Field-of-Use Licensing

SANDRA L. SHOTWELL, *Managing Partner, Alta Biomedical Group, LLC, U.S.A.*

ABSTRACT

Field-of-use licensing provides the licensor with greater control over the use of its intellectual property, while maximizing the use and value of the technology. In order to maximize the use of a given technology, managers will have some additional work to do as they identify, negotiate with, and manage more than one licensee. Special issues related to multiple licensees in distinct or overlapping fields will have to be handled with forethought and a balancing of interests. When is field-of-use licensing worth the extra effort? When more than one company is needed to fully develop a technology's potential, when different licensees are needed to address different markets, or when field-of-use licensing has the potential to significantly increase the financial return from a technology. In all of these situations, field-of-use licensing can produce better results for everyone involved.

1. INTRODUCTION

Innovative organizations can license a technology exclusively or nonexclusively without any limitations on its commercial use. The licensee can use the technology to make soup, pharmaceuticals, or integrated circuits. Use is limited only by the obligations set out in the license agreement (and the current and future applications of the technology).

Often, however, value can be obtained from limiting the uses available to any *single* licensee. One company may not be able to develop *all* the possible uses of a technology because of its business focus or limited resources. Having multiple licensees with different fields of use may help to ensure that many uses of a technology are developed, may speed different types of products to market, and may increase the return to the licensor. Guidelines issued by agencies that fund inventions can sometimes be honored, in part, through field-of-use licensing.[1] It also can be used to focus company attention on humanitarian markets and ensure commercialization of products to serve the different needs of those markets (though this may be handled through territory limitations, rather than field of use). For any of these reasons, field-of-use licensing can be valuable. On the other hand, a restriction on field of use imposed by a potential licensor can reduce the motivation of a potential licensee, so a balance must be struck between the needs and motivations of each party to the license.

Even if a licensor sees only one possible field of use for an invention, it makes sense to limit an exclusive licensee to that field. Technology changes so rapidly that a new use for the invention would have a very good chance of developing during the life of the patent. A licensor should

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

Editors' Note: We are most grateful to the Association of University Technology Managers (AUTM) for having allowed us to update and edit this paper and include it as a chapter in this Handbook. The original paper was published in the *AUTM Technology Transfer Practice Manual* (Part IX: Chapter 4).

© 2007. SL Shotwell. *Sharing the Art of IP Management:* Photocopying and distribution through the Internet for noncommercial purposes is permitted and encouraged.

keep open the option of working with the best possible licensee for a new use, should one arise.

2. TECHNOLOGIES THAT ARE APPROPRIATE FOR FIELD-OF-USE LICENSING

A field-of-use license grants rights to the licensee to practice, not all uses of the licensed technology, but only a subset of those uses. The scope of the license could be limited by a general field of use (for example, digital recording or therapeutics) or a very specific field of use (for example, products for the treatment of human non-Hodgkin's lymphoma). In any case, the licensee's right to use the technology is limited in scope, leaving the licensor free to work with other companies on other uses.

Many types of technologies are appropriate for field-of-use licensing. In general, any technology that has, or may come to have, multiple, distinct uses may warrant this approach. Examples are easily found in the electrical engineering, computer, chemical, and health care areas. In the biochemistry department of a university, for instance, a new gene may be isolated and sequenced and its protein product expressed. This sounds like one technology, but it could easily lead to at least nine separate commercial uses:

1. Selling the protein product to the research reagent market
2. Making and selling antibodies directed against the protein to the research reagent market
3. Making and selling antibody-based diagnostic products
4. Making and selling DNA-based diagnostic products
5. Performing DNA-based diagnostic tests as a service
6. Making and selling the protein as a therapeutic product (this may be further focused by disease if the gene is involved in multiple disease states)
7. Using the gene and protein in-house for screening pharmaceutical drug candidates
8. Using the gene in gene therapy
9. Using the gene to develop a therapeutic based on antisense approaches

A company that sells to the research reagent market may not be in a position to make and sell therapeutic drugs (too much investment required). A company that develops therapeutics may not be interested in performing DNA-based diagnostic tests as a service (not enough return). A company that provides the DNA-based diagnostic service may not be capable of putting the protein on the research reagent market (no marketing and sales staff). Yet, each of these products is useful, further develops the technology, and is a potential source of revenue for the licensor.

What approaches can a licensor take when presented with a technology that has many distinct uses? There are at least three options:

1. License it to one company with no limitations, sit back, and hope that as the company maximizes its value from the license, all the markets will be served, and the licensor's returns also will be maximized
2. License it to one company with the requirement that it develop all uses, either directly or through sublicensing, and work closely with that company to ensure that it meets its obligations
3. License it to multiple companies with field-of-use licenses

This chapter is about the third option, a do-it-yourself approach, which entails more work, provides more control, and has a higher probability of maximizing the return for the licensor.

3. STRUCTURING THE LICENSE AGREEMENT TO LIMIT THE FIELD OF USE

Some technologies clearly have multiple uses from the outset. For other technologies the potential uses may not be so obvious, but it is worth planning for the possibility. In either case, a licensor has several approaches available for drafting agreements for distinct fields of use.

First, however, some homework must be done: one must ascertain the possible fields of use. For example, the potential licensor could ask: Is the latest product from the organic chemistry department useful as a fertilizer? A food additive? A perfume ingredient? A pharmaceutical? If it is

useful as a food additive, can it be used in liquid products? Dried soups? Animal feed? If it is useful in animal feed, will it be useful in pet food? Livestock feed? Included as part of the normal market-evaluation process that most technology transfer professionals undertake, this exercise will yield essential information for developing the best field-of-use approach to take.

Once the possible fields of use are clearly defined, the next step is to market the technology to companies serving one or more of the markets those fields represent. Given a willing licensee and agreement on the scope of the license, several approaches can be evaluated for limiting the field of use in the actual license agreement.

3.1 *The grant clause*

The field of use can be limited in the grant clause by adding a phrase that delineates the field. The examples in this and the following two sections use various modifications to grant clauses from publicly available agreements to limit the field of use granted. (The original clauses and full agreements can be found on the example licensor's Web pages. Addresses can be found in endnotes.)

a. **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the field of use of veterinary medicine and to practice and have practiced any **Licensed Processes** in the field of use of veterinary medicine.[2]

The approach in example *a* works well if the term being used to describe the field of use has a commonly accepted meaning. If it does not, or if clarification is needed, an additional (for example, exclusionary) sentence can be added to the grant, as in the following example:

b. Subject to the terms and conditions of this Agreement, Stanford grants Licensee a license under Licensed Patent to provide DNA-based diagnostic services in the Licensed Territory for providing DNA-based diagnostic services. This license specifically excludes the right to sell Licensed Product(s).[3]

In example *b*, there might be some ambiguity about whether the field of use of "providing DNA-based diagnostic services" includes selling DNA-based diagnostic products that enable others to carry out a diagnostic test. The additional sentence clarifies the limitation on the licensee: the licensee cannot sell Licensed Products. Providing diagnostic services must therefore be limited to an activity in which the licensee itself uses the Licensed Products.

In these two examples, the underlined language in the grant clause limits what otherwise would have been an unlimited license for any and all uses of the technology. Note that the language can define what is included in the field, as well as what is excluded. This approach to limiting the field of use in the grant can be taken with no other field-of-use-specific language in the license agreement, or in conjunction with related language in the Definitions section, as described below.

3.2 *Defining the field*

Perhaps the most common approach to limiting the field of use in the license agreement is to establish *Field* or *Licensed Field of Use* as a defined term in the agreement. It then can be used to limit the field in the grant clause. This approach has the advantage of simplifying the grant clause, while allowing a full definition of the field elsewhere. This is especially advantageous in a grant clause that is already lengthy or segmented, or for a field that cannot be expressed adequately in a few words. Examples of possible paired definition and grant clauses follow:

a. Field of Use, shall mean the field of research reagent products. LICENSED FIELD OF USE specifically excludes the field of human diagnostic products.

OHSU hereby grants and Licensee accepts, subject to the terms and conditions of this Agreement, a nonexclusive license under the Licensed Patent Rights in the Licensed Territory to make and have made,

to use and have used, and to sell and have sold any Licensed Products and/or Licensed Processes in the Licensed Field of Use.[4]

b. FIELD shall mean the field of human vaccines and human therapeutics for Acquired Immune Deficiency Syndrome.

Dartmouth hereby grants to Company and its Subsidiaries an exclusive, royalty-bearing license under Dartmouth Know-How and Dartmouth Patent Rights to make, have made, use, and/or sell Licensed Products in the Field in the Territory. Notwithstanding the foregoing, Dartmouth expressly reserves a nontransferable royalty-free right to use the Dartmouth Patent Rights and Dartmouth Know-How in the Field itself, including use by its faculty, staff and researchers, for educational and research purposes only. Company agrees during the period of exclusivity of this license in the United States that any Licensed Product produced for sale in the United States will be manufactured substantially in the United States.[5]

An alternative construction would include a phrase *in the Grant* to limit the license, and then define that phrase in the Definitions. As an example:

c. Human Cancer Therapeutics shall mean the treatment of human patients exhibiting malignant tumors, including but not limited to carcinomas, sarcomas and lymphomas.

Subject to the terms and conditions of this Agreement, Stanford grants Licensee a license under Licensed Patent in the field of Human Cancer Therapeutics.

Example *c* has the advantage of being custom tailored, while examples *a* and *b* have the advantage of being model documents that can be revised more simply for a new technology. The only change needed to the model document during drafting is in the Definitions; the Grant is designed to be used without modification and to be limited as to field of use by an appropriately defined term.

3.3 *Limiting rights through reference to patent claims or separate patent applications*

A third general approach to limiting the field of use of a license involves limiting the grant of rights to specific patent claims, or to a specific family of related patent applications. A well-written patent application will cover broad areas related to the technology. If the claims, however, fall into distinct groups, one could reference the claims necessary for the intended field of use or specifically exclude claims that cover uses not intended for inclusion in the license. Here are some examples of grant language that could be used in this type of approach:

a. Where an issued patent exists and is all that is referenced in the Definitions section under patent rights, the approach is straightforward. Determine the issued claims that are required for the field of use and reference them by number in the Grant. For example:

PHS hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, an exclusive license under claims 1 through 7 in the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** and to practice and have practiced any **Licensed Processes**.

b. Another reasonably straightforward situation is where a distinct invention associated with the field of use is contained within one patent application within a family of related applications that otherwise covers broader uses of the technology outside of the intended field of use. In this situation, the patent application can be the basis of the definition of licensed patents, but care must be taken not to intermingle different uses of the technology between patent applications during prosecution. The grant language would be unchanged, and the definition of the patent rights to be licensed would be limited to the appropriate patent application, as in the following example:

Licensed Patent Rights shall mean:

1) U.S. patent application (serial number) filed (filing date), the inventions claimed therein, and to the extent that the following contain one or more claims directed to the inventions claimed in U.S. patent application (serial number), all divisions and continuations of this application, all patents issuing from such application, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;
2) to the extent that the following contain one or more claims directed to the invention or inventions claimed in U.S. patent application (serial number): *i)* continuations-in-part of a) above; *ii)* all divisions and continuations of these continuations-in-part; *iii)* all patents issuing from such continuations-in-part, divisions, and continuations; and *iv)* any reissues, reexaminations, and extensions of all such patents;
3) to the extent that the following contain one or more claims directed to the invention or inventions claimed in U.S. patent application (serial number): all counterpart foreign applications and patents to *a* and *b* above.

Licensed Patent Rights shall *not* include *a, b,* or *c* above to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in U.S. patent application (serial number).

Note that this patent rights definition allows for the usual possibilities during prosecution (divisions, continuations, foreign counterparts); but where a normal descendant, a continuation-in-part, may bring in new matter, the definition limits that case's inclusion to claims related to the subject matter of the original patent application. This provides some assurance that uses of the invention beyond the intended field of use will not be wrapped into the license during the process of attempting to get a patent to issue.

It should be noted that there are some drawbacks associated with limiting the field of use solely by reference to a patent application still in prosecution. It is much cleaner to refer to an already issued claim (see section 3.3, paragraph a, above). The claims of a case still in prosecution can change through modification, deletion, or addition; in theory, they could change in ways that are not consistent with the intended field of use. Thus, when working with a patent application, as opposed to an issued patent, the approach outlined in this section can be combined with language that specifically states the field of use (see 3.2.a and 3.2.b, above). This "belt and suspenders approach" ensures that the field of use will be clearly defined, while separating out the claims to that field in a separate patent application. The additional value of having one licensee's claims in a separate patent property will become apparent in the following sections on "Reimbursing patent expenses" and "Handling patent infringement/interference issues."

4. SPECIAL ISSUES IN FIELD-OF-USE LICENSING

Several problems may be encountered if, instead of granting all rights associated with a technology to a particular company, a licensor divides those rights by field among several companies. These problems, which are described in the following three sections, arise whether or not the field-of-use licenses are exclusive; in fact, some of the problems are the same as those that occur when licensing nonexclusively without limitation as to field of use. The good news is that, with some planning, a licensor can minimize these problems.

4.1 *Overlap of rights between licenses*

In the field-of-use licensing, the licensor works to clearly define the possible fields of use for a technology. While attempts can be made to distinguish fields as much as possible with currently available information, only hindsight can be crystal clear. The licensor and licensees should be

aware that overlap in fields might occur in the future. An overlap could be due to different interpretations of the rights granted under licenses or to unexpected future technical developments.

Such overlap could have significant economic impact on a licensee. For example, it could render nonexclusive a market segment that the licensee expected to hold exclusively, which could reduce a licensee's income stream in its field of use. While the economic interests under dispute affect the licensees, it is through the contract with the licensor that the situation can be resolved most effectively.

It is wise to lay the groundwork early on for resolving potential disputes related to this specific issue. A provision in each license that allows the licensor to resolve disputes may be acceptable. Alternatively, there could be a commitment to mediation, arbitration, alternative dispute resolution, or some other means short of litigation. Of course, the best course involves ongoing, constructive dialogue between the licensee and licensors, so that when problems arise, good communication and strong relationships needed to encourage negotiated solutions will already exist. If all parties enter the relationship with awareness of the potential need for dispute resolution, and if they agree, before problems arise, on a balanced way to deal with a dispute, then such problems will be easier to manage if and when they arise.

A variation on this theme is the issue of cross-prescription or cross-marketing—when the licensee sells products for use under its field, but the products are usable by the purchaser outside that field, in a field licensed to another company. Again, advance planning can help head off serious problems. For example, in the area of therapeutics, it would be worthwhile to group together fields that will use the technology in the same delivery form, and then grant a license to one company for these fields. If a therapeutic can be used intravenously, at similar concentrations, to treat both cancer and heart disease, it may be wise to license both uses to one company. There are multiple benefits to all parties in such instances. One party can handle research, development, regulatory approval, and sales more efficiently. Cross-prescription will not be a problem because proceeds flow to the same licensee. In addition, the licensee can choose independently to work with another company through sublicensing to develop one or more of the uses, staying in closer control while accessing needed resources. Grouping related uses together in a larger field provides the licensee with a larger incentive to invest in the technology and reduces problems for the licensor.

4.2 *Maintaining control of patent prosecution*

The interests of licensee and licensor do not always overlap during prosecution. This truism is amplified when a licensee has a limited field of use. The licensee may not be willing to support prosecution of certain claims or may seek to modify claim language to enhance the patent's value to the licensee at the expense of other licensees or the licensor. For this and other reasons, it is recommended that the licensor retain control over patent prosecution, while seeking to fairly distribute costs over field-of-use licensees.

4.3 *Reimbursing patent expenses*

As with any program involving multiple licensees for a technology, the field-of-use licensor must manage patent expenses creatively. With no single licensee committed to paying or reimbursing all costs, the licensor must choose another mechanism to cover patent expenses. The possibilities include the following:

a. The licensor covers patent expenses up front, reimbursing them from the royalty stream. This model results in licenses that have no patent-reimbursement language.
b. If the field-of-use licenses have been structured to relate to distinct patent applications or patents, costs can be cleanly linked to a specific license, and patent-reimbursement language as per a standard, exclusive license agreement will suffice.
c. The licensor prorates patent expenses over multiple licensees. This approach involves patent-reimbursement language in the license, with a variation on the standard theme. For example, *"On March 1 of each year during the term of this Agreement, Licensor shall provide Licensee an invoice for Patent Expenses equal to the patent costs for*

the prior calendar year divided by the number of licensees of Licensed Patents during that calendar year. Costs will be prorated for licenses that are effective for only a portion of said calendar year. Licensee shall pay this invoice within thirty days of receipt."

d. In some situations, considerable patent expenses can accrue before a technology is successfully licensed. In this scenario, if costs are to be reimbursed by the licensees, language can be used to include future licensees in that reimbursement. A fixed sum of past patent expenses can be attached to each license, or the initial licensee(s) can reimburse all the costs to make the licensor whole and then use those payments as credits as new licensees sign up. This last approach has the advantage of providing some incentive to licensees to have other companies also licensed under the technology.

4.4 *Handling patent infringement/ interference issues*

In field-of-use licensing, as with nonexclusive licensing, the lack of an all-inclusive license held by any one company reduces the licensee's motivation to protect the patent in an interference or infringement situation. The exclusive field-of-use licensee has more motivation than a straight nonexclusive licensee, because it has some exclusivity and would possibly have significantly more competition in the absence of a valid patent. Other parties (the other licensees), however, would also benefit from the patent being upheld, so that any one company may be unlikely to agree to bear the total cost of interference or litigation.

Again, there are clear advantages to designing the patent filing strategy for field-of-use licensing. If a field-of-use licensee is the only licensee of a particular patent or application in a family of related patents on a technology, the standard arrangements made with an exclusive licensee still can be used, focusing on that particular case.

If the field-of-use licensing has been undertaken in such a way that more than one licensee has an interest in a particular patent property, the simplest approach is for the licensor to carry interference and infringement costs alone, recovering them through royalties or settlements. Using this approach, the licensor retains more control. The approach also places the risk and cost on the licensor, and thus should be taken only when the potential reward justifies the resources required. Financial and legal support for these events could be obtained from other sources within the licensor's organization, supplied from a set-aside created at the beginning of the royalty stream, or covered by an insurance product carried by the licensee or licensor. Part of the planning process for field-of-use licensing (as for nonexclusive licensing), therefore, includes developing a strategy to manage the possibility of sizable future costs that might be borne solely by the licensor.

Another approach to addressing 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. For example, a licensee could be allowed or required to take the lead in litigating infringement in its field of use. The net proceeds could be treated as net sales or profits, as appropriate, for earned royalty purposes. Alternatively, both parties could share the costs and proceeds within the licensee's field, or the licensor could take the lead in litigating infringement, retaining all proceeds. These suggestions are much the same as those a licensor would select from for any exclusive license. In this case, the licensed field of use limits the infringement or interference actions that would trigger licensee responsibility.

It should be noted that the existence of more than one exclusive licensee makes it more likely that a licensor will be drawn into litigation as the only party having standing to sue. The license can require that the licensee cover any licensor legal costs, but for licensors that do not want to be named as a party to a lawsuit, a single exclusive licensee with an undivided interest that is required by the license agreement to take the lead in litigation may still be preferable.

4.5 *Diligence*

Managing diligence by the licensee is one of the issues that become simpler with field-of-use licensing. For example, if one company has responsibility for developing products for less

developed countries, or for developing a human therapeutic, it is straightforward for the licensor to assess licensee performance. Having a field of use isolated from other fields removes the need to stage commercialization of products for multiple fields because of resource limitations for a single licensee with responsibility for more than one field.

5. CONCLUSIONS

The guidance provided here is intended to help licensors maximize the reach of their innovations into multiple fields, whether those fields exist at the time of the license, or arise as the innovation develops. Sometimes one licensee can develop the full potential of a technology, but often it will take multiple partners, each with its own focus, resources and expertise, to fully realize that potential. ■

SANDRA L. SHOTWELL, *Managing Partner, Alta Biomedical Group LLC, 7505 S.E. 36th Avenue, Portland, OR, 97202, U.S.A. shotwell@altabiomedical.com*

1 For example, the National Institutes of Health from time to time issues guidelines intended to ensure broad access to certain types of technologies, such as biomedical research tools, and suggests limitations on how such technologies should be licensed. (See, for example, Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts at ott.od.nih.gov/policy/rt_guide_final.html#20.) The approach some institutions have taken to follow these guidelines has been to issue nonexclusive licenses for the research reagent market and exclusive licenses for therapeutics or other fields requiring significant investment.

2 See model agreements at ott.od.nih.gov.

3 See sample documents at otl.stanford.edu/industry/resources.html#documents.

4 See sample agreements at www.ohsu.edu/tech-transfer/index.shtml.

5 See www.autm.net/aboutTT/aboutTT_policies.cfm or www.dartmouth.edu/%7Etto/standard.html.