Pharma patents: tips and tricks to optimise and secure patent protection

The successful building and handling of a strong pharmaceutical patent portfolio requires a great deal of engagement and proactivity. Neglecting just one factor could be sufficient to compromise an otherwise high-quality patent; a patent is only as strong as its weakest link

By **Tomas Lundquist** and **Inga-Lill Andersson**, Awapatent AB, Stockholm

Much effort goes into securing patent rights for forthcoming pharmaceutical products. Early patent filings are vital assets, since the key concepts of future pharmaceutical products are often established during the early development phases. For example, when a novel set of compounds, proteins or monoclonal antibodies is generated and tested, patent applications are prepared and filed.

Where an application covers a potential new product, the application is often made without the relevant party knowing what the final product's exact active ingredient will be. When substances are tested further, the most promising ones are put through further clinical testing.

Applicants should consider certain questions. Did you adequately cover your lead substances? Are they specifically mentioned in the claims? Have you followed the most important requirements in order to avoid possible invalidity challenges in the future? This article highlights some important considerations to be taken into account during the different stages of the patent lifecycle.

Filing stage

Because at the time of filing it is impossible to know which products will become vital to your company's business, you should file every patent application on the assumption that it will become your company's most important application. Priority applications and US provisional applications should be treated as though they are likely to become fundamental to the protection of a product that will reach the market. Every entity (eg, compound, protein or antibody) that has been tested should be carefully described. The description should leave open the possibility for subsequent claim amendments. For example, it should be possible to carve out a "single compound" claim from the description.

Your first filing may turn out to be the basis for a worldwide patent portfolio with a lifespan of 20 years or more. All statements, wording, conclusions and test data should be treated as though they are likely to be questioned or challenged. In this light, it is clearly worthwhile spending all necessary efforts to ensure that applications are clear and accurate from the beginning.

Prosecution and grant stage

When it has been decided which entity should be taken forward into further development, it is important, where possible, to adapt your patent application to reflect this. For example, hopefully, you will have taken all necessary precautions during the filing stage so that you have the opportunity to make claim amendments. During the prosecution stage, there will be several opportunities to customise your claim set, either voluntarily or in response to office actions issued by the patent authorities. The final patent on which you wish to rely should preferably have a claim that specifically describes or names the active ingredient.

When a patent is about to be granted,

you should consider whether any continuing or divisional applications need to be filed. This could be the case, for example, if you know that the application covers entities that may be brought into further development, but you do not yet know what exact structure it will be.

In addition, a continuing or divisional application may be advisable if it is expected that a very broad patent is to be issued. A patent with broad claims may be vulnerable for an invalidity attack based on obviousness, since the broader the protection, the more prior art may be used to challenge patentability. In such instances, a parallel patent that comprises a "single compound claim" could be a valuable asset.

Post-grant stage

Depending on the clinical status of your future product, at the grant stage (at the latest) it is necessary to analyse where and when there are opportunities to apply for patent term extensions or supplementary protection certificates. Such protection could provide up to five extra years' protection as compensation for regulatory delays. The deadlines for filing such applications vary between countries. For instance, in the United States, you must file your patent term extension application 59 days after either Food and Drug Administration (FDA) drug approval or grant of your patent, whichever occurs first.

Litigation

If and when your product successfully enters the market, you should prepare yourself for generic competition. At this stage, it is important to put your competitors under surveillance and guard your interests. The patent system does not function on its own; patent infringers must be tracked down by conscious patent proprietors.

If you are suing a competitor for patent infringement, you can expect that competitor to attack the validity of your patent. In order to optimise your chances of winning or surviving eventual invalidity attacks, it is crucial to know the strengths and weaknesses of your patents. Initialising court proceedings relating to a patent which has apparent shortcomings could be detrimental.

Besides the importance of having a solid case in view of the basic patentability requirements (ie, novelty and inventive step), there are other aspects that you should deal with in order to create a powerful and healthy patent portfolio. For example, it is vital to ensure that accurate inventorship determination has been made and that this is reflected in the patent to be granted. The inventorship should be accurately recorded at patent offices around the world, both where patent applications are pending and where they have already been granted. Analogously, all necessary measures should be taken to make sure that all ownership issues are in place.

In the United States, it is important to attend to the proper handling of the duty of disclosure/information disclosure statements. You should present all material information before the examiner, prior to the issuance of a patent. Such information includes patents, patent applications and scientific articles of which the inventors and the patent attorneys handling the cases have become aware. It is highly recommended that you seek advice on such matters with your US patent counsel before the grant of your patent.

You should also consider listing the patent in the US FDA Orange Book in order to take advantage of the benefits deriving therefrom (eg, a 30-month stay in eventual court proceedings). However, if you are

Tomas Lundquist
European patent attorney
and partner
Awapatent AB
Stockholm
Tel +46 8 440 95 71
tomas.lundquist@awapatent.com

Tomas Lundquist drafts and prosecutes patent applications worldwide in the pharmaceutical field and is often involved in conducting infringement and validity investigations and freedom-to-operate analyses. He has been responsible for major due diligence analyses and has built up expertise in procedures for obtaining supplementary protection certificates. Mr Lundquist has also been appointed technical expert for Swedish patent courts. With his long industrial experience in the pharmaceutical industry, he currently leads Awapatent's pharma team.

"The patent system does not function on its own; patent infringers must be tracked down by conscious patent proprietors"

Inga-Lill Andersson
European patent attorney
and partner
Awapatent AB
Stockholm
Tel +46 8 440 95 37
inga-lill.andersson@awapatent.com

Inga-Lill Andersson has extensive experience of the drafting and worldwide prosecution of patent applications, mainly in the fields of chemistry, biotechnology and medicine. She has also been involved in due diligence investigations and freedom-to-operate analyses. Ms Andersson has experience of oppositions and appeals before the European Patent Office, as well as of national litigation procedures. She is head of the life sciences specialist group at Awapatent and has lectured at numerous continuing legal education seminars in the United States.

> "The evaluation of granted patents is comparatively straightforward, while the assessment of pending applications is likely to be more challenging"

aware of weaknesses in your patent, listing that patent in the Orange Book might have negative consequences.

Further, in the event of discovery proceedings in the United States, where each and every detail is scrutinised in the seeking of evidence, you do not want to end up in a situation where unfounded or hasty comments or statements may be revealed to your disadvantage. So, ensure that you keep your correspondence and files free from any unnecessary opinions on infringement and casual statements on patentability.

Freedom to operate

Ideally, freedom-to-operate investigations should be performed iteratively as a part of business intelligence. Depending on available resources, this is not always feasible. Nonetheless, you should strive to perform a freedom-to-operate search and analysis as early as possible, although such search and analysis is difficult to carry out before you know what your final product will be. One way to tackle this problem is to carry out a search and analysis as soon as you have decided which entity will be your active ingredient.

A freedom-to-operate analysis may reveal some relevant granted patents, as well as patent applications that are pending where the final scope of protection is not yet decided upon. The evaluation of granted patents is comparatively straightforward, while the assessment of pending applications is likely to be more challenging. Some applications may include broad claims which could potentially dominate your product, depending on their final scope upon grant. The continued prosecution of such pending patent applications should therefore be monitored.

If you are developing pharmaceutical products and you become aware of any dominant third-party patent rights that could potentially be infringed, relevant measures should be taken immediately. You could either challenge the validity of the patent or approach the patent owner in order to negotiate possible licence rights. The latter alternative is likely to be easier and less expensive. A further way of handling disturbing third-party rights could be to "design around" existing patents – that is, to modify the product to fall outside the claim scope. Either way, it is crucial to avoid – at least, as far as possible – the risk of spending a lot of time and money on the development of a product which is later discovered to be blocked from market introduction due to existing patents.

With regard to challenging the validity of patent rights, opportunities differ across jurisdictions. For instance, according to the European Patent Convention, it is possible to file third-party observations as early as the prosecution stage. In addition, there is a nine-month window of opportunity in which to file oppositions against granted patents. Thereafter, legal action can be taken in national courts.

Ownership and maintenance

One important legal issue is the ownership of patents and patent applications. The ownership chain of title should be cleared and it is essential that the whole chain can be tracked and confirmed by signed documents and, where applicable, licence agreements. The chain must lead from the first inventorship determination to the current owner or applicant. It is recommended that employment history be analysed for inventors in order to ascertain whether there could be other inventorship obligations towards previous employers.

If not secured, it is of utmost importance that you check and double

check the system and routines for payment of annuity and maintenance fees. You do not want to lose rights due to non-payment of such fees.

Further protection

Early patent filings usually comprise the most important assets; however, further protection on product developments might become just as important. Such protection could include new inventions related to formulations, manufacturing processes, new crystalline forms with improved properties and combination therapies.

In order to identify potential new patent candidates, a proactive approach is required whereby research work is closely followed and monitored in order to catch any new ideas and further developments. In addition, reward systems could be implemented to encourage innovation.

Status and risk analysis

In order to identify potential risks connected with the patent portfolio, you should perform status and risk analyses at various critical business stages at which decisions related to large investments are to be made (eg, initiation of a large clinical study). Preferably, such analyses should be carried out by external counsel and not the patent attorneys who normally handle the patent portfolio.

As an example, in a status-and-risk analysis of a patent portfolio intended to cover a pharmaceutical product, the following questions should be considered:

- Do the granted patents/pending patent applications appropriately cover the product?
- Are appropriate fall-back positions available, for example, by dependent claims and/or by divisional applications on file?
- Has an independent analysis on patentability been performed?
- Have opportunities for patent term extensions and supplementary protection certificates been analysed?
- Has freedom to operate been searched and analysed? If so, does the process need to be repeated?
- Have all eventual ownership issues been resolved?
- Is full documentation available to prove that you are the sole and beneficial owner of the relevant patent rights?
- Have all eventual inventorship issues been resolved?
- Has the protection of future developments of the products been established?
- Has the duty of disclosure been properly handled?

Conclusion

The successful building and handling of a strong patent portfolio requires a great deal of engagement and proactivity. Although the steps recommended here may seem obvious, it is striking how often an essential aspect of patent protection is overlooked. Particularly where a patent portfolio is growing, it can become difficult to maintain a comprehensive view of the portfolio and the risk of mistakes increases. Neglecting just one factor could be sufficient to undermine an otherwise high-quality patent; a patent is only as strong as its weakest link. ■

Awapatent AB
Drottninggatan 89
PO Box 45086
SE-104 30 Stockholm
Sweden
Tel +46 8 440 95 00
Fax +46 8 440 95 50
www.awapatent.com