Building a strong patent portfolio

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Patents are tangible assets which, if properly managed and utilised, create increased value in a company. One of the commercial impacts of a strong patent portfolio is a strategic collaboration or alliance between a pharmaceutical giant and biotechnology company. Patents provide a tangible value in that they are often a means for attracting investors or providing a source of revenue through patent licensing. Moreover, patents inspire confidence in shareholders for a company's competitive position in the marketplace, since patents protect specific products and create a barrier to competition in the marketplace.

Patents are a very effective means of protection for the assets of any technology-based business. An ideal patent portfolio provides sufficient coverage to practise a technology and deterrence of competitors from encroaching on the competitive advantage of that technology. An ideal patent portfolio provides a sufficient defensive and optimal offensive position regarding the product, in order to provide a competitive advantage in a highly competitive and lucrative environment.

Defining the invention

Patents set forth the metes and bounds of the protection afforded as a series of claims, which the patent recites. These claims describe the product or aspect of the invention for which protection is sought. In the biotechnology/pharmaceutical industry, claimed inventions are typically a drug, formulation, construct, chemical, device, kit, etc. In many instances, a working version of the invention (ie, a nucleic acid, protein, compound, etc) is "in hand"; thus, a working version exists. In some cases, patents are obtained when there is a sufficient basis and preliminary models, etc indicating that obtaining a working version is a matter of "when" and not "if"; for example, an in vitro assay which indicates a compound is useful for a particular condition, prior to experimental model or clinical trial data being available.

Ideally, the claims are broader in scope than the specific elements of the technology in hand. The breadth of claimed coverage obtained is a particularly important means of preventing competitors from introducing minor variations to an otherwise protected product as a means of circumventing the patent.

Claims, however, should not be so broad as to lack support when viewed by the standard of what is known or available in the state of the art and what is described in the patent. This is particularly important in view of the rising incidence of patent invalidation during litigation proceedings.

An important consideration in the preparation of a patent application as a whole, and the drafting of claims specifically, is a requirement for an intimate familiarity with the state of the art, which in turn enables drafting of claims which specifically exclude, or carve out, a territory not currently known or patented.

From patent to portfolio

A multi-layered approach is best in protecting the desired technology, since it becomes that much more difficult to practise the technology or any applicable aspect thereof.

For example, when the technology is directed to a compound, the application should ideally claim the compound *per se*, a generic structure that covers the compound, uses of the compound and uses of the generic structure. Such claims must be supported by a broad, descriptive specification which provides multiple embodiments for the claimed genus and species.

Understandably, it is also desirable to claim the process for preparing the

compound and intermediates produced in preparing the compound, or the generic structure.

With time, results supporting these claims typically accrue. Thus, initial results may be directed to isolating or producing the compound and projected uses, based on a structural analysis of the compound. In time, *in vitro* and *in vivo* data may be obtained, including clinical trial results. Often the latter obtained results are somewhat unexpected – for example, providing a dosage that is optimal, a combination that is particularly useful, a treatment regimen that is useful, etc.

A series of putative Rule Changes by the United States Patent and Trademark Office was recently published. These rule changes, which are expected to take effect in some form, impact on strategic decisions regarding a given patent portfolio. The multi-layered approach described herein will find greater importance in providing optimal protection and greater care in terms of dividing different aspects of a platform technology will also be necessary. Ideally, more distinct subgenera should be claimed in separate applications, each of which covers an aspect of a technology which may likely be exploited by a competitor.

While the multi-layered approach increases the costs associated with protecting the core technology, it provides much added value in terms of the potential for the portfolio, as the technology itself is protected and competing with the technology becomes much more difficult since the protection afforded by the portfolio is broader than the technology alone.

Over time, further improvements to the technology are often obtained. These improvements in turn can be claimed in subsequently filed applications. Such improvements are importantly claimed, as they provide in some instances a means of extending patent life and in other instances, at the very least, a means of preventing a competitor from similarly filing and effectively blocking practice of at least some aspects of the technology and/or competing for the same market share.

Thus, a portfolio is born, which comprises a core patent directed to the essence of the technology, patents which are broader in scope than the technology comprising the marketed product and patents which claim improvements to the technology.

Pitfalls in patent prosecution

Once filed, the next stage in the life of the application is its prosecution. In general, when prosecuting an application, "less is more". The least argument present on the record in regard to prosecuting the patent the better, since it is less likely to create estoppel issues that in turn narrow the scope of the claimed invention. Often needless arguments are submitted, which in turn may be used later to restrict the scope of the invention. Interviews with the Examiner may be useful in furthering prosecution, yet provide a minimal record in terms of the content of what was discussed.

Typically, applications face some kind of rejection during prosecution. These rejections are important, particularly in terms of issues which may come up later, if and when the party faces litigation, regarding the issued patent. Since a patent, once issued, is given the presumption of validity, any issues raised during prosecution become almost impossible to revisit later during litigation.

Rejections to claims of an application are often directed to the amount of written description provided in the application, in terms of supporting the breadth of the claims and placing the public in possession of the claimed invention, in view of the level of skill in the art at the time the application was effectively filed.

Other classic rejections to claims are when the claimed subject matter is deemed by the Examiner to be broader in scope than that which is enabled in the application. For example, claims to use of a genus of compounds for treating a particular disease may be thus rejected if only a single compound is described in the context as being useful in treating the disease.

Other common rejections to an application are that the claims lack novelty or are rendered obvious in view of competing technologies identified or publications directed to identical or comparable material claimed. Such identification in turn may result in the introduction of amendments to the claims, which may result in changes in the scope of the claimed invention. Should there be no identification of competing technologies, there exists the possibility of broadening even further the scope of protection obtained. If the application supports a broader claim scope, such amendments can be readily introduced, or it may be advantageous or at times necessary to file a subsequent application.

While allegations of lack of novelty are rebutted in a straightforward manner, recent case law suggests that what renders an invention obvious hinges on how predictable

Short and long-term objectives

Short-term objectives should at least include the following:

- Filing applications directed to the core technology and products.
- Filing applications directed to changes or improvements to the core technology and products.
- Structuring the portfolio to file separate applications directed to subgenera, which are related yet distinct, which cover the core technology and products.
- Maintaining patent watches and competitive landscape searches with regard to applications/patents related to the technology and product.
- Maintaining patent watches with regard to applications/patents related to the market in which the technology and product expect to compete.
- Scheduling regular meetings with R&D scientists and business strategists to confirm the portfolio protects the marketed products and technology.

Long-term objectives should at least include the following:

- Growing the portfolio to comprise patents/applications claiming related technology, which is broader in scope than the core technology.
- Growing the portfolio to comprise patents/applications claiming unrelated technology, which nonetheless, if patented, affects the market share of the core technology.
- Enforcing issued patents with regard to competitors.
- Expanding the core technology and/or the market in which the company seeks to compete, to provide a broader revenue base.

it would be for the skilled artisan to obtain the claimed result. Care should be taken adequately to address any unexpected nature of the results, and in particular the lack of predictability of the obtained result in view of what was known to the skilled artisan at the time the invention was made.

Patent nuts and bolts

It is desirable to have an expert in the art draft the patent application. Traditionally, someone who has obtained a PhD in the subject matter for which the patent is sought, or a related discipline, and has experience in drafting and prosecuting patent applications should prepare the application. For example, for applications related to antibiotic compounds, a PhD in medicinal chemistry or microbiology is an appropriate candidate for drafting such an application.

A solid patent portfolio includes patent applications filed in the United States and multiple jurisdictions around the world, particularly in countries where it is expected that the technology will find a market or in which the company will compete in an established market. It is particularly important that the preparation and choice of filing of applications are conducted with appreciation for the possibility that the patents may ultimately be litigated.

While global protection is a worthy goal, some form of cost-benefit analysis should be conducted which considers the market share and the level of protection obtained in each jurisdiction.

In this context, appropriate naming of inventors safeguards against patent invalidation further down the road. Similarly, appropriate assignment of rights ensures a company's ownership of a core technology and provides it freedom to operate the technology.

Documentation with regard to all aspects of the development of an invention can often critically affect the level of protection obtained. Notebooks documenting a discovery can often be invaluable in terms of establishing dates for the reduction to practice of an invention, which can impact on the obtaining of a patent, for example, in the United States. Notebooks – in particular, those that have been witnessed and dated – may be used in other disputes, for example regarding inventorship.

Working together

While a technology perspective makes the described incremental occurrences in the establishment of the portfolio seem obvious, a company's commercial perspective may not be satisfied with this scenario. For example, a competing technology for patent purposes may not be competing in the marketplace. Similarly, a competing product in the market may in fact be practised without infringing any claim of a patent in the company's IP portfolio.

A strong IP portfolio provides protection not just for technologies which are directed to similar products, but also for those which compete for the same market share. To achieve this, business strategists and IP practitioners must work cooperatively, yet it is not uncommon for there to exist a significant disconnect between the two. Too often, patent strategists are not privy to business strategy decisions affecting product development. It is also not uncommon for business strategists to lack a true grasp of a company's IP portfolio. The latter may result in strategists assuming that specific aspects are protected by patents when in reality such protection does not exist. Further, business decisions may result in changes in the product which are not adequately protected prior to their launch, which in turn can compromise a company's ability to protect this innovation. Lastly, it is also possible, in such a scenario, that the change may be one for which the company does not have freedom to operate. All of these occurrences can prove disastrous in terms of investor confidence and wasted resources. Communication between business developers and IP practitioners is therefore critical for building a strong IP portfolio.

Similarly, a company's research and development (R&D) group must be intimately involved in the establishment and maintenance of the company's IP portfolio. Often it is the company's R&D arm which is best suited to:

- Provide argument used during the prosecution phase of an application.
- Appreciate related technologies, which may be considered to be potentially within the scope of the claimed invention.
- Assess the potential strength of a technology in a given market.

Frequent meetings between R&D scientists, business strategists and patent practitioners are invaluable in terms of providing a greater understanding of the underlying scientific principles which form the foundation for the product line, the approach taken for product development, the market involved and specific business objectives in this context.

The strength of a given IP portfolio is thus dependent upon:

- The strength of the technology for which protection is sought, in terms of its innovation in view of the state of the art.
- The strength of a company's competitive position, in terms of the market sought for commercialisation of the product.
- The ability to address evolution of the technology.
- The construction of the portfolio.

Clearly, the strength of an IP portfolio is influenced significantly by the skill of the practitioner who prepares, guides and maintains the portfolio. Such skill is reflected not only in the drafting and prosecution of the patent applications that comprise the portfolio, but also in consideration of the importance of the timing of filing; the level of disclosure, in view of changing law regarding what constitutes "enough"; and an appreciation of whether it is in fact in the company's interest to disclose the technology at all or maintain it as a trade secret.

Skill alone is insufficient, however. The strongest IP portfolios arise from meticulous planning and constant vigilance. Such planning should comprise:

- Identifying a core technology which supports the company's business objectives.
- Directing initial IP resources towards protecting the core technology.
- Evolving the portfolio at least to maintain freedom to operate the core technology.
- Appraising business strategists of the scope of the protection present and any evolution thereof, including potential competitors.
- Adjusting the portfolio to compensate for changes in business strategy with regard to the technology.
- Developing short and long-term objectives (see "Short and long-term objectives" on page 42) with regard to the portfolio, wherein both IP practitioners and business strategists are involved in setting the objectives, and any changes thereof.

In this context, it is important to review the status of the portfolio and freedom to operate the technology on an ongoing basis. Consistent searches of the competitive landscape are essential to maintain a defensible position and, moreover, may require enforcement, to ensure a competitive position in the market.

Thus, the strongest IP portfolio is formed through a dynamic interaction between R&D scientists, IP practitioners and business strategists in forming the portfolio, with an intimate appreciation of the technology, its limits and the state of the art *vis-à-vis* the technology.

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