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editorial

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Patents discipline is key to securing big pharma investment

In the increasingly high-cost and high-risk field of new drug development, drug discovery companies are finding it more difficult to secure big pharma investment without undertaking at least early-stage clinical trials. In these more exacting times, companies have an increased need to maintain discipline in their invention and patent management, not least in order to avoid errors such as accidental early disclosure, which could cost them dearly.

The formation of a high number of spin-out drug discovery companies in the 1980s and 1990s, many from universities with strong research departments, has brought about a significant evolution of the pharmaceutical industry. Until recently, these companies majored on small molecule drug discovery by seeking out compounds with promising characteristics in terms of their pharmacology and physicochemistry and assessing these key parameters without necessarily progressing to significant human clinical trials. A proof of concept at a relatively low level may have been sufficient to secure big pharma interest and, in some instances, this led to acquisition or exclusive licencing investment deals around the time of entry into Phase I clinical trials.

However, due to escalating economic and regulatory factors, large pharma companies have become increasingly risk averse. As a very significant part of governmental and institutional spending, global healthcare budgets now face intense scrutiny and the criteria in satisfying the regulatory requirements of drug approval authorities have become increasingly stringent. This has had a considerable knock-on effect in the marketplace and pharmaceutical businesses have been forced to cut costs and, in certain cases, consolidate their offerings.

At the same time, the attrition rate of new molecular entities has been high, creating greater pressure on research budgets. It is well known that, out of the thousands of new molecules tested each year during initial research, only a few compounds become lead candidates and even fewer end up for sale in the marketplace. The ''me-too'' drugs, which provided in some cases an efficient route to marketing success, are now facing more rigorous scrutiny by regulatory authorities who are seeking stronger evidence of improved efficacy or safety of proposed new products.

Some businesses have looked to bio-pharmaceuticals to reap greater financial rewards in a potentially more fruitful space, but high-profile incidents such as the Northwick Park drug safety trial in the UK, have highlighted the potent effects and risks associated with clinical research involving more powerful and complex molecules. In 2006, the novel drug, TGN1412, manufactured by German pharmaceutical company TeGenero, was being tested as a potential treatment for certain autoimmune diseases and leukaemia, but it caused multiple organ failure in six men who were injected with it at Northwick Park Hospital. It is cases such as this that have led to non-clinical results often being regarded as no longer sufficient to secure investment.

Drug discovery companies now have to take further steps to reassure and effectively demonstrate reduced risk for potential investors. Many are now undertaking Phase I volunteer studies, Phase II and even Phase III studies at their own cost, to demonstrate proof of concept and safety in humans – previously primarily the domain of big pharma players.

The risks of undertaking clinical trials without patent discipline, however, are high. There have been instances of businesses,

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inventors and academics giving away their inventions by making an easily avoidable mistake of accidental public disclosure. In most countries other than the United States, if you publish or otherwise publicly disclose your invention to another person, whether orally, in writing, or in any other way, without agreement that the information you are about to impart will be treated as confidential, that disclosure becomes part of the 'prior art'. If you then subsequently attempt to protect your idea or invention using registered IP rights, such as patents, your own 'prior art' could prevent such protection being successfully obtained. In a worst case scenario, this could stall investment from third parties and the product (e.g. a proposed new drug) would have little or no prospect of ever entering the market.

One difference in the law between the US and most of the rest of the world has been a cause of error for businesses and researchers in accidentally disclosing their ideas. In the US, a grace period exists, which allows an inventor to disclose their invention, and then have a period of 12 months in which to file a patent application for it. If the application is filed within this period, the disclosure will not count against it for prior art purposes. This grace period is of no use, however, for resurrecting the possibility of patent protection in most other territories. In addition, recently enacted changes in US law are likely to reduce the usefulness of the US grace period in any event.

Overall, therefore, it is essential for companies to ensure that any discussion with pharma companies or other potential collaborators be conducted under a confidentiality agreement, which effectively protects both parties.

Getting a tight grip on disclosure is really just the start. Whilst many drug discovery companies have a good awareness of patents and IP protection, there will be some that could increase their chances of securing big pharma investment by ensuring a more professional approach to IP at each stage of the drug discovery process. Whilst investors are primarily interested in the innovation itself, a core of professionalism towards IP embedded within the business will help to instil their confidence.

Human resources management policies and procedures can directly affect the security and therefore the value of any IP owned by a business. An essential first step in securing confidential technical information is, in most circumstances, to make sure that all employees have contracts which make it clear that this information is the property of the company. Workers who are under consultancy agreements should also have clear terms within their contracts as to the ownership of inventions.

Companies also need to adopt a rigorous approach to documenting inventions and should encourage employees to record valuable, confidential information. A simple standard procedure should also be established within the company to ensure that an appropriate person is alerted to potential new inventions.

Typically, smaller companies in this area will have someone who is nominally responsible for patents and IP, often a researcher with an interest in patent and IP issues. These individuals not only provide an important administrative function internally within the business, but are also an imperative central point of contact for potential big pharma investors. They are particularly effective when backed up by external patent attorneys who can provide specialist, strategic guidance on developing a robust patent portfolio. Clear internal responsibility for IP matters can also help to ensure that the company is kept 'due diligence-ready', by maintaining documentation in good shape.

It is sometimes a pitfall of smaller companies, particularly those derived from an academic background, to invest time and money into what are sometimes pejoratively referred to as ''vanity projects''. Drug development companies would be wise to examine and review the patent applications that have been filed to assess whether such applications are still aligned with the strategic interests of the business. Moreover, freedom-to-operate checks are sometimes forgotten, something patent attorneys can assist with. This will also help to inform market intelligence research and enable the business to assess which drugs are most likely to be able to access and succeed in the marketplace.

As an example, Thiakis Limited, a biopharmaceutical drug discovery company invested carefully in its IP strategy and benefited financially as a result. Founded in 2004 as a spin-out company from Imperial College, it developed a group of peptides for the treatment of obesity and associated conditions. The company had a full-time employee with responsibility for IP and was supported by patent attorneys at Withers & Rogers LLP. In 2008, the company was bought by US-based Wyeth Pharmaceuticals, now part of Pfizer, for a consideration of £100m and also retained the rights to royalties on the sale of Thiakis' product family through an ongoing exclusive licence arrangement.

A more selective approach to R&D activity can be a good way to demonstrate that a business has considered the long-term strategy that investors might take. For instance, when filing a patent application for a new molecule, it is worth considering where the probable markets will be for that particular drug in 10–15 years' time and in which territories a big pharma investor would want to seek protection. The geography could be different to today, particularly with drugs becoming more affordable in emerging markets such as Latin America and India.

Drug discovery companies are adapting to the new world of drug development and succeeding in securing big pharma investment despite considerable market constraints. Attention to patent discipline could help them to achieve even more.

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