Technology and Product Licensing

Buyers want to get the most for their money; sellers want to get the most for their products. Put differently, no one wants to pay more for an item than what is necessary. And sellers expect a fair price for their products.[1] These universal pricing concerns apply not just to food, shelter, and any other goods and services, but also to intellectual property. As a licensee, how much should you pay for a license? How much should a licensor charge for a license? And what form should payments take? Royalties on products sold? Fixed payments per year? Equity in a business? Provision of services (bartering) or some other form of remuneration? And what exactly are you paying or charging for? Answers to these questions are always complex.

The chapters in this section offer some points of reference from which to explore these and other questions that emerge during **IP licensing transactions** (a license being the transfer of certain property rights between two or more parties under a specified sharing of rights *and* obligations between those parties). These considerations apply to companies and public sector institutions alike. With a *license*, as distinguished from a sale, possession of property does not transfer but remains with the original owner.

Negotiation is one way to establish the terms under which a transaction takes place. But negotiation is just one aspect of establishing the terms of a specific transaction. Preparation for a negotiation can—or should—require at least ten times more time than the actual negotiation, since the **goal of a negotiation** is to formulate an agreement that meets the needs of both the licensor and the licensee in a manner that ensures mutually beneficial future relationships between the institutions and individuals. Anticipating the other party's needs and wants, and considering alternatives for resolving possible competing interests, is just one aspect of the preparation. Price, quite often, will not be the most difficult aspect to negotiate. Other terms can be more critical and of greater relevance, and value.

The first chapter by Freeman[2] discusses the central issues that licensors and licensees need to consider before negotiating agreements. After providing an **overview of licensing in the field of biotechnology**, he considers the main components of a license agreement, highlighting concerns specific to the field of biotechnology. A license agreement will include several key components:

- The *background section* sets out the factual predicates for the license, including the names of the parties, the effective date of the agreement, and the parties' motivations and expectations.
- The *definitions section* explains key terms used in the agreement.
- The *grant section* establishes whether only the licensee may practice the invention (an exclusive license) or whether others may

Krattiger A, RT Mahoney, L Nelsen, JA Thomson, AB Bennett, K Satyanarayana, GD Graff, C Fernandez and SP Kowalski. 2007. 11: Technology and Product Licensing.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.). MIHR (Oxford, UK), PIPRA (Davis, USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil), and *bio*Developments-International Institute (Ithaca, USA). Available online at www.ipHandbook.org.

practice it. This section may stipulate rights to sublicense or rights to assign, or it may say that there are no such rights.
- The section on *fixed payments and royalties* sets out payment terms of the agreement.
- The *confidentiality section* specifies provisions for and restrictions on the disclosure of information shared between the parties.
- A section on *enforcement against infringers* specifies which party shoulders the burdens and realizes the benefits of enforcing the licensed patent against infringers. This enforcement often involves allocating the risks and rewards of the overall success of the venture.
- The *term of the agreement and termination procedures* should be fully spelled out. As with most licenses, the biotechnology license will often have a term that coincides with the patent term.

Freeman discusses a series of other points that require special attention, including the complexities of confidentiality clauses that are particularly pertinent when working with academic and public sector research institutions. Finally, to help make negotiations easier and more realistic, the chapter discusses incentives for licensors and licensees and considers some of the finer issues of developing collaborations.

Cahoon[3] addresses issues related to **agricultural biotechnology (agri-biotech) licenses**. Although these license agreements are similar in many ways to other kinds of license agreements, agri-biotech license agreements have some unique elements. The chapter explores the basic nature and purpose of a license agreement, and preferred licensing methods and terms are suggested. The chapter then turns to the complex—but highly important—singularities of agri-biotech licenses, focusing on such issues as multiple property types that cover a single technology and/or product, freedom-to-operate issues that may drive anti-royalty-stacking provisions, philanthropic and humanitarian-use clauses, and stewardship obligations. The chapter emphasizes the uniqueness of agri-biotech licenses in regard to the concept of *field of use*, which may be broadly or narrowly defined.

The complex and rapidly evolving nature of agri-biotechnology requires (at the moment) that each license agreement be tailored to the particular context in which the invention will be used. Still, such licenses do not have to be invented from the beginning, and Cahoon's chapter elucidates both the common and unique aspects of agri-biotech licensing. For practical purposes, any organization engaged in high-volume licensing will find it useful to develop its own internal template agreements[4] that are then modified and adapted to suit each special circumstance.

In addition to the more generic licensing aspects, this section of the *Handbook* contains a series of chapters that review more specific IP licensing strategies. The **in-licensing and out-licensing of plant varieties** are the two sides to the licensing equation. In-licensing of plant varieties can increase market share, building a competitive advantage by providing for customer needs. In-licensing varieties also enhances or completes a company's variety portfolio, both for in-house breeding programs (facilitating access to breeding materials) and for in-licensed varieties ready for commercial distribution. The most common reason for out-licensing varieties is for a company to maximize return on investment by allowing others to produce and sell varieties in markets that cannot be reached satisfactorily through the current marketing setup.

Importantly, the licensing of varieties is increasingly becoming more important for public sector breeding institutions. These are often funded, at least in part, by governments, and so they have a fundamental mission of serving the public interest. The same applies to the Centers of the Consultative Groups on International Agricultural Research (CGIAR). These institutions are eager to ensure that resource-poor farmers have the greatest possible access to value-added crop varieties. The central question here is how can these public sector breeding institutions provide **broad access to improved germplasm**? How can a combination of plant variety protection (PVP) and licensing accelerate the dissemination and adoption of improved varieties?

Private sector licensing expert Nilsson openly addresses plant variety licensing, sharing the

experiences and approaches of a private sector entity. Nilsson[5] illustrates how plant variety licensing is a practical tool that plant breeding companies (in the private sector) or institutions (in the public sector) use to commercialize or provide access to their products (crop varieties). Licensing also facilitates technology transfer (where technology is defined as know-how, improved germplasm, a range of breeding tools, and genes) in a simple delivery mechanism:

- the seed as a vehicle for technology transfer
- the seed itself as a commodity-embedding technology

Nilsson provides practical guidance for in-licensing and out-licensing crop varieties, with a special focus on developing countries. Because of decreased funding of public sector breeding, the seed sector is gradually being served by private companies, often small-scale and local enterprises. This has created increased demand for new varieties, and seed companies are seeking to in-licence varieties while private sector breeders may desire to out-license their varieties. Capacity for negotiating and executing license agreements, therefore, is becoming all the more critical. In an organized, detailed, and understandable fashion, Nilsson's chapter presents the fundamentals of seed licensing, emphasizing how the licensee and the licensor should focus on the practical content of a license agreement: exclusivity to plant material and territory, plant variety protection, variety trials, national registration, royalty payments, and information transfer.

The best licenses are those that recognize that relationships—like markets—are not static. An agreement should thus include sufficient flexibility for evolution. The agreement should reflect changes in the market, competitors, technology, seed legislation, and PVP laws. Enabling such flexibilities is perhaps the greatest art in drafting and negotiating variety licensing agreements.

Overall, the successful licensing of varieties is contingent on the strength of PVP legislation. A PVP framework generally supports the interests of the variety owner and the farmer, facilitates the transfer of technology, and provides incentives for further investments in the development of new plant varieties. In many countries, PVP legislation is based on the Convention of the International Union for the Protection of New Varieties of Plants (UPOV). The relevance of UPOV in accelerating access to improved varieties is its harmonization and documentation of a PVP aspect that facilitates licensing by foreign seed companies and public sector institutions alike.

Due to numerous complexities in terms of geographical, cultural, and paradigmatic distances, prospective licensors and licensees frequently spend a lot of time becoming acquainted and developing a certain level of trust. Over time, they reach a point where they are speaking the same language of contracts and licenses, and they reach a satisfying agreement. This lengthy process, however, can deter or derail licensing efforts. Companies may not wish to invest such time and energy, because even commercial licenses with entities in the developing world simply take up too much valuable management time and resources; the necessary funds for extended and repeated face-to-face meetings are simply unavailable.

A complementary approach is therefore needed—a way to bridge this communication gap and more rapidly arrive at a common language. Modern computer and Web technology might provide an answer. The chapter by Krattiger, Dodds, and Bobrowicz[6] examines the **potential of a software decision tree linked to template contract language** that allows individually customized contract documents to be generated and that could ameliorate many of the aforementioned problems. Provided that some key players agree to the basic template, an appropriate software package could improve opportunities for assembling a greater array of potential partners. A test version of such a computer-generated contract template (CoGenCo) system has been developed and could be a pragmatic step toward increased licensing of proprietary and finished varieties that may or may not incorporate proprietary technologies for input or output traits. The CoGenCo system is aimed at establishing a certain international standard license, that is, a standard that all understand and agree on. In this way, a meeting of the minds is facilitated and accelerated. A standard

license can be downloaded for free from the online version of the *Handbook*.[7]

The approach of CoGenCo is to facilitate the awarding of out-licenses of germplasm to developing country institutions, including by and for the CGIAR and national programs. Under the legally binding terms of CoGenCo-generated license agreements, several entities in a given country could compete against one another on price in poor countries but would not be allowed to compete against the patent holder in developed countries, in which revenues and the incentives for developing new varieties and new technologies would be undiminished. Under appropriate circumstances, the germplasm and/or traits could be licensed royalty free. Use of out-licensing in this way separates these fundamentally different markets and promotes access to improved germplasm and technologies, all by reaffirming various statutory protections as indispensable for successful agricultural research and development.

Moving on to other forms of IP licensing, **the licensing of trade secrets** presents an entirely different set of challenges. A trade secret (also called know-how in certain jurisdictions) is any proprietary technical or business information, often embodied in inventions, know-how, show-how, and tacit knowledge. The most common definitions agree on three requirements that should be met for enforceable trade secrets to exist. The proprietary information should be:

1. *Secret* in the sense that it is not generally known in the trade
2. *Valuable* to competitors that do not possess the information
3. The *subject of reasonable efforts* to safeguard and maintain the information in secrecy

Everyone knows that trade secrets are secret. Patents, on the other hand, require inventions to be publicly disclosed. But does this mean that these two forms of IP protection cannot be used together? The chapter by Jorda[8] argues emphatically that **trade secrets are complementary to patents**. By using both trade secrets and patents, the combined IP protection is stronger than if either one were used alone. But how is it possible to use both patents (which are publicly disclosed) and trade secrets (which are kept secret) to protect something? In practice, there is no conflict between the two. Patent applications are usually filed early during the research stage to get the earliest possible filing or priority date. The patent claims tend to be narrow to achieve distance from prior art, and the specification normally describes rudimentary laboratory experiments or prototypes and/or embryonic embodiments of an invention. The best mode for commercial manufacture and use are almost invariably developed later. The results of such later research need not be disclosed to obtain the patent on the early invention and can be kept as trade secrets.

As a practical matter, therefore, **patent licenses are most valuable when coupled with access to associated know-how**. A patent license alone is often inadequate for commercial development of a technology. This associated know-how is immensely important and should be part of licensing agreements; effective technology transfer requires not only patent licensing but also, and perhaps more importantly, trade secret licensing.[9]

Anyone engaged in product development, including developing countries in particular, will want to keep in mind that trade secret protection operates without delay and without undue cost. Patents, on the other hand, are territorial and thus expensive to obtain and maintain, and they can be acquired only in certain countries.

When considering the forms of IP protection available for plants, what usually comes to mind are PVP and utility patents. But as the chapter by Tucker and Ross[10] points out, **trademarks are an effective form of IP protection for plants and plant products**, either used alone or in combination with one or more other forms of IP rights protection. Furthermore, trademarks can be used to effectively protect IP rights for plant varieties internationally. Similarly, the value of trademarks for varieties and products from developing countries can be tremendous. The relative strength of trademarks is determined by how distinctive the mark is. When consumers see the trademark, they are able to easily distinguish the goods or services of the trademark owner from the related goods or services of competitors.

Two international agreements, the Madrid Arrangement and the Madrid Protocol govern international trademark registration. For plant trademarks, understanding and utilizing these provisions will become increasingly important to developing countries. Many tropical and subtropical regions are rich sources of novel fruit products, and an owner of such a product will want to adopt a strategy that both stimulates global demand for the product and maximizes commercial returns. Trademarks will be integral for such IP rights protection and global marketing strategies. In particular, three critical aspects should be considered if new branded fruit products are to be successfully launched from developing countries:

1. Determine what is to be trademarked.
2. Promptly register the trademark in the countries in which it will be used.
3. Enforce the trademark.

A successful global trademark program, built around exciting products, may be more achievable than a PVP-based strategy that relies only on licensing for returns. Instead of managers and lawyers securing licensing deals, the market itself can fuel value creation in the trademark. If successful, the returns can be tremendous.

Shifting topics once again, a very important and quite difficult aspect (especially for public sector entities) is **the granting of options and rights of first refusal**. As either a stand-alone agreement or as a clause within a broader agreement, options are a unique way of granting rights to intellectual property. The chapter by Anderson and Keevey-Kothari[11] provides a detailed discussion of the various forms of options, with tips and strategies, sample causes, and template agreements. The chapter delves deep into the legal and commercial promises and perils of granting options and concludes with a helpful section on administering options.[12]

Of special interest to university administrators and technology transfer professionals will be the sections on **incorporating options as a part of research agreements**. Universities in the United Kingdom and the United States have different approaches to handling privately sponsored research. In the United Kingdom, sponsors are often granted an option to acquire a license to develop and commercialize results, or the sponsor might in some cases own all the results. In contrast, a university in the United States normally retains ownership of any intellectual property resulting from its own research, though the university may grant rights to a sponsor to commercialize results. This emphasis on university control of research in the United States stems, in part, from provisions in the Bayh-Dole Act that prohibit universities from transferring ownership of intellectual property created from government-funded research.

Also instructive to university personnel will be the chapter's discussion of where and when not to grant a **pipeline agreement to a university spinout company**. A pipeline agreement generally refers to an option granted to a university spinout company to acquire rights over intellectual property that may, in the future, be generated by university faculty. Although a pipeline agreement may make sense, universities should be careful to stipulate how pipeline intellectual property will be identified. They will likely want to limit the agreement to intellectual property generated by specific faculty members and their labs. Universities should also recognize that in some cases spinouts may not be the licensee of choice and should therefore craft pipeline agreements with care.

Licensing is about choices, and it can be argued that no choice is more important than the field of use granted in a license. When licensing complex technologies, the licensor usually can partition patent rights based on time (duration of license grant), location (where rights may be practiced), and field of use. Shotwell[13] explains and clarifies the last of these three considerations. By partitioning a bundle of patent rights and distributing them to one or more licensees, field-of-use licensing maximizes value, optimizes delivery, and facilitates the most effective use of new technologies, whether in agriculture, biotechnology, pharmaceuticals, vaccines, or diagnostics.

With field-of-use licensing, the licensor gains greater control while maximizing the use and value of the technology. However, field-of-use licensing requires more work. The technology licensor should identify, motivate, negotiate with,

and manage more than one licensee—and quite possibly many. Nonetheless, this hard work can increase royalty streams to the licensor, since multiple licensees, each with different and specialized access to the technology, can efficiently speed different types of products to market.

When using field-of-use licensing, a licensor should be flexible. For example, even if a licensor envisions only one possible field of use for an invention, it makes sense to specifically limit a licensee to just that field. This is because technology changes so rapidly that a new use for the invention has a very good chance of developing later during the life of the patent. By limiting licensees to a particular field, a licensor retains the ability to work with the best possible licensee(s) for a new use when it arises.

Shotwell recommends that the licensor retain control over patent prosecution, while seeking to fairly distribute costs over field-of-use licensees. When considering reimbursement, the field-of-use licensor should manage patent expenses creatively. For example, the licensor can cover patent expenses up front, later reimbursing them from the royalty stream, or, if costs are to be reimbursed by the licensees, language can be used to include future licensees in that reimbursement.

One of the complexities of field-of-use licensing is that it raises the important question of how to deal with patent infringement/interference problems with multiple licensees. As with patent costs, the simplest approach is for the licensor to carry interference and infringement costs alone, recovering them through royalties or settlements. This approach retains more control for the licensor and correspondingly less for the licensees. Another approach to address possible infringement and interference actions would be to work out a mechanism to share the costs and management of these activities with one or more licensees.

Possible problems with field-of-use licensing include rights that overlap across licenses. This can arise from different interpretations of the rights granted under licenses or from unexpected future technical developments. It is therefore wise to lay the groundwork for resolving disputes related to these types of potential issues.

Licenses that include **royalty stacking and royalty packing clauses** are becoming more ubiquitous because virtually all products developed now using biotechnology, genetic engineering, and chemistry are technologically complex and incorporate many different inputs. As if this were not enough, there is also the added consideration of relevant IP rights, held by third parties that may be attached to these many inputs. For example, a vaccine might be identified and tested using proprietary research tools with IP rights owned by several companies. Later, the vaccine might be produced using patented recombinant techniques and proprietary DNA sequences. Transformation vectors might be owned by others. Production of the vaccine might employ a proprietary cell line. The vaccine might be packaged with one or more proprietary adjuvants and then be delivered using a patented device. Hence, when the vaccine is ultimately "ready for use," it will likely be subject to royalty obligations to several different companies, or licensors. A dilemma results, as the various licenses involved can combine to impose aggregate royalty obligations, perhaps up to 20%, and sometimes more, of the selling price of the product. There will also be separate reporting and accounting obligations to each of the licensors. Similar problems arise in agriculture when a genetically engineered crop might be made using proprietary varieties, vectors, gene sequences, and research tools—each with IP rights owned by different entities.

Jones, Whitham, and Handler[14] discuss two scenarios that can arise when multiple royalty rates are attached to one product—royalty stacking and royalty packing:

- *Royalty Stacking.* A biotechnological product might have multiple patents attached, and thus require multiple licenses in order to make, use, or sell the product.
- *Royalty Packing.* With some biotechnologies, it usually is necessary to combine one technology with many other technologies. (In this situation, the royalties imposed on each of the proprietary products that are administered will be "packed" together.)

The chapter then presents several techniques for managing royalty stacking and packing:

- *Royalty Ceiling.* A licensee may seek a ceiling for royalties in agreements it makes with licensors.
- *Royalty Floor.* A licensor may seek a floor below which its share of the royalties may not be reduced.
- *Variable Royalties.* Licensees and licensors also might agree to have variable royalties that are conditioned on the importance of the technology in relation to the creation of the product.
- *Royalty Alternatives*. Finally, alternatives to royalty bearing arrangements can also be considered; these include lump-sum payments and patent pooling.

The last point shows that managing royalty stacking and packing does not necessarily require royalty streams. For example, a lump-sum payment for the use of a research tool may be an optimal way to disseminate and exploit a patented technology. Some technologies may be best assembled in patent pools that provide either free use of or fixed-price access to the technologies. Patent pools can thereby facilitate R&D using a variety of proprietary technologies without the need to negotiate licenses.

As all of the above chapters make clear, in our post-TRIPS environment, leaders in developing countries who seek to improve economic development and public health are advised to be well-versed in the details of global IP management. Unlike the past, today no country can comfortably remain isolated from the global IP system. Yet among many public sector institutions in developing countries, knowledge of IP licensing practices is often insufficient. To address this gap in expertise, the chapter by Satyanarayana[15] lays out several of the important features of in-licensing agreements, **common problems faced by developing countries** in constructing and implementing these agreements, and ways to avoid these common pitfalls.

In-licensing by public sector institutions is a useful, if complex, method for bringing technologies into the public sector through patent license agreements with the private sector. Although the interests of the private and public sector entities involved in these agreements will almost necessarily be in tension, it is possible for a well-crafted license to allow all parties to feel as though they have benefited from the agreement. From a public sector perspective, as Satyanarayana argues, the goal is ultimately to provide a product (be it a vaccine, drug, or new agricultural crop) to people who would not have access to it without government support. For developing countries, the good news is that legal expertise is often locally available, since many firms are already familiar with basic licensing procedures. The trick is to put this knowledge in the service of public officials to develop a comprehensive and effective plan to license and develop much-needed-technologies. These strategies include:

- developing a business strategy that balances the needs of the public sector with the needs of the private sector
- developing a marketing strategy that prices products realistically and is based on good market research to aid valuation
- forming partnerships with other suitable agencies to help manufacture and market new products
- making sure legal, business, and scientific experts are working together for optimal success
- establishing, as an important initial step, a national technology transfer office

The final chapter by Bobrowicz[16] offers a useful **checklist for negotiating licensing agreements**. For the seasoned technology transfer professional or contract attorney, the idea of preparing a detailed checklist for every licensing agreement may seem like unnecessary busy-work. Yet these same professionals could probably relate stories where a missed detail or vague contract provision led to a costly and protracted legal battle. Given the high stakes, it is certainly in the best interest of those involved in IP deal making to make sure that every last detail is checked and rechecked. When multiple deals are being negotiated at once, it is only reasonable to assume that something could get missed. To help avoid

this unfortunate and potentially costly error, this chapter provides a comprehensive, yet flexible, checklist that can be deployed to help manage the details of license agreements. Although the author provides a template for most elements of the license, she is quick to note that users should feel free to alter the checklist to suit their particular business practices.

The checklist covers all the major elements of a standard IP license, particularly as used in agriculture, starting with a section detailing the most basic, yet crucial, matter of getting all the parties' pertinent contact information. Sections covering clauses, definitions, rights granted, sublicenses, improvements, warranties, and infringement, and other matters are discussed, with useful sample checklists included for each component. The chapter concludes with a consideration of boilerplate sections, including confidentiality and arbitration stipulations. Although each section is annotated, an online version can be downloaded without accompanying text.

In sum, licensing is about the development of relationships. As important as the terms of agreements are, few are more important than the long-term opportunities offered by forging good partnerships, be they between companies or between public and private sector entities. Negotiating an agreement is just the beginning of what may—or should—become a long-lasting and beneficial relationship. ■

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 In an ideal world, exchanges would take place based on "fair" and "equitable" pricing, in both the eyes of the seller and buyer. But equitable exchanges are at least in part based on perceived moral obligations that are difficult to capture in financial and market terms. Such nonmonetary and moral perceptions, often strongly personal-, cultural-, and even religion-based, are important, but there is no system, at least for the moment, for weighing different perspectives on morality or ethical grounds or for translating them and making them work in the marketplace. To be sure, it can be satisfying to the buyer and seller when each perceives a transaction to have been equitable. And we need to strive for better balance in an inequitable world. But how much is owed to whom and for what and how to achieve general satisfaction has surely eluded our modern society (and, indeed, has eluded societies for centuries, if not millennia). We can all support equity, or at least pay lip-service to it, but it is far more difficult to determine what equitable transactions, in fact, consist of.

2 Chapter 11.1 by JW Freeman titled Licensing Biotechnology Inventions, p. 991.

3 Chapter 11.2 by RS Cahoon titled Licensing Agreements in Agricultural Biotechnology, p. 1009.

4 The online version of the *Handbook* provides a large number of template agreements from myriad organizations. These templates include confidentiality agreements, material transfer agreements, contract research agreements, collaborative research agreements, and a range of licensing agreements.

5 Chapter 11.3 by M Nilsson titled The In- and Out-Licensing of Plant Varieties, p. 1017.

6 Chapter 11.4 by A Krattiger, J Dodds, and D Bobrowicz titled Potential Use of a Computer-Generated Contract Template System (CoGenCo) to Facilitate Licensing of Traits and Varieties, p. 1029.

7 www.ipHandbook.org.

8 Chapter 11.5 by KF Jorda titled Trade Secrets and Trade-Secret Licensing, p. 1043.

9 This is perhaps the principal reason why (1) most issued patents are not practiced in developed countries although their information is freely available on the Internet and (2) why compulsory licensing has tremendous limitations.

10 Chapter 11.6 by WT Tucker and GS Ross titled Use of Trademarks in a Plant-Licensing Program, p. 1059.

11 Chapter 11.7 by M Anderson and S Keevey-Kothari titled Commercialization Agreements: Practical Guidelines in Dealing with Options, p. 1069.

12 These include practical suggestions for keeping track of options, including tips for writing standard operating procedures (SOP), generating nondisclosure agreements, developing a useful database for data, and if and when necessary, calling in legal professionals for more-specialized advice.

13 Chapter 11.8 by SL Shotwell titled Field-of-Use Licensing, p. 1113.

14 Chapter 11.9 by KJ Jones, ME Whitham and PS Handler titled Problems with Royalty Rates, Royalty Stacking, and Royalty Packing Issues, p. 1121.

15 Chapter 11.10 by K Satyanarayana titled In-Licensing Strategies by Public-Sector Institutions in Developing Countries, p. 1127.

16 Chapter 11.11 by D Bobrowicz titled A Checklist for Negotiating License Agreements, p. 1133.

FOR GOVERNMENT POLICYMAKERS

- ✔ **Licensing is highly context specific**. For this reason, blanket policies on minimum requirements for licensing terms applicable to public sector institutions can discourage creative and beneficial deals and reduce the potential for national institutions to forge international linkages.

- ✔ Notwithstanding the above, public sector institutions should, as a matter of policy, consider the routine **incorporation of philanthropic use provisions** in their licenses and should always **retain research and teaching rights** to any of their inventions.

- ✔ The dual goals of **economic growth and social/humanitarian benefits** through licensing are not mutually exclusive. Indeed, they are often complementary.

- ✔ Companies regularly license their own varieties to third parties as a strategy to maximize returns on investment and reach markets that the company itself cannot easily reach. Conceptually at least, **public sector plant breeding institutions have much to gain from variety licensing** as a strategy of serving markets they do not typically reach.

- ✔ Overall, the successful licensing of varieties between and among public and private sectors is **contingent on the strength of plant variety protection legislation**. Such legislation can support the interests of the variety owner and the farmer, facilitates the transfer of technology, and provides incentives for further investments.

- ✔ Recognizing that patent applications are usually filed early in the research stage and require full disclosure, companies typically keep inventions developed later on as trade secrets. These may include the best mode for commercial manufacture. Patent licenses are most valuable when coupled with access to associated know-how. Comprehensive and enforceable **trade secret laws are thus conducive to the transfer of know-how** through licensing. The two, disclosed patents and protected secrets, are thus complementary.

- ✔ Using **trademarks as a strategy allows public and private institutions to capture more added value**. To benefit from trademarking strategies, internationally accepted legislation is important. Also important is the maintenance of high quality standards and stewardship, since trademarks (and geographical indications) provide the consumer with information on the source of the products.

- ✔ Although IP rights are governed by national statutory protection, **contract law is arguably even more important than statutory protection law**, as contracts allow institutions to exchange intellectual property in an orderly and predictable manner.

- ✔ Along with investing in a country's R&D infrastructure and capacity, it is important to sustain long-term growth. **Human and institutional capacity in IP management adds value to R&D efforts**. In- and out-licensing in particular enhance an institution's economic and social impact. Among a government's top priorities should be providing support to public sector institutions for establishing and operating effective technology transfer offices, coupled with training programs for creating capacity commensurate with the complexities of modern biotechnological products. Ideally, these capacities should reside at the institution level because of the context-specific nature of licensing.

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.)

- ✔ **Licensing is highly context-specific**. For this reason, blanket policies on minimum requirements for licensing terms applicable to your technology transfer office can be counterproductive to making sound deals and can reduce the potential to forge international linkages.

- ✔ Public sector institutions should, as a matter of policy, **consider the routine incorporation of philanthropic-use provisions** in their licenses and should, as a matter of routine, always **retain research and teaching rights** to any of their inventions.

- ✔ The dual goals of **economic growth and social/humanitarian benefits** through licensing are not mutually exclusive. Indeed, they are often complementary. Much will depend on a sound institutional licensing strategy and on good relationships with licensees.

- ✔ The value of trademarks for both varieties and products, from developed and developing countries alike, cannot be understated. To **benefit from trademarking strategies**, particularly of global reach, the maintenance of high quality standards is important, since they provide the consumer with information on the source of the products. In addition, using trademarks as a strategy allows public and private sector institutions alike to capture more of any added value.

- ✔ Licensing is about choices, and it can be argued that no choice is more important than the **field of use** granted in a license. A public sector institution should have a clear policy statement on how it deals with field-of-use licensing and may even wish to consider making field-of-use licenses the preferred method of licensing. This is especially applicable to platform technologies and diagnostics. However, field-of-use licensing requires more work. A well-trained and well-staffed technology transfer office will be essential.

- ✔ A public sector institution can contribute significantly to its mission through **in-licensing intellectual property from private sector entities**. For this, it is useful to develop a set of strategies (business, marketing, partnership building, and legal) during discussions with the licensing office that balance the needs of the public sector with the needs of the private sector.

- ✔ **Business decisions, more than legal aspects, should determine licensing terms**. Nevertheless, lawyers should ensure that the contracts comply with prevailing law. This is equally applicable to private sector and public sector deals.

- ✔ **Patent licenses are most valuable when coupled with access to associated know-how**. Comprehensive staff training in the handling of confidential information from third parties is therefore critical.

- ✔ But public sector organizations should **exercise caution when accepting trade secrets** (as opposed to confidential information). In some jurisdictions there may be significant liability obligations related to trade secrets, and public sector institutions may not be in a position to cope with all such obligations.

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

- ✔ Ideally, you will leave detailed aspects of negotiations, such as collaboration or license agreements, to the relevant offices of your institutions. However, do **participate in the internal discussions** prior to in- or out-licensing negotiations. Your input will be important and should be valued.

- ✔ The dual goals of **economic growth and social/humanitarian benefits** through licensing are not mutually exclusive. Indeed, they are often complementary. Much will depend on a sound institutional licensing strategy and on good relationships with licensees. Your role in the latter may be critical.

- ✔ Make an effort to consistently document the **origin of biological and other materials** you use in your research, and keep a comprehensive record. Although it is not your responsibility to resolve IP conflicts, your detailed records will help if such a conflict arises.

- ✔ Interface with the technology transfer office (TTO) in order to understand **options** and whether you might have a role in their implementation or fulfillment. Although options are complex and a matter most appropriately addressed by your TTO officers, the granting of options may significantly impact your research options. Make sure you discuss the implications with them prior to the incorporation of options in licenses that relate to your research.

- ✔ When you disclose an invention to your TTO officers, inform them of any ideas you may have on the various fields of endeavor in which your invention could find applicability. This will help the TTO write better patent applications and, later to draw up license agreements for many different players under different **field-of-use licenses**. This approach can maximize the value of your research and may **accelerate commercial and humanitarian development** of technologies based on your research.

- ✔ **Your role in field-of-use licensing is essential**. You can provide your TTO with valuable information on licensable components for different applications and entities.

- ✔ The products arising from your program's research efforts, particularly from product development activities, will invariably embody numerous technologies, including components and processes that might have IP rights from third parties attached to the technologies. This can create complex IP management and licensing issues as these products approach commercialization. If you are engaged in product development, **maintain a good line of communication with your TTO** and ensure that early on they address IP ownership by third 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.

FOR TECHNOLOGY TRANSFER OFFICERS

- ✔ Besides reflecting the business deal that has been made, few components are more important in a license than clear and unambiguous **definitions**.
- ✔ For practical purposes, any organization engaged in high-volume licensing will find it useful to develop its own **internal template agreements** that are then modified and adapted to suit each special circumstance. **Checklists** for different types of recurring licensing negotiations should be reviewed prior to and during negotiations.
- ✔ Recognize that relationships—like markets—are not static. Any provision in an agreement must, of course, be adhered to, but the practice of including **sufficient flexibility in licensing agreements** can be a valuable strategy in forging strong partnerships.
- ✔ The granting of options (rights of first refusal, pipeline agreements, and so forth) can be a rather controversial aspect for public sector licensing. But **options can be tremendously powerful** in forging strong and lasting relationships and in optimizing your institution's economic returns and humanitarian effects.
- ✔ **Field-of-use licensing** should be adopted as the preferred method of licensing whenever possible. It allows you to gain greater control while maximizing the use and value of your licensed technology. But be flexible and study the licensee's motivations and business model carefully as a way of conferring the highest possible incentives. Always strive to retain control over patent prosecution and infringement actions when adopting a field-of-use licensing strategy.
- ✔ Familiarize yourself with the various ways to deal with **royalty stacking and royalty packing** issues as a way of balancing risks and returns. The choice will depend on how far downstream into product development your institution stays involved.
- ✔ Negotiating about low-probability events can sidetrack progress toward agreement on core issues, so care should be taken during the negotiation to **attend to issues in a manner commensurate with their strategic importance**. It is often best to focus on the overall deal before entering into discussions about specifics.
- ✔ In a license agreement, the **rights to sublicense and assign a license** ought to be explicitly articulated.
- ✔ In research collaborations, in which employees of two or more entities share ideas and information, **confidentiality provisions** are important. Make sure the scientists in your institution understand these obligations and rights.
- ✔ Licensee agreements are contracts. Hence, a practical understanding of contract law will be fundamental to negotiating and drafting good license agreements. Many smaller TTOs use outside counsel to **ensure that agreements are compliant with national law**.

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