Designing Patent Applications for Possible Field-of-Use Licensing

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ABSTRACT

Patent applications should be organized and drafted with a long-term objective that carefully considers the multiple possibilities, and opportunities, of field-of-use licensing. This is particularly the case in the agricultural, pharmaceutical, biochemical, and chemical disciplines, as inventions can have multiple applications that are sometimes impossible to foresee. Technology managers must, therefore, focus strategically, not only on the basic idea of an invention but broadly, in order to consider the various ways such an invention might be put into more widespread and more profitable use. Therefore, the more details, examples and alternatives that are thought through and then disclosed in the patent application, the greater the opportunity for future divisional or continuation applications, as well as future claims that can be exclusively (field-of-use) licensed. By making all of the institution's licenses, in effect, field-of-use licenses, the technology manager retains the ability to take a possible future use and license it to someone else, maximizing the benefits of the inventions and generating higher royalties for the institution.

1. INTRODUCTION

The life of a technology transfer administrator is not an easy one. With tight budgets, the more that a university can make from its licensing program, the better. One of the great benefits of field-of-use licensing is that it allows a licensor to license the same patent or related patents to different parties in different fields, thereby maximizing the income stream from patent royalties. For example, part of a biotechnology invention could be used to make diagnostic tests for a disease, while another part of the same invention could be used to prepare pharmaceuticals to treat the disease. One company may have expertise in the sale and distribution of diagnostics while another company has all the resources to get U.S. Food and Drug Administration (FDA) approval for human pharmaceuticals. Either of these companies could be licensed to cover both areas, but maximum sales and royalties would be obtained by having each company sell in its area of expertise. This chapter focuses on specific examples of field-of-use licensing and discusses how a manager can aid in the development of well-written patent applications that support this licensing approach.

It might be useful to consider making every license a field-of-use license. Even though a particular invention suggests a single use that appears to perfectly fit a potential licensee, there is simply no way of knowing what other uses may develop over the life of a patent. A piece of control technology developed solely for automobile manufacturing may turn out to be useful for operating a rocket system developed several years

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thereafter. Rather than simply licensing such a patent exclusively to a particular automaker, an inventor should consider licensing the patent to a particular automaker in the field of automobile manufacturing. When a particular field of use is properly licensed, other fields of use developed in the future would remain the property of the university for later exploitation.

2. THE VALUE OF A QUALITY APPLICATION

There are some basic concepts that can apply to all patent applications, not just those that are appropriate for a potential field-of-use license. First, it is important to have a well-written patent application. Far too many technology managers look at the cost of preparing and filing a patent application as opposed to the *total cost* of obtaining a patent. It is not the cost of filing the application that counts, but the total cost of getting the patent. Although cost alone is not a determining factor of a well-written application, a frugally prepared patent application may contain mistakes or omissions and/or may not be sufficiently thought out to provide broad coverage or ideas for possible future expansion into other opportunities. These initial oversights could lead to expensive amendments, the necessity of filing continuation applications, and even continuation-in-part applications to rewrite the application and thus, raising the overall cost of the application.

2.1 *The patent application as a sales document*

One benefit of a properly written patent application is that it provides a far more useful sales document than one that is poorly prepared. Often, a particularly new and valuable development does not yet have a licensee. Thus, a well-written patent application is important for convincing a potential licensee that the invention is worth licensing. Both the potential licensee and the patent examiner need to be confident of the value of the invention, but for different reasons. The patent examiner will look for "statutory" value—whether the invention sought to be patented is novel, useful, and non-obvious to one skilled in that art. The potential licensee, in addition to statutory value, may seek value based on the potential commercial or humanitarian value of an invention. An application that is poorly constructed and includes typographical errors or scientific inconsistencies will make a negative impression on a potential licensee and on a patent examiner.

2.2 *Allow for future coverage*

A well-written application will reflect considerations of possible areas of future coverage, describing not only the basic idea developed in the lab, but also peripheral ideas and extrapolations. Including such information supports broad and valuable coverage in a patent. It suggests areas for future development that can be covered in more detail in continuation applications. Specifically, if these future ideas are at least sketched out in an application's specification (that is, are adequately disclosed in the original application), there can be a basis upon which to reach back to the earliest filing (priority) date for subsequent claims and related amendments disclosed in the original parent application. Thus, the institution would have the benefit of a filing date that will avoid what otherwise would be prior art.

Coming up with alternative uses of an invention, or other ideas for development, should be a collaborative effort between the patent attorneys, the technology managers, and the inventors. Recognizing that managers often prefer to minimize direct contact between inventors and the attorneys in order to keep costs down, this is one instance where direct communication can prove to be particularly useful and valuable, as even the best patent attorney cannot think of all of the alternative uses of an invention or all the modifications or possible future uses of an invention.

Such contact between the inventor and the attorney is critical for developing examples of adaptations or permutations needed to provide for future field-of-use licensing. Prior to this communication, the technology manager may wish to encourage the inventor to describe additional alternatives or other possible future uses and simply forward these descriptions to the patent attorney. This exercise could begin the creative thought process—the "what if" thinking—needed to come up with other possible future uses. The more the inventor engages in this type of

thinking, the less time it will take for the patent attorney to consider and describe the potential of the invention. A monetary savings can sometimes be realized as well since it will take less time for the patent attorney to prepare the application.

2.3 *Retain control over the patent application*

All too often, a university will turn over the writing of the patent application and the control of the patent prosecution to the licensee. This creates an inherent conflict of interest and a potential for future litigation. (The conflict arises because a licensee may prefer relatively narrow patent protection to minimize the amount of royalties it might have to pay in the future.) In patent prosecution, decisions need to be made as to what level of protection to seek. Relatively narrow patent claims can often be obtained without too much difficulty and expense. Broad coverage, however, may be far more important for a university because it would allow for future licensing and would cover more products to be sold by the licensee. While broad coverage may have been originally sought to cover a licensee's future developments, if, during patent prosecution, the claims are narrowed so that the licensee's future developments are outside of those patent claims, the university could lose significant royalties.

Specific to a potential field-of-use licensing situation, the patent application will have disclosures and possibly claims to uses of the invention that are outside a particular licensee's interest. That licensee would, of course, have no incentive to spend any time or money expanding on the concepts outside of its own interests.

Where the university controls the patent prosecution, it has the ability to determine the breadth of the patent protection it wishes to seek and whether to dedicate resources to expand the patent coverage into other fields of use. When preparing the patent application, one should think of all possible uses of the invention, not just those of a present licensee. These do not have to be worked into all of the claims, but the disclosures should appear in the patent application. At some future time, should another potential licensee show interest in that area, a continuation (or possibly, a continuation-in-part) application can be filed, expanding on that particular aspect of the basic concept. Thus, the institution has the benefit of the earlier filing date, and a new application can expand on and claim the particular new development.

While the university should retain control over the patent application, it is still possible for the license agreement to have the licensee pay for the prosecution of the patent application. In the case of two licensees for the same patent, the patent expenses can be divided equally between the two licensees. This also is discussed in greater detail in the preceding chapter.

3. STRUCTURING THE PATENT APPLICATION

In structuring the patent application, it is best to incorporate as many alternatives as possible for future expansion. Doing so can have two direct effects: (1) the application will support broader claims than might otherwise be possible—this can be particularly important in the biotechnology and chemical areas, where it is often necessary to give more than a simple example to support broad claims in the patent application—and, (2) having ideas for future uses in the application allows for continuation applications to these developments. This is a version of the "throw in the kitchen sink" approach. It is difficult to predict what will have future value, and it may not be worth having claims for ideas for potential uses in the application, but it is worth having at least a sentence or paragraph about a possible alternative. Two or three pages of a patent application can include a great many of these "sleeper" inventions that can remain dormant and be brought to life when they are found to have a particular value.

This is not a new idea. The 1876 Alexander Graham Bell patent titled Telegraphy describes Bell's invention as a multiple telegraph using different frequencies of sound to simultaneously transmit several telegraph messages over the same wire. A reference is made toward the end of the patent that the invention can be used to transmit sounds and, if certain modifications are made, even the human voice. The value of this last extrapolation can be seen by the number

of infringement lawsuits referred to as "The Telephone Cases."

The claims of the patent application can also be structured for field-of-use licensing. There can be broad claims to the general overall concept that are licensed to more than one party on a field-of-use basis; there can also be narrow claims directed to specific fields of use that are licensed only to a particular licensee. The narrow claims can be written to define the field of use, for example, the use of the invention as a diagnostic for a particular disease in farm animals; another narrow claim could define the use as a similar diagnostic for humans. Future continuation or divisional applications could have claims directed to other specific fields of use.

The approach described here has the benefit of providing specific claims or specific patents that can be exclusively licensed to a particular licensee. Generally, licensees prefer to have an exclusive license, even if it is only for a specific claim or a specific patent. In addition, defining specific narrow claims for different licensees can provide a mechanism for allocating the reimbursement cost of prosecuting the patent applications as well as for determining which licensee will be responsible for or involved with suing a potential infringer. For example, the license agreements can be structured such that if a patent claim exclusively licensed to a particular licensee is infringed, then that licensee is required to take part in the infringement litigation. If different claims exclusively licensed to separate licensees are infringed, then both licensees would be involved in the litigation. The idea is that if each licensee's exclusive "turf" is invaded, they would want to be involved. Separate patents for exclusive licensing to different licensees can arise as a result of restriction requirements. This issue is discussed in more detail below.

3.1 *Biotechnology example*

One of the wonders of biotechnology is the discovery that genetic information can be used to code for proteins or parts of proteins. For example, it has been found that relatively short lengths of polypeptides can be used to form vaccines. Prior to this discovery, vaccines had been made from proteins obtained from dead or weakened viruses.

By way of a fictional example, a scientist has discovered the gene coding for one of the envelope proteins of "RBS" virus. Suppose the RBS virus has only recently begun to infect the human population and some of its potential effects include a revival of a previously conquered illness. The scientist has also discovered that a 20-amino acid residue polypeptide which is named "Merkin" and which can serve as a vaccine against the dreaded RBS. In addition, the scientist has found that when the Merkin polypeptide is injected into animals, the animals exhibit an immune response and begin producing harvestable antibodies that react with RBS virus in a sample. The scientist has also recently successfully created a monoclonal cell line that produces antibodies to RBS.

These anti-Merkin antibodies are particularly valuable because they have a high affinity for the RBS virus and, at least in the lab, protect precious bodily fluids from infection. Therefore, a possible use of the antibodies would be to create a direct treatment for an RBS virus infection: the antibody would be collected and then injected into the patient as a form of treatment.

Another use for the Merkin polypeptide is in an assay to detect the presence of anti-RBS antibodies in human blood serum. It was found that using the antibody as a means to detect RBS was not successful because the RBS virus does not generally appear in a high concentration in blood. However, when the Merkin polypeptide was used, it reacted with antibodies in the patient's blood and other precious bodily fluids to indicate whether there had been antibodies produced to fight the RBS virus, now present in the blood. One type of HIV assay system works similarly. It does not detect the presence of HIV itself, but rather it detects the presence of HIV antibodies in the patient's blood. The success of the test depends on the assumption that if HIV antibodies are in the patient's blood, the patient has been exposed to or infected by HIV.

Thus, it appears as though the Merkin polypeptide has at least two immediate uses. The first is as part of an assay system to check for an RBS virus infection, and the second is for future development as a vaccine. The antibodies that have been developed appear to have possible uses for a

future assay as well as possible future therapeutic value.

A potential licensee, Assay Specialists, Inc. (ASI) has shown particular interest in the use of the Merkin polypeptide for conducting diagnostic assays. ASI is a large company that has a great deal of experience in assays of this type, although it has little to no experience in therapeutic treatments and vaccines. Another company, Vaccinia, has indicated an interest in possibly developing a vaccine and therapeutic treatment. At this point, Vaccinia's interest is lukewarm, because preliminary studies of using a vaccine on animals are still being conducted.

Based on this, therefore, a properly prepared patent application could cover the following inventions:

1. The gene used to make the envelope protein.
2. The purified envelope protein.
3. The part of the gene that codes for the Merkin polypeptide.
4. The Merkin polypeptide.
5. A vaccine based on the Merkin polypeptide.
6. Antibodies to the Merkin polypeptide.
7. The monoclonal cell line.
8. Diagnostic products based on the Merkin polypeptide or its antibodies.
9. A therapeutic treatment based on the antibodies.
10. A cure for the recurring illness.

A field-of-use license can be granted now to ASI directed to diagnostic products. This would be a non-exclusive but field-of-use license to the claims directed to the Merkin polypeptide generally (4) and an exclusive license (meaning that ASI will be the only licensee) for those claims that are specifically directed to the use of the Merkin polypeptide for diagnostics (8). There can also be a non-exclusive license for the use of the part of the gene that codes for the Merkin polypeptide (3) so that ASI can also make the polypeptide, using DNA cloning techniques. This results in a licensee signed up in the initial stages and provides a source of revenue to support the patent application(s) and further research.

As matters progress and Vaccinia becomes more interested, a non-exclusive but field-of-use license can be granted to Vaccinia on (3) and (4). Vaccinia would be the only licensee for the vaccine based on Merkin (5). At some future date, if there is a revival of the previously conquered illness in epidemic proportions, there may be another potential licensee and, therefore, justification for a divisional patent application directed to a cure for the recurring illness (10).

3.2 *Chemical example*

Dr. Lovejoy has discovered a highly toxic compound that he has named oxymoronic acid. This compound is very useful in treating certain mental disorders. The only known source of oxymoronic acid is certain mutant desert bushes that grow only in the area surrounding nuclear test sites. The elimination of open air testing of nuclear weapons, however, has put great restrictions on the number of mutant plants available. All attempts to cultivate oxymoronic-producing plants have thus far been unsuccessful, but Dr. Lovejoy has recently found a way of synthesizing a precursor of oxymoronic acid that he has named protomoronic acid that can be manipulated to form oxymoronic acid. Through this synthesis scheme, it is possible to produce oxymoronic acid in the quantities needed for medical treatment purposes.

Through encouragement by the technology manager and the patent attorney, Dr. Lovejoy has worked out alternative synthesis schemes for other possible precursors of oxymoronic acid, one of which is called "AP." While these schemes have not been fully tested, they appear to provide other ways of making oxymoronic acid synthetically and thus may prove to have value in the future. A patent application is prepared having claims in the following areas:

1. Oxymoronic acid in a purified form as a pharmaceutical.
2. The precursor, protomoronic acid.
3. Various alternative precursors, including AP.
4. The methods of making oxymoronic acid using the various precursors.
5. A rat poison based on oxymoronic acid.

The last category listed above was a gratuitous discovery when one of Dr. Lovejoy's graduate students, who had a laboratory in a less than desirable location, dropped some oxymoronic acid on the floor and it was sampled by one of the visiting rodents. It was discovered that it made an extremely effective rat poison.

Because this discovery was fortuitously made and was not considered to have any immediate commercial value, the idea of using oxymoronic acid as a rat poison was put in as a sentence or two in the patent application. This did not cost anything, but it left open the possibility of future options. Some years later, while one of the patent applications was still pending, a major pesticide company came to the university asking for a license to further develop this rat poison. Because a divisional application was still pending, it was possible to file a continuation (or a continuation-in-part) application having claims directed to the use of oxymoronic acid as a rat poison and thereby grant the pesticide company an exclusive license in the field of using oxymoronic acid as a rat poison. In such a case, the graduate student could likely be a co-inventor (as opposed to the rat who actually made the discovery but did not live to tell about it).

An exclusive field-of-use license in the medical area was granted for (1), the pharmaceutical, above. Later it was found that AP had particular usefulness as an adhesive and was licensed to a bumper sticker company because no exclusive license had been granted for (3) above.

4. RESTRICTION REQUIREMENTS AS OPPORTUNITIES

It is quite likely that a patent examiner reviewing a patent application directed to the above examples would take the position that there is more than one invention present in a given application (in some jurisdictions referred to a lack of unity of invention). For example, the examiner may say that the gene is one invention, the polypeptide is a second invention, the diagnostics are a third invention, the vaccine is a fourth invention, etc. When this is the case, the patent application is "restricted" to only one invention, and then one, or possibly more, divisional patent applications are carved out of the original parent patent application.

The typical reaction to this is annoyance. After all, what has been filed as one patent application will now be split up into four and perhaps as many as ten parts. However, one should not necessarily complain, as there might be a silver lining in this gray cloud. This situation, albeit initially annoying, can often be done relatively simply, and present new opportunities.

Since the U.S. Patent and Trademark Office has taken the position that there are separate inventions in the patent application, these inventions can be prosecuted as separate applications. Thus, one can continue to prosecute the claims directed to the diagnostics until those are allowed. The diagnostic patent issues, and that patent can be exclusively licensed to ASI. Meanwhile, a series of other patents may be obtained from the same core invention (the parent application) via a series of divisional patent applications arising out of the restriction requirement. Each patent can be directed to a different field of use and licensed separately. Furthermore, depending on the circumstances of each application, there might be opportunities for patent term extensions due to delays in the patent office, certain administrative proceedings (for example, successful appeals), or for regulated medical products to compensate for regulatory delays. Thus, a restriction requirement, when strategically managed, can become an unexpected series of opportunities.

5. CONCLUSION

The main point presented in this chapter is to encourage creative thinking when preparing patent applications. The technology manager should focus not only on the basic idea, but should also encourage inventors to think broadly regarding all the various ways their invention might be put into use. When the patent application is filed, there is no way of knowing every possible use of the invention. Thus, the more invention ideas that can be put into the patent application, the more support there is for future divisional or continuation applications, or future claims that can

be exclusively licensed. By making all of the institution's licenses, in effect, field-of-use licenses, the technology manager has retained the ability to take one of these possible future uses and license it to someone else, maximizing the benefits of the inventions and generating higher royalties for the institution. ■

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