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Practical Steps for Building a Strong Life Science Patent Portfolio Worth Billions of Dollars

By Kimberly J. Miller, Ph.D.

In the last four years, several companies with antiviral drug programs, including Alios BioPharma, Idenix, Inhibitex, InterMune and Pharmasset, have been acquired by large pharmaceutical companies ("big pharma").[1] One of the main reasons these companies are attractive to big pharma is that they have developed a drug that shows promise against a disease where there is not yet a suitable cure. Another important aspect to big pharma is the company's patent portfolio. Some interesting statistics regarding drug development are: (1) a drug takes an average of 10-15 years to develop and costs billions of dollars; (2) only one out of 5,000-10,000 new chemical entities ever reaches the consumers; (3) only two out of 10 drugs that undergo clinical trials reach the market; and (4) of those drugs that reach the market, only three out of 10 drugs earn enough money to match or exceed the associated research and development costs. Therefore, to be attractive to big pharma seeking to protect such enormous investments it is important for a company that its drug be protected by a strong patent portfolio.

[1] Johnson & Johnson acquired Alios BioPharma, Inc., in 2014 for approximately $1.75 billion in cash; Merck acquired Idenix for about $3.85 billion in 2014; Bristol-Myers Squibb Co. acquired Inhibitex, Inc., for about $2.5 billion in 2012; and Gilead Sciences Inc. acquired Pharmasset Inc. for about $11 billion in 2011.

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Landscape Searching Is a Useful Tool

At the beginning, an important step in creating a strong patent portfolio is landscape searching. This includes both patentability and clearance searching. Often a company conducts its own in-house searching using available programs and/or search engines, such as SciFinder®. This initial searching is useful to identify potential competitors and some initial references. However, a company should consider spending the money and commissioning one or more searches by an outside search company. Searching is a process that includes many variables, and an outside search company has experience in identifying and considering these variables.

The costs associated with conducting a search can vary and become significant. Two factors that influence the cost of the search is the time spent by the searcher and the number of references retrieved. To assist in getting a useful search at a reasonable cost, there are some simple steps that can be taken. One step is to effectively communicate the scope of the search with the searcher before he/she initiates the search. By doing so, the number of references that are retrieved can be controlled and limited to a reasonable number that can be reviewed and analyzed, thereby controlling the cost of the search. During this pre-search communication, variables and options that may come up in the search can be discussed and agreed upon prior to a significant amount of time being spent by the searcher. Another step that can be taken before the references identified by the search are retrieved is to have the searcher convey the number of hits identified by the initial search criteria. If the number of hits identified is too many and cost prohibitive, modifications to the search can be discussed. Although this may take several conversations with the searcher, it is often less expensive overall. Another important aspect of communicating with the searcher is that the company will know how the search was conducted, including its strengths and weaknesses.

Another important advantage is that possible "blocking" patents or patent applications can be identified. No one wants to buy a lawsuit. By identifying possible blocking patents or patent applications early in the re-

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search and development process, a company can explore and develop potential alternatives, which saves the company both time and money. The company can also develop positions regarding the blocking patents or patent applications that may be scrutinized by an acquirer conducting due diligence with respect to the potential infringement risk in commercializing the drug. For example, in the instance of a blocking patent, a company can develop invalidity and/or non-infringement positions ahead of time. In addition, the company can consider conducting licensing negotiations with the owner of the blocking patent or application early on, which may save the company, and a subsequent acquirer, considerable amounts of money in the long run.

Another step a company should consider is to monitor the status of any identified blocking references. In the case of a blocking patent application, a company should monitor the prosecution of the application to know what claims are being pursued and if additional applications are being filed, for example, a continuation and/or divisional application(s). For an issued patent, a company can monitor whether the maintenance fees are being timely paid so as to know whether the patent is still in force or has become abandoned.

Searching is also useful in the process of drafting a patent application. Today, many patent offices prefer and may even require literal support for each claim and/or claim amendment. By identifying patent and/or literature references via a search and being aware of their subject matter, the application can be drafted taking into account the subject matter in those identified references. For example, provisos carving around known subject matter can be written into the patent application, thereby providing the potentially needed literal support. Additionally, statements and/or references can be incorporated into the patent application, which may be useful during prosecution.

Establish Ownership

Ownership of the drug and the intellectual property around the drug is always a question that comes up during due diligence of a company's patent portfolio. A company should take steps to ensure the company owns both the drug and the associated intellectual property, such as patent applications or patents. One way to safeguard ownership is to obtain assignments from the inventors. To ensure execution of the assignment documents, the company should prepare them and obtain inventor signatures shortly after the application is filed. At this point in time, the whereabouts of employees and/or contractors is usually known, and the relations between employees and/or contractors and the company are often on good terms. If a company waits, the execution of the Assignments documents may become difficult and even costly as employees and/or contractors have moved on and/or relations between the company and the employee and/or contractor may have soured. Likewise, where a portion of the company's patent portfolio is licensed in from a third party, the company should ensure that any such license agreement provides all necessary rights for commercialization, and that such licensed rights are assignable to an acquirer.

Timing of Each Filing and the Claims Being Pursued Are Two Important Factors

Pursuing a patent portfolio is an expensive endeavor. Therefore, it is important that a company consider where and how to spend its money. At the early stages, a company should contemplate when to file. Once a patent application is filed, the time clock starts running. For example, the filing of U.S. provisional application starts a one-year statutory clock for filing the non-provisional U.S. application(s) and some foreign applications, such as a Patent Cooperation Treaty application. Therefore, a company should consider each patent filing as a stake in the ground that begins a time clock. With respect to filing a U.S. provisional application, there are two significant advantages. One is that the official fees associated with a U.S. provisional application are minimal, and the other is that the provisional application is not publicly available until after a U.S. non-provisional application and/or foreign application is filed. The company should keep in mind that there can be a considerable amount of attorney fees associated with preparing the provisional application. However, those preparation fees often can be managed. As the company conducts further research during this one-year period, a company should consider filing further follow-on provisional applications that supplement the initial provisional application.

A company also should consider the appropriate breadth of claims to pursue in each application. A company should pursue claims that specifically cover the drug. In addition, the company should pursue claims that generically cover the drug. These generic claims can provide protection against conventional design-arounds. If the generic claims are too narrow, there is a risk that one or more conventional design-arounds may be missed. However, if the generic claims are too broad, there is a risk that the company will not be able to get a patent issued on such broad claims, and at the same time, risk creating a patent publication that can be used against the patentability of the company's later application(s). The earlier application may disclose enough to be used as a ''prior art reference'' against a later application, but still not disclose enough to support the broad claims. Thus, a company should be conscious of what subject matter is included in each application in view of the direction of research.

To obtain broad claims, more patent offices are requiring actual examples. Actual examples include showing how the compound was made via the inclusion of analytical data, such as nuclear magnetic resonance and/or mass spectrometry. Additionally, patent offices are often now looking for biological data, such as one or more *in vitro* assay results. To obtain a generic claim, such as a broad genus claim, a company can consider the claim as a whole being a dart board. If the company wants to obtain a claim the size of the whole dart board, it will need to have examples that are spread all around the whole dart board. This does not mean the company has to have a dart in each section. Rather, the company should have enough examples so as to convey to the patent office that the dart board is sufficiently covered. This is not an exact science, and what is considered sufficient by one patent office may not be considered sufficient by another.

The timing of each patent filing is a factor that a company should consider. For example, by filing Applica-

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tion A prior to the publication of Application B, in many jurisdictions Application B can only be asserted against the novelty of Application A, but not against the inventive-step/non-obviousness of Application A.[2] By being aware of other applications being pursued by the company, the company has at least one of the tools for making an informed decision regarding the timing of each patent filing. Being aware of other applications being pursued by the company is also important during the prosecution of the applications. By knowing the subject matter and claims that are being pursued in each application, a company can try to avoid prosecution pitfalls, such as double-patenting and/or the submission of contradictory statements. Similarly, by considering the disclosed subject matter and claim scope being pursued in the various applications, the company can try to maximize the scope of exclusivity and competitive advantage provided by the portfolio as a whole. As a result, the company can strategically build a patent portfolio in which the potential negative and positive effects of the various applications and/or issued patents on one another have been taken into account.

Follow-on provisional applications should be drafted to allow the company to add further subject matter to the initial provisional application. However, the company should be aware that each claim is accorded a priority date (i.e., the earliest filing date for which a claim derives support). That priority date can change each time a claim is modified and/or data are added to the application. The priority date of a claim can become especially important when, for example, a prior art reference is asserted against patentability. Thus, a company should consider the priority date of each claim being pursued so as to have an application that has flexibility to overcome such a reference.

Think About International Prosecution Strategies

Once it comes time to file internationally, the associated costs can become prohibitive. According to an article in the American Intellectual Property Law Association (AIPLA) Quarterly Journal, filing in approximately 11-15 countries, including the U.S., covers more than 90 percent of the world pharmaceutical market.[3] A company also may consider one or more of the following factors when deciding where to file internationally: (1) the prevalence of the disease in the country, (2) the population of the country, (3) the gross national product of the country, (4) the location of the clinical trial(s), and/or (5) the official fees and costs associated with prosecuting and obtaining a patent. One of the larger costs associated with international applications is the translation of the application. Translation costs can be reduced by sharing translations, for example, a Spanish translation between Argentina and Mexico. Claim fees account for another large expense. These fees also can be reduced by amending the claims at the appropriate time in prosecution, such as at filing, when requesting exam and/or before grant. If the claims are amended early, the overall claim fees may be reduced, and the claims can be brought into conformance with a country's patent laws. As a result, the company can avoid one or more rejections pertaining to form and/or unpatentable subject matter. A further option for reducing international prosecution costs is to take advantage of any accelerated examination and/or Patent Prosecution Highway (PPH) programs that may be available. In many instances, there are no official fees for requesting accelerated examination or acceptance into a PPH program. Additionally, according to a presentation by the U.S. Patent and Trademark Office, the number of actions to disposal of a PPH application is lower and the overall allowance rate of PPH applications is higher.[4]

Another important factor a company should keep in mind is that each country has its own patent laws. Therefore, just because a patent was obtained in one country using one strategy does not mean that it is the best strategy in another country. Therefore, a company should be flexible in its patent prosecution strategy. For example, pursuing multiple patents in one country with a limited number of claims in each patent may be the best strategy for obtaining strong patent protection. However, in another country, obtaining only one patent with 50-200+ claims may be the best strategy.

Communication Is Key

It is important that the company communicate about what is happening during research and development. Companies typically send representatives to attend conferences where results are disclosed, issue press releases and/or publish articles. To guard against a disclosure that could damage a patent portfolio, a company should set up a disclosure protocol, which should include their patent counsel. The disclosure can be reviewed for potentially damaging statements, checking that certain subject matter is incorporated into one or more patent applications, and the protocol can be used to assist in developing prosecution strategies.

Another important reason to have regular communication is to assist in capturing improvements and the current developments in research and development. A drug can earn millions of dollars a day, and therefore, a company wants to maintain patent exclusivity for as long as possible. Patent exclusivity can be maintained by follow-on applications that capture the aforementioned improvements and current developments. The subject matter of these follow-on applications can vary, for example, pharmaceutical formulations, dosing regimes and methods of use.

One additional aspect that can come out of regular communication is possible ''defensive'' applications/patents. Often the subject matter of these defensive

[2] See Article 54(3) European Patent Convention, ''Additionally, the content of European patent applications as filed, the dates of filing of which are prior to the date referred to in paragraph 2 [The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application] and which were published on or after that date, shall be considered as comprised in the state of the art.''

[3] Robert Silverman, ''Patent Filing Strategies for Pharmaceutical Products: A Simple Cost-Benefit Analysis Based on Filing Costs and Pharmaceutical Sales,'' AIPLA Quarterly Journal (Spring 2005) 33(2): 153-187.

[4] Overall allowance rate: PPH cases are 91 percent, Non-PPH cases are 44 percent; Actions per Disposal: PPH cases are 1.7, Non-PPH cases are 2.7. Patent Prosecution Highway (PPH) presentation by the U.S. Patent and Trademark Office (http://op.bna.com/hl.nsf/r?Open=rkun-9urrea).

applications/patents comes from research into possible alternatives. By capturing the possible alternatives in an application/patent, a company can deter and even block competitors from entering into the space around the company's drug. A potential further advantage is that these ''defensive'' applications/patents may be a source of revenue for a company from licenses.

Concluding Considerations

Building a strong patent portfolio worth billions of dollars takes a lot of work and strategy. However, there are some easy steps that a company can undertake that can save the company both time and money. Several of these steps along with points to consider have been discussed in this article, and include landscape searching, the establishment of ownership, the timing of patent filings, claim strategies, international prosecution strategies and communication. By implementing one or more of these strategies, a company can build a strong patent portfolio worth a substantial amount of money, and facilitate bringing a new drug to market.

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