Patent Licensing for Small Agricultural Biotechnology Companies

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ABSTRACT

A small agricultural biotechnology (agri-biotech) company needs to establish a strong IP portfolio. Such a portfolio provides a foundation for R&D, encourages outside investment and funding, and supports product commercialization. An important step in establishing an IP portfolio is in-licensing patent rights from third-party patent holders. Nonexclusive licenses typically give a company freedom to operate and open up the possibility of creating commercializable products. Exclusive licenses give a company an exclusive position for commercialization under the patents in question.

This chapter discusses in-licensing as it applies to small agri-biotech companies. It describes the types of technologies that may be subject to in-licensing, the procedures attendant upon in-licensing, and the terms that may be delineated by in-licenses.

1. INTRODUCTION

In order to be successful, a technology company needs to build a proprietary position in intellectual property (IP); that is, it needs to build a strong IP portfolio. The portfolio should be composed primarily of both company-developed patent rights and patent rights acquired through licensing, but it may also include know-how, trade secrets, copyrights, and trademarks. The IP portfolio should include a diverse set of IP rights that provide the company with both freedom to operate (FTO), which clears the path to commercialization, and a position of exclusivity, which provides a unique competitive position. Acquiring license arrangements and the FTO or exclusivity they provide increases a company's value, its attractiveness to funders, and its chances for acquisition or public offering.

Company-owned intellectual property is an important part of any company's portfolio, but R&D to develop IP takes time and money. In-licensing allows a company to obtain IP rights at an early stage, without having to invest in research. Nonexclusive in-licensed rights, that is, rights granted to more than one licensee (see below), provide FTO under the given patent rights. On the other hand, exclusive in-licensed rights, that is, rights that are granted to only a single licensee (see below), provide FTO under the given patent rights and assure the licensee of a commercial position of exclusivity on production, sales, or use, at least for a certain length of time.

A strong IP portfolio is key for companies based in countries with established patent systems. A strong IP portfolio can also be an asset for companies in the rest of the world: it makes them more competitive in their home countries. Moreover, a strong IP portfolio may be necessary if such a company wishes to export its products to countries with established patent systems.

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2. NONEXCLUSIVE AND EXCLUSIVE LICENSES

An IP license (or IP license agreement) is a contract in which a holder of IP rights (the licensor) grants certain rights to another party (the licensee) in return for compensation (monetary or otherwise). The scope of a license depends on the rights that are licensed, as well as how, when, and where these rights may be used or practiced. The rights granted by a patent license include rights granted under the patent itself, but may also include trademark rights, copyrights, know-how rights, or rights over tangible material (personal property). The characterization of an IP license depends on one's perspective: the licensee considers it an *in-license* (because the licensee takes the license, as well as responsibilities and benefits thereof, *into* its IP portfolio) and the licensor considers it an *out-license* (because the licensor grants IP rights *out* of its own portfolio). In the case of a *cross-license*, parties pay for in-licenses from each other by granting out-licenses to each other.

In-licensing of patent rights may be either on a nonexclusive or an exclusive basis. Each type of licensing arrangement serves a different purpose, involves different contractual terms, and comes with a different price tag.

In general, a *nonexclusive license* gives the licensee FTO for the patented technology, but not an exclusive position. The licensor may grant licenses to others for the same technology. A nonexclusive license may contain a *nonassert* clause: that is, the licensor agrees not to assert any other patents against products developed by the licensee using the original license. It is not uncommon for small agri-biotech companies to acquire a series of nonexclusive licenses so that they have the right to develop technologies that they can eventually use to create new products.

In contrast, an *exclusive license* gives the licensee FTO for the patented technology and an exclusive position on its use; in other words, having an exclusive license to a patent is, in certain ways, like holding the patent itself. Exclusive licenses can help a new company to establish itself in a research area and to generate income for its own research activities. The trade-off is that an exclusive license typically costs more than a nonexclusive license.

"In-between" licensing positions may also be possible. For example, a company could seek a nonexclusive license with the option within a certain period of time to convert the nonexclusive license to an exclusive license. Such an option grant is normally more costly for the licensee than a nonexclusive license alone because the licensor agrees not to grant licenses to others during the specified period of time.

3. TYPES OF AGRICULTURAL TECHNOLOGIES COVERED BY LICENSING

A small agri-biotech company should develop a competitive IP portfolio that includes patents and licenses for enabling technology, trait technology, and also plant material.

Enabling technologies (in other words, research tools) are used to bioengineer new organisms. Enabling technologies include plant transformation technologies; promoters and other expression systems, including constitutive, inducible, tissue-specific, and temporal-specific promoters; markers, including selectable and screenable markers; vectors; gene-suppression technologies; leaders, transits, and signals; excision technology; and other components introduced into a bioengineered plant that are not trait- or phenotype-specific.

In-licensing is typically nonexclusive for enabling technologies. Nonexclusivity allows the licensor to grant many licenses and thus widen its revenue base; at the same time, the licensee can acquire technology and FTO at a lower cost. At times, however, in-licensing of enabling technologies may be exclusive, either for broad use or for specifically defined use, such as a defined crop area or a defined trait area. Licensing enabling technologies may involve a transfer of rights over tangible property (for example, DNA sequences) that may be regulated by material transfer agreements or bailments.[1]

Trait- or *phenotype-specific technologies* can be used to create plants with new genes that express desirable traits. The genes may be derived from any type of organism, for example, viral, bacterial,

fungal, plant, or mammalian. The genes may be expressed as desirable agronomic traits, for example, biotic or abiotic resistance, or desirable consumer traits such as color, flavor, texture, or fragrance.

In-licensing is often exclusive for trait-specific technologies. A license may only authorize the licensee to work with a particular crop or group of crops. Exclusive licenses allow the licensor to be compensated for genes that it is not currently exploiting itself; at the same time, such licenses allow the licensee to hold an exclusive position with respect to the use of these technologies and to develop new commercial products with them. Licensing of trait technologies may involve a transfer of rights over tangible property, for example, genes or gene constructs, which may also be regulated by material transfer agreements or bailments.

A third type of technology is the *plant material* into which enabling technology and trait technology can be introduced. Plant material encompasses model plants, for example, *Arabidopsis*, that are used in early-stage research, as well as commercial-crop plant material (either breeding material or varietal material) that is used both in research and later-stage development or commercial work.

Plant material can be in-licensed if it is protected by patents (or plant patents) or by plant variety protection/plant breeder's rights. If the plant material is not protected by intellectual property, access may be through material transfer agreements or bailments. However, not all plant material is protected by IP laws; some is in the public domain or freely available, for example, from the U.S. Department of Agriculture.

4. LICENSING PROCEDURES

Licensing is a time-consuming and expensive procedure. Normally, each company involved in licensing has a team that includes one or more in-house technical people (and often the head of research), as well as one or more business people. In addition, in-house and outside patent specialists should be available to provide input. Patent specialists include patent counsel (in the United States, lawyers who are qualified to practice before the U.S. Patent and Trademark Office, or PTO) and patent agents (in the United States, nonlawyers with technical training who are qualified to practice before the PTO). If the company is not large enough to have in-house patent counsel, then outside counsel who understand the company's technology and budget requirements should be retained. Even when in-house patent counsel (and/or in-house patent agents) is present, outside patent counsel should still be held at the ready to assist with difficult or special situations.

The company should develop a patent plan for each R&D project it hopes to undertake. In addition to planning IP protection for company-developed inventions, the patent plan should identify the existence and status of third-party patents for which it would be useful to obtain licenses. As the research plan matures, and as the third-party patent landscape changes, the patent plan will need to be revised.

The process of identifying third-party patents is detailed elsewhere in this *Handbook*.[2] But briefly, third-party patents may be identified based on information available from a number of sources, including published patent applications, patent grants, publications, conference presentations, Web sites, Securities and Exchange Commission submissions, and the popular press. Patent applications are published by the PTO; by the World International Patent Organization, which publishes patent applications under the Patent Cooperation Treaty; and by individual foreign patent offices.

Although it is important to consult published patent applications, a few caveats are called for. First, the patent application is published 18 months after the patent is filed, so it does not contain up-to-date information. Second, the published patent application normally contains the claims as filed, not as may be amended in prosecution or as will be granted. After the patent application is published, however, the patent file is made available to the public and it will be possible to track any changes of the patent claims during the patent prosecution. Third, there is no guarantee that the patent application will issue as a patent. Fourth, it is not uncommon for more than one applicant to seek patent rights for the same invention. In countries outside the United

States, the general rule is that the first to file a patent application is entitled to the patent. In the United States, however, it is the first to invent who is entitled to the patent.

Once important third-party patents are identified, they and their file histories should be studied to determine the scope of patent claims and their applicability, or lack thereof, to the project being considered. If the patent is applicable to the project, if a license is available, and if its price is within the company's budget, the company might decide to seek the license. If the patent is applicable to the project but a license is unavailable, or not economically feasible, the project plan should be reevaluated; there may be *work-arounds*, that is, alternative ways of achieving the same results, that avoid the patent.

If the company decides to seek a license, the company should determine whether it wants nonexclusive or exclusive rights, decide what it is willing to pay for them, and decide whether it wants license rights or option rights.[3] Contact with the patent holder (the potential licensor) can be made directly or through an intermediary, such as an outside law firm. Using an intermediary may be useful if the company does not want to identify itself to the potential licensor until it is certain that a license is available. Negotiations can be direct or conducted through an intermediary and are often governed by mutually agreed-upon confidentiality agreements. During the negotiations, the licensor may ask for a business plan from the potential licensee(s) if the licensor is deciding among several potential licensees and/or in order to calculate the level and type of compensation it will request. The negotiation is normally conducted under the direction of, or at least with the input of, each company's business and legal team. Typically, discussions lead to the creation of a term sheet, which in turn is followed by negotiation of the terms and language of the license agreement.

5. TERMS OF LICENSE AGREEMENTS

The core of a patent license agreement consists of two parts: first, the rights to be granted to the licensee, and second, the compensation to be paid to the licensor. The rights granted are generally determined by the scope of the patent, though not always. The license may also delineate other rights that are to be granted, for example, tangible property rights, copyrights, know-how, trade secrets, or trademarks. The licensor receives compensation by way of a negotiated payment arrangement of fixed fees and/or royalty fees. Other key provisions of the license agreement typically include responsibility for liability; diligence requirements (defined below); the licensee's rights of participation in patent procedures; the term or duration of the agreement; and license assignability (defined below).

5.1 *Patent rights*

The rights conferred by a license, or *patent rights*, are normally based on the rights covered by one or more defined patent applications or patents, along with rights to any related filings (such as continuations, divisionals, and reissues). If the license is to be applicable in a foreign country, patent rights will also include rights under the counterpart patent(s) of that country. As noted above, the license may also confer rights under any other patents of the licensor that cover products covered by the defined patents (nonassert clause).

5.2 *Rights granted to the licensee*

According to a strict definition of an exclusive license, the licensor keeps the title to the patent but retains no other rights for itself (although, as noted below, in practice the license will often specify certain retained rights for the licensor). In a *sole* license, the licensor grants a single license while retaining full rights for itself. In a *coexclusive* license, the licensor grants licenses to a defined number of licensees (typically two).

There are several key ways that a license grant, either nonexclusive or exclusive, can be limited or defined. First, the grant can be limited *territorially*, for example, it can be restricted to certain countries, or certain geographical areas within the United States. Second, the grant can be limited in terms of *duration*, for example, it can be limited to the life of a given patent, or some other defined period of time. Third, the grant can be limited to

a defined *field of use* (for example, research use, or use of certain crops or traits).

The grant, even where exclusive, may also be limited by specified *retained rights* of the licensor, that is, those rights that continue to be held by the licensor or that can be granted by the licensor to other licensees interested in a different business area, in a different territory, or for different fields of use. For instance, the Public Intellectual Property Resource for Agriculture (PIPRA) recommends that agri-biotech licensors retain rights that will allow them to license their technology to others for humanitarian purposes.[4] If a patented technology is developed using U.S. government funding, any license is subject to the rights of, and the obligations owed to, the U.S. government (Bayh-Dole Act, 35 U.S.C. § 200 et seq.).

Normally, the grant will specify whether or not the licensee has the right to grant sublicenses to affiliates, other corporate partners, or other third parties. There may also be express sublicense rights to allow others to make or sell products on behalf of the licensee. Exclusive license agreements often allow broader sublicensing rights than do nonexclusive license agreements.

In addition, the grant may also provide for release or forgiveness for past acts of infringement by, or on behalf of, the licensee. The license may also grant additional rights in the form of *most-favored-nations clauses*, in nonexclusive licenses, or in the form of *right-of-first-refusal clauses* for future licensor improvements. A most-favored-nation clause provides that, in the event the licensor grants more favorable terms in a license with another party for the same patent rights, the licensor will offer the same more favorable terms to the original licensee. A right-of-first-refusal clause provides that, in the event the licensor develops improvements of the licensed patent rights and chooses to make those improvements available for licensing, the licensor will offer to license such improvements to the licensee before offering to license them to others.

5.3 *Compensation due to the licensor*

Compensation may be a combination of fixed fees, which can be paid up-front and/or periodically, and earned royalty fees. Both the level and timing of compensation are important to the company with respect to its planning and budget. In determining what compensation it is willing to pay, the company will need to estimate the potential value of the licensed technology and assess the potential value of any commercialized products that might be developed under the license. This analysis should take into account many factors, including the product's potential market size, its likely market share, the nature of any competition, the strength of the licensor's patent rights, the scope of the license, advantages (whether monetary or otherwise) of in-licensing, projected costs of future development, and the likelihood that the product will be successfully commercialized. Previous licensing agreements for the same or similar technology are relevant to the analysis. The licensee may seek to pay less if it must obtain licenses from other licensors in order to commercialize a product covered by the license agreement (*stacking* royalties).[5]

Compensation may also take nonmonetary forms: stock in the licensee company, an exchange of license grants, or cross-license arrangement, or a *grantback* to the licensor. Grantback compensation involves the licensee granting the licensor rights to future inventions made by the licensee using rights received from the licensor.

5.4 *Liability*

The licensee may want the licensor to provide assurance of the right to license, and assurances with respect to the scope or strength of the licensed patents rights. The licensor may want the licensee to indemnify the licensor against liability resulting from licensee's activities under the license agreement. Additionally, the licensor may seek to impose insurance requirements on the licensee. Such liability-related clauses often are the subject of negotiation.

5.5 *Diligence terms*

The licensor typically wishes to ensure *diligence* on the part of the licensee in developing products and making certain that the products reach the commercial market. Diligence is particularly important for exclusive licenses, since the licensor may not receive sufficient benefit from its

patent rights absent diligent licensee activity. In nonexclusive licenses, diligence on the part of the licensee may likewise be important as a means of ensuring both that the license arrangement provides some value to the licensor and that the products created by the licensed technology will enter the marketplace.

Diligence terms (or requirements), particularly in the case of exclusive license agreements, typically identify *milestones*. These are specified steps in the process of research, development, and commercialization that the licensee is required to reach by specified dates. In agri-biotech, such milestones may include the development of a model plant system, the development of a crop system, field trials, obtaining regulatory approval, initial commercialization, and commercialization at predetermined levels. If the licensee fails to achieve the specified milestones at the specified times, the licensor may terminate the license or, if the license is exclusive, reduce it to nonexclusive status. The diligence terms may include a provision for extending timelines in exchange for additional compensation. The licensee will want to protect itself against a loss of rights if unforeseen circumstances slow down the process of development and commercialization; the licensor, on the other hand, will want to make certain that it has recourse in case the licensee does not fulfill its end of the bargain.

In addition to, or occasionally in place of, the fulfillment of milestones, diligence terms may require the licensee to make periodic payments (often minimum annual payments), regardless of the licensee's level of sales under the license agreement. Such payments may be set at a fixed amount or be gradually increased according to business projections. The licensor may ask for both periodic payments and the fulfillment of milestones, in order to ensure that it will receive compensation and that the technology will enter the marketplace.

5.6 *The licensee's responsibilities vis-à-vis the patent*

In a nonexclusive license agreement, the licensee may not be required to pay patent costs, that is, the costs of filing, prosecution, and maintenance of patent filing; under such an agreement, the licensee typically will not have the right to participate in patent decisions, such as the opportunity to review and comment on patent submissions. On the other hand, a nonexclusive licensee may be asked to pay a pro rata share of patent costs; or, if it is the first licensee, it may be asked to pay all the patent costs until other licenses are granted.

In an exclusive license agreement, the licensee is often asked to pay patent costs. In return, the exclusive licensee typically has the right to participate in patent decisions. The exclusive licensee may also have the right to opt out of patent costs in the event such steps as appeals, interferences, or oppositions are undertaken, but the licensee may give up its own rights to such filings by opting out. The exclusive licensee may also have the right to control prosecution and maintenance of any licensed filings that the licensor chooses to abandon.

License agreement terms may delineate the licensee's rights in case of patent enforcement procedures, for example, if and when a licensee is entitled to participate in enforcement actions, or how or whether the licensor and licensee, or licensees, will share the costs of enforcement proceedings and any compensation that may result from them.

5.7 *License term and termination*

The term of a patent license agreement typically extends for the life of the patent. The licensee is typically allowed to terminate the agreement at any time, so long as the licensee provides adequate notice and pays any accrued fees and any applicable patent costs. In contrast, the licensor is usually only allowed to terminate the agreement if the licensee violates the license, for example, by a material breach or failure to satisfy the diligence requirements.

5.8 *Assignability*

A small company licensee will likely be concerned about the *assignability* of the license agreement by the licensee, that is, the licensee's right to transfer the license to another party in the case of corporate restructuring or acquisition of the licensee. The licensor may not wish to agree to

such assignability in advance because the licensor cannot know who the successor licensee will be. In order to resolve such conflicts, various in-between terms are possible; assignability might be allowed only in certain situations, for example. The licensee, on the other hand, may want an express clause to the effect that in any assignment of the license by the licensor, the new holder of the license (new licensor) will be bound by the terms of the license agreement.

5.9 *Other provisions*

License agreements typically contain a number of other provisions, often called *boilerplate* or *standard* clauses, such as clauses for reporting of the licensee's progress; confidentiality of communications; procedures for arbitration or litigation of disputes between licensor and licensee; compliance with requirements of applicable laws and regulations; and choice of governing law.

6. CONCLUSIONS

A small agri-biotech company, whether based in a developed or developing country, can help substantially to build its patent portfolio and commercialization position through patent license agreements with third parties. The company should determine what license rights it wants to seek, whether it wants to seek these rights on a nonexclusive or exclusive basis, and under what terms it is willing to license the rights. Such license agreements can provide the company with an important complement to its company-owned intellectual property, both in terms of the company's freedom to operate and in terms of the company's exclusive proprietary position. ■

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1 See, also in this *Handbook*, chapter 7.3 by AB Bennett, WD Streitz and RA Gacel.

2 See, also in this *Handbook,* chapter 14.2 by SP Kowalski.

3 See, also in this *Handbook*, chapter 11.7 by M. Anderson and S Keevey-Kothari.

4 See, also in this *Handbook,* chapter 2.1 by AB Bennett.

5 See, also in this *Handbook*, chapter 11.9 by K Jones, ME Whitham and PS Handler.