiple rounds of appeals, is a common problem when litigating transnational disputes. The end result of arbitration, however, is a final, binding award.
- The mediator's role is to broaden dispute resolution options, allowing the parties, with the help of the mediator, to craft innovative, common-sense solutions that (preferably amicably) settle the dispute.
- Mediation involves low risk. If a party feels that it is not making any progress, that the procedure is becoming too costly, or that the other party is not acting in good faith, the party may withdraw from a mediation process at any time and seek to resolve the dispute through litigation or arbitration.

Min provides a list of the kinds of concerns addressed by dispute-resolution clauses. She also highlights the usefulness of arbitration and mediation for developing countries, but public sector entities in many parts of the world will find the discussion, and these tools, useful. Such entities often lack the resources to pursue extended litigation, a process that also frequently places them on unfamiliar cultural and legal ground. By formulating dispute resolution policies, institutions in developing countries can place themselves in a fairer, less expensive, and less antagonistic forum for resolving disagreements.

**FIGURE 1: PRINCIPAL STEPS IN A TYPICAL MEDIATIONS AND (WIPO) ARBITRATIONS**



Source: Min7

Finally, the chapter discusses extensively the activities and services of the **Arbitration and Mediation Center**, which functions under the World Intellectual Property Organization (WIPO).

A different type of dispute may emerge under **parallel trade** practices (involving “gray market” imports). As Matthews and Munoz-Tellez write,<sup>8</sup> parallel trade occurs when products produced under the protection of a patent, trademark, or copyright in one market are subsequently exported to a second market and sold there without the authorization of the local owner of the IP right. Often, the local owner of the IP right will also be a local dealer who, through a license or other exclusive agreement, has been authorized by the patent, copyright, or trademark holder to market the protected product. Naturally, when the licensed dealer has an exclusive agreement, he or she expects to be the only party supplying the product in the local market. Importantly, parallel trade does not refer to the trade of pirated or counterfeit products. These are unauthorized versions of products that infringe an IP right. Parallel imports, on the other hand, are imports of genuine, often branded, products that do not violate an IP right per se, but importing the product will not have been authorized by the right holder.

Engaging in parallel trade is a legal option provided within the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). The Doha Declaration reaffirmed that developing countries can use parallel imports to support public health. Such countries can obtain access to lower-priced patented and/or branded products, such as medicines and basic agricultural inputs, by incorporating legislation to allow for parallel imports. TRIPS permits member states of the World Trade Organization (WTO) to design their own *exhaustion of patent rights* regimes. Hence, the state’s legal framework for parallel trade is based on its own exhaustion of patent rights doctrine:

- *national exhaustion*, whereby the exclusive rights of patent holders cease only after the first sale of a product within the national borders (parallel imports can be blocked at the border)
- *regional exhaustion*, whereby the exclusive rights of patent holders cease after the first sale in the regional market (parallel trade permitted within the regional group)
- *international exhaustion*, whereby the exclusive rights of patent holders cease after the first sale in any market (parallel trade permitted)

The chapter focuses on how parallel trade can provide developing countries with greater access to medicines and to basic inputs for agricultural production (such as pesticides and fertilizers) at lower prices.

Thus, developing countries can incorporate into their national laws the principle of international exhaustion of rights, thus allowing for parallel imports on an international scale. In other words, developing countries can decide whether or not to allow parallel importation for all or particular IP rights.

Although parallel trade has obvious benefits for developing countries, there are also potential disadvantages. For example, the chapter notes that parallel trade might:

- reduce incentives for investment in the pharmaceutical and agricultural sectors
- reduce the incentives for rights holders to donate products at low cost or free of charge to developing countries due to fear of re-importation elsewhere
- reduce the willingness of rights holders or licensed local owners to supply particular markets

When implementing measures to facilitate parallel trade, developing countries should ensure an effective system by adequately regulating the quality and safety of parallel imports. At the same time, they need to prevent low-priced patented products in developing countries from entering high-priced developed country markets. Otherwise, patent holders, particularly in the pharmaceutical industry, could be discouraged from pricing their products differently in different markets in order to benefit developing countries. The chapter offers model legislative provisions to enable parallel imports and concludes by urging

policymakers in developing countries to promote access to medicines and to support poor farmers by fully utilizing the parallel trade options available under TRIPS. ■

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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](http://www.ipHandbook.org). The online version contains for each chapter a detailed Editor's Summary, Implications, and Best Practices.

- 1 Chapter 15.1 by HH Feindt titled Administration of Technology Licenses, p. 1395.
- 2 Although impressive, such revenue flow is not the OTT's principle mission. Rather, by instituting and running an organized and professional office, the NIH furthers its mission of a timely introduction of new products and technologies into the marketplace. In this way, the fruits of NIH research and development are made commercially available, fostering economic development and serving the greater public good through the introduction of critical advances in health care. Furthermore, the NIH OTT fully recognizes that potential licensees will be from both developed and developing countries, such that the range of beneficiaries is truly global in scope.
- 3 This database has been provided by the Whitehead Institute for Biomedical Research. See also Chapter 6.12 by A Hamzaoui titled WIIPS™: Whitehead Institute Intellectual Property System (A Relational Database for IP Management and Technology Transfer), p. 649.
- 4 Chapter 15.2 by HW Haeussler titled Policing Intellectual Property, p. 1405.
- 5 This may happen pursuant to two defenses in equity: (1) *laches*, when the patentee waits too long (an inexcusable delay) before taking action against a presumed infringer and (2) *equitable estoppel*, when the presumed infringer, relying on actions or communications from the patentee, reasonably believes that he or she can practice the patented product or process.
- 6 Chapter 15.3 by EJ Min titled Alternative Dispute-Resolution Procedures: International View, p. 1415.
- 7 *Ibid.*
- 8 Chapter 15.4 by D Matthews and V Munoz-Tellez titled Parallel Trade: A User's Guide, p. 1429.



## FOR GOVERNMENT POLICYMAKERS

- ✓ A fundamental best practice in IP management, regardless of whether an institution is public or private and whether located in a developed or developing country, is to view **intellectual property as an evolving and dynamic asset** requiring ongoing attention, management, monitoring, and policing. Only such an “IP cultivation” will allow institutions to protect the value and utility of the intellectual property.
- ✓ A country’s statutory code, combined with a reliable system of **fair adjudication and judicial enforcement**, is the requisite basis for enforcing institutions’ IP rights. Supporting policies that promote this legal infrastructure is essential.
- ✓ **Court action** is often stymied because of cost, length of procedure, legal uncertainty, the decision maker’s lack of expertise, confidentiality/publicity, the difficulty of seeking action in foreign jurisdictions, and the negative impact on existing business relationships. But public and private institutions alike should always have the flexibility to opt for court action if this seems to be in their best interests.
- ✓ Policymakers should strive to promote policies and advocate for laws that encourage **alternative dispute resolution procedures** as the best alternatives for settling differences between parties to an agreement. These procedures are particularly important in international contract dispute resolution.
- ✓ Governments and public institutions can help make arbitration or mediation procedures accessible and available by identifying and supporting neutral institutions that can provide cost-efficient, timely dispute-resolution services. The World Intellectual Property Organization offers such services through the **WIPO Arbitration and Mediation Center**.
- ✓ Pursuant to the TRIPS Agreement and the Doha Declaration provisions on parallel trade, countries can **implement patent rights exhaustion regimes** that either permit or restrict **parallel importation**. As a result, developing countries can decide whether or not to allow parallel importation for all or for particular IP rights. Despite the evident benefits of parallel trade, there are also disadvantages, and both the benefits and the risks should be carefully considered. (Drawbacks of broad parallel importation practices include the reduction in incentives for investment in the pharmaceutical and agricultural sectors and the reduction in incentives for rights holders to donate products at low cost or free of charge to developing countries due to fear of re-importation to lucrative developed country markets. Re-importation hinders the ability of governments in different countries to maintain price controls on pharmaceutical products within their territory and reduces the willingness of rights holders or licensed local owners to supply particular markets.)

*Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.*



## FOR SENIOR MANAGEMENT

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

- ✓ A fundamental best practice in IP management is, regardless of whether an institution is public or private and whether located in a developed or developing country, to view **intellectual property as an evolving and dynamic asset** requiring ongoing attention, management, monitoring, and policing. Only such an “IP cultivation” will allow institutions to protect the value of intellectual property and maximize its utility.
- ✓ Your institution’s technology transfer office should have systematic procedures to **administer, monitor, and enforce** its technology licenses. This includes compliance with royalty payments and reporting obligations in a nonconfrontational manner.
- ✓ Public and private institutions alike should always have the flexibility to opt for **legal action** if this seems to be in their best interests. But legal action is often stymied because of cost, length of procedure, legal uncertainty, a decision maker’s lack of expertise, confidentiality/publicity, the difficulty of seeking action in foreign jurisdictions, and the negative impact on existing business relationships.
- ✓ Encouraging **alternative dispute resolution procedures** can be a viable strategy and, indeed, often a preferred one, for settling differences between parties to an agreement. These are particularly important in international contract dispute resolution.
- ✓ Public sector institutions should have an **institutional policy on the use of arbitration and mediation**.
- ✓ Public institutions can help make arbitration or mediation procedures accessible and available, by identifying and supporting neutral institutions that can provide cost-efficient, timely dispute resolution services. The World Intellectual Property Organization offers such services through the **WIPO Arbitration and Mediation Center**.
- ✓ Where permitted by national legislation, **parallel importation** may provide universities and public sector research institutes with lower-cost access to legitimate imports produced in other markets.
- ✓ For universities and research institutes in particular, **parallel importation may have substantial benefits** as it allows for the lower-cost import of copyrighted products (books, computer software, periodicals, and related products). Hospitals may also benefit from parallel-trade imports by access to cheaper, patented pharmaceutical products. Sometimes, however, the final cost of the parallel-imported product is higher than locally supplied goods, while quality and warranty may be lower.
- ✓ But **parallel importation also has drawbacks**. These include the reduction in incentives for investment in the pharmaceutical and agricultural sectors and the reduction in incentives for rights holders to donate products at low cost or free of charge to developing countries due to fear of re-importation to lucrative developed country markets.

*Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.*



## FOR SCIENTISTS

- ✓ A fundamental best practice in IP management, regardless of whether an institution is public or private and whether located in a developed or developing country, to view **intellectual property as an evolving and dynamic asset** requiring ongoing attention, management, monitoring, and policing. Only such an “IP cultivation” will allow institutions to protect the value of intellectual property and maximize its utility.
- ✓ As a scientist, you should **regularly review** all of the agreements that relate to your projects. This specifically includes ensuring that milestones are met, royalties paid, and that any other obligations are taken care of.
- ✓ Your institution should continuously monitor **patent infringements** through various surveillance protocols. A lack of patent enforcement can lead to a loss of patent rights. Your role in this is important, since you are well connected in the area of your research and can indicate to the technology transfer office which companies might be practicing your inventions.
- ✓ Keep laboratory records and notebooks organized, ideally consistent with your institution’s **laboratory notebook policy**. These can be essential for drafting patent applications, prosecuting patents and, if necessary, pursuing litigation.
- ✓ If your institution conducts alternative dispute resolution procedures such as **mediation or arbitration**, you might be called upon to participate, particularly if aspects of your research program are involved in the ongoing discussions.
- ✓ If your university or institution is in litigation with a partner you have been collaborating with, **do not let disputes interfere with your research or your relationships with colleagues** at the other institution. Many companies litigate with other parties while, at the same time, negotiating on other licenses or joint ventures with that party. **Litigation is nothing personal** and should never influence your research collaboration. Notwithstanding this, you should always be cautious when speaking about matters related to the topic of dispute. It is best never to comment on ongoing litigation matters.

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## FOR TECHNOLOGY TRANSFER OFFICERS

- ✓ A fundamental best practice in IP management, regardless of whether an institution is public or private and whether located in a developed or developing country, is to view **intellectual property as an evolving and dynamic asset** requiring ongoing attention, management, monitoring, and policing. Only such an “IP cultivation” will allow institutions to protect the value of intellectual property and maximize its utility.
- ✓ A technology transfer office must have systematic procedures to **administer, monitor, and enforce** its technology licenses. This includes compliance with royalty payments and reporting obligations in a nonconfrontational manner.
- ✓ A TTO should **regularly review** active license agreements. This specifically includes ensuring that milestones are met and royalties paid.
- ✓ Potential **patent infringements** should be monitored continuously through sound surveillance protocols, and action taken to remedy infringement is an essential part of IP asset management. The lack of patent enforcement can lead to a loss of patent rights.
- ✓ If **litigation** seems to become inevitable, credible communication that the IP owner is serious about protecting its IP assets will go a long way to bringing infringers to the table to discuss the issues and negotiate a mutually beneficial outcome. Importantly, early communication with potential infringers and good license and licensee diligence, are the foundations for policing and maintaining intellectual property, irrespective of whether the intellectual property is owned by a public or a private entity.
- ✓ Essential to contract management is a **well-organized electronic filing system**, possibly with archival, working, and computer files with integrated interactive modules organizing data on contacts, inventions, patents and license applications, royalties, receipts, and reporting. A TTO should establish such a system as early as possible and before the number of agreements and licenses becomes large.
- ✓ The online version of the *Handbook* allows users to **download an electronic contracts-management system** free of charge.
- ✓ Most **IP disputes should not end up in litigation**, as there are many options and strategies for resolving disputes. Good contracts and good licensing practices anticipate that disputes arise with partnerships and licenses.
- ✓ **Mediation and arbitration** can be effective dispute-settlement procedures, provided they have been agreed upon and established in contract clauses at a time when a license or partnership is being negotiated—and before any problems arise.
- ✓ The success of an arbitration or mediation depends largely on the **“quality” of the arbitrators and mediators**. The challenge is often to find candidates who have arbitration/mediation skills, have experience with the specialized knowledge of the disputed subject matter, and are acceptable to both parties.

*Given that IP management is heavily context specific, these Key Implications and Best Practices are intended as starting points to be adapted to specific needs and circumstances.*