FROM LEAD COMPOUND TO STRONG MARKET POSITION

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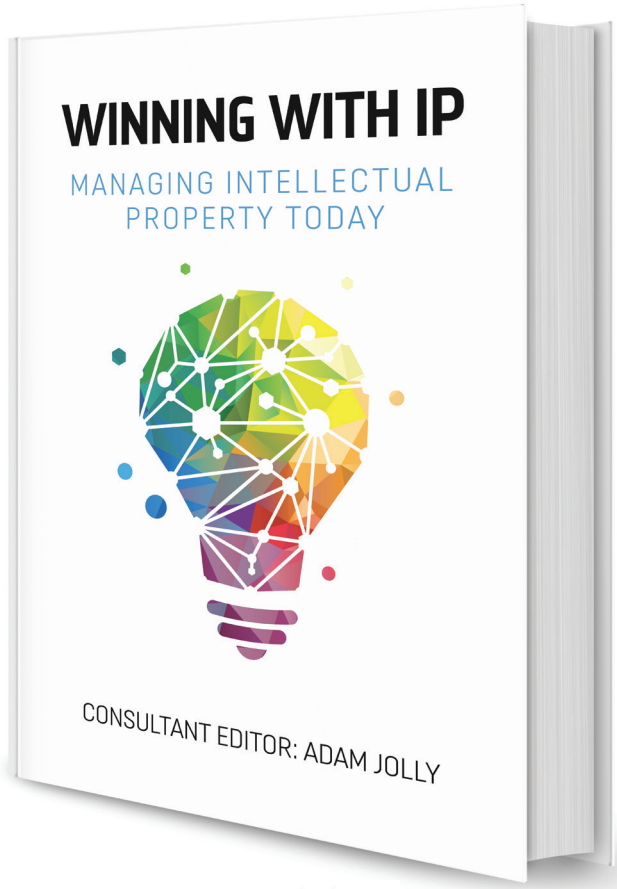
In a book about how today's winners are lining up their IP, Stephan Held and Christoph Behrens at Meissner Bolte discuss strategies for extending patent portfolios in an industry as research intensive as pharmaceuticals

The aim of each patent strategy is the optimal protection of R&D results, preferably over a long period of time with low costs. While this is valid for all technical fields, in pharmaceuticals specific circumstances have to be taken into account. For example, it is well known that in pharmaceuticals the research activities are highly intensive, because most of the development candidates fail to lead to a marketable product. Also, the costs of taking a product to market have increased dramatically over the years for several reasons. For one, science has become much more complex with increasing knowledge acquired through genome projects. Many more potential targets can be addressed by a drug to treat a given disease and, at the same time, much more is known about avoiding collateral targets that might cause undesired side effects. As a further consequence, regulatory approvals have become more and more stringent, and clinical trials are becoming more extensive with an increased rate of failure of development candidates.

Without patents, pharmaceutical research would not be possible, at least not at the level on which it is done today. Pharmaceutical companies need patents in order to recover the investments necessary for the development of new drugs. In addition, smaller pharmaceutical companies, who do not themselves have the financial capacity for taking a drug to market approval, need patents to raise the venture capital for the development of their product, as investors usually want security for a return on their investment.



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Drawing on the knowledge and experience of 24 top-level IP performers, including the innovation support team at the European Patent Office, this book reports on how IP is being used to create tech solutions, pick up the latest thinking, take a competitive lead, negotiate the best deal, knock back any challengers and open up a path to breakthrough growth. It gives a series of lessons and insights about how today's winners are lining up their IP to transform early-stage ideas and technologies into assets around which competitive business models can be designed.

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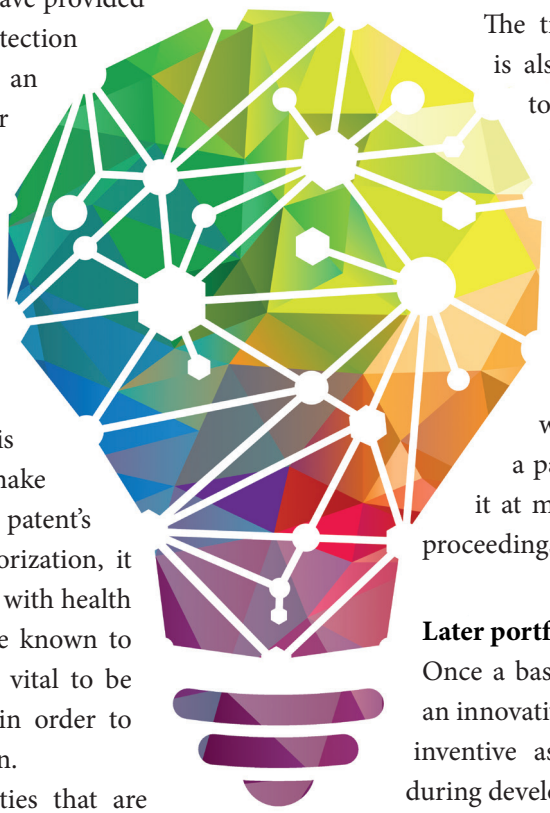
Extending protection and exclusivity

Due to the regulatory and safety requirements for a new drug, the time in which a patent can be exploited is regularly much shorter than for other products. For example, while technical products, such as cell phones, usually have a development time of about one to two years, a new drug from lead compound to the final active compound, tested for pharmacology and toxicity, may take five to six years; clinical tests until market authorization may take another five years. With the regular term of a patent of 20 years, the actual time span where it can be exploited is thus much shorter than for most other products.

To alleviate the problem of shorter effective protection of new drugs by patents, legislators have provided the possibility of supplementary protection certificates that could provide an additional five years (or even another half year if the drug is approved for paediatric use). Even so, the duration of protection and market exclusivity for a new pharmaceutical product is still regularly shorter than for other products, while at the same time significantly higher investment is required. In addition, many drugs make the highest profit only at the end of a patent's lifetime, as, even after market authorization, it usually takes time to negotiate prices with health services and for the drug to become known to prescribing practitioners. Thus, it is vital to be aware of possible patent strategies in order to receive the best and longest protection.



Here patent law offers possibilities that are unique to pharmaceuticals. In the following sections, we would like to give an overview of which research results can be protected.

When starting a new candidate

Right at the beginning of a new development, it is of the utmost importance to carry out a state-of-the-art search to clarify whether or not it is possible to obtain exclusive rights on an innovation. In addition, when, at the latest, a patent application has been filed and the further development of a drug is set to go, a wider freedom-to-operate analysis should identify which competitors' protective rights might cover a drug development candidate. This is especially important for start-ups whose business model is often based on a limited number of inventions. Many of them in fact concentrate on one single idea.

An innovative company that has discovered a new product usually tries to protect it as broadly as possible, for example, by means of a broad claim that covers generic compounds via a Markush formula (ie, a schematic representation of a chemical structure with multiple independently variable groups). If done right, competitors will be prevented from developing easy workaround solutions on the protective right by slight changes of the structure. Since competitors will always try to find gaps in patents on commercially successful products, the application should be carefully drafted considering all conceivable variants.

The timing of filing a patent application is also critical. If the application is filed too late, a competitor may have filed a similar application earlier and thus prevent a company from obtaining protection for their invention. On the other hand, if it is filed too early, the duration of market exclusivity is shorter and the application may contain too little experimental data, which can make it more difficult to get a patent, as well as subsequently putting it at more risk in opposition or revocation proceedings.

Later portfolio building

Once a base application or a patent is in place, an innovative company will try to protect further inventive aspects of the product that emerge during development. There are a lot of possibilities to consider.

For example, it is possible to protect an optimized method of making the product that avoids the formation of difficult-to-remove side products. In addition, it is possible to protect polymorphs, derivatives, metabolites and prodrugs of the product that may have a better pharmacological profile or other advantages. A further possibility are patents on combinations of the product with one or more other active ingredients. Such combinations of drugs, often in concrete concentration relationships, may provide lower toxicity or more effectivity than the new product alone. In pharmaceuticals, moreover, a frequent type of invention lies in the selection of a specific compound which falls under the scope of a known generic compound,

but has not been previously disclosed individually. Such so-called selection inventions are often dependent on existing patents and require approval from the previous owners.

It should also be remembered that patents can be obtained on a known compound for use as a pharmaceutical in general (so-called first medical use) and for use in the treatment of a specific disease (so-called further medical use). As in the case of selection inventions, a pre-described first medical use does not preclude the patenting of a further new medical use.

Accordingly, where a substance or composition is already known, it may still be patentable, if the known substance or composition was not previously disclosed for use in the pharmaceutical area. In such a case, broad use-related product claims are even possible, if the compound has been found to have utility in the treatment of only one single disease or condition.

Even where a substance or composition is already known to have been used as a pharmaceutical, the substance or composition may still be patentable for any new second or further pharmaceutical use. Such second or further medical use is not only the treatment of a different illness, but can also be a different dosage regime or a different mode of administration, for example, oral, instead of subcutaneous, administration.

Even the use of the same substance or composition for the same therapeutic purpose can be patentable, if it is based on a different technical effect, which leads to a new clinical situation that can be distinguished from the known situation, if novel and inventive.

Aspects, which are not associated with specific compounds, but for which protection should still be considered are, for example, new screening methods, as patent protection for such methods can make it more difficult for competitors to investigate compounds directed at the same target.

All of these subsequent and second generation patents can be filed sequentially and may serve to prolong the protection for the core inventive product.

Second generation patents

Second generation patents provide protection for companies not only to recoup the research investments in therapeutic advances based on known chemical substances or compositions, but are also used for lifecycle management purposes to give additional protection after the expiry of a base patent. If second generation patents are obtained by another company, they can often not be exploited directly, because the respective products fall within the scope of protection of the first patent. Still, by allowing the owner of the second generation patent to block the earlier patent holder from using the later invention, they can lead the way to possible cross-licenses. Since owners will want to avoid such devaluation of their patents, a good strategy involves a tight monitoring of others' activities in their core area of interest and an active role in trying to oppose such patents.

Disclosure of experimental data

With any application for a pharmaceutical patent, it must be kept in mind that at the filing date it has to contain sufficient experimental data to make a new therapeutic effect plausible. Otherwise the application may not be granted for lack of sufficiency of disclosure, or could be vulnerable in opposition proceedings, if this requirement is contested. However, this does not mean that at the filing date the compound must be in clinical trials or is even approved as a drug. Rather, to make the therapeutic effect plausible, it is regularly sufficient to provide in vitro or animal data, if there is a clear and accepted established relationship between the observed physiological activities.

As indicated above, applications in pharmaceuticals have to be drafted carefully, because patents protecting successful products are often opposed or attacked in revocation proceedings. Also in recent years, second generation patents are more often not granted or revoked, because they do not contain sufficient experimental data. Therefore, more than in other fields, the motto is: quality before quantity.

The first patent application is often the basis for a larger number of patent applications throughout the world. After the application has been filed, it can only be changed within certain limits during the priority year. Therefore, the application should be as perfect as possible from the start.

Validation strategy and organizational aspects

A further point to consider early is in which countries patent protection should later be pursued. While having various national patents on the basis of the first application is desirable, the costs of applications in many countries may be prohibitive. Here a well-conceived strategy, which includes an evaluation of possible partnerships in non-key business countries, can save money. Dependent on the specific invention, the countries in which patent protection is useful should take into account whether the patent can be enforced and successfully commercialized.

To enforce the rights obtained, pharmaceutical companies put in place the personnel and the finance, so they have the capacity to defend their patents against filed oppositions or revocations proceedings.

To maintain strategic flexibility in such later proceedings, it is worth considering the filing of divisional applications, which could be tailored to emerging infringement forms and which have the additional benefit of maintaining some insecurity in the minds of competitors about the final scope of protection of a patent family. Since divisional applications can only be filed while the main application is pending, such applications have to be lined up prior to the actual grant of the parent patent.

Meissner Bolte is a full-service IP law firm comprising European, German and UK qualified patent attorneys, as well as specialist IP lawyers. **Stephan Held** is a partner who has worked in chemicals, pharmaceuticals and life sciences for more than 25 years and **Christoph Behrens** has also specialized in these areas of IP for more than ten years.. For further details, t: +49-89-212186-0 e: mail@mb.de or www.mb.de

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