Intellectual Property Strategies 'Crucial' to Protecting Future of Medical Innovation

PEER REVIEWED

Robust intellectual property protection is essential to safeguarding the future of revolutionary biomedical innovations, which transform healthcare for millions of people worldwide.

The biotechnology and medical industries are among some of the most progressive in the world with billions spent annually on creating industry-leading drugs, techniques, therapies, and technology which transcend expectation.

Driving the creation of these countless medical advancements is the vast investment in research and development by thousands of leading medical researchers and firms.

According to the Medical Research Council in 2015/16 its gross research expenditure, funded by Business, Innovation, and Skills budgetary allocation and contributions from other bodies, was £927.8 million compared to £771.8 million in 2014/15.[1]

This significantly increased sum which is spent on enhancing medical research, demonstrates the value of the biotechnology and medical industries as a multi-billion-pound commercial entity with limitless potential.

It is this commercial value attributed to the medical industry that supports continuous innovation, with abundant financial returns helping to fund ongoing research and development.

Realising the financial benefits also spurs on researchers and firms which plough vast sums into the initial development of revolutionary treatments, and must also be assured of a return on their investment through the subsequent financial monopoly when the product reaches the marketplace.

For example, with an average cost of over £500 million spent to develop a new pharmaceutical, the aim for businesses which invest in research and development (R&D) is to make a profit when the product is marketed so as to return a dividend to investors and help fund future R&D work.

However, without safeguarding the rights to a product through an effective intellectual property strategy, they could face infringement by competitors, which damages the product's commercial exclusivity, leading to devastating financial losses.

Patent attorney and partner at a leading intellectual property firm, Jim Robertson, said protecting products within this field was "crucial" in order to safeguard the future of innovation and research.

Mr Robertson, who specialises in advising the biotechnology, pharmaceuticals, diagnostics and medical devices industries, said: "Nowhere is an efficient and targeted plan more productive than in the biotech industry, particularly in protecting the rights of medical researchers and firms involved in developing the latest industry-leading drugs, therapies, medical devices and related technologies.

"These transformative creations not only have an intellectual value, which could enhance the care of millions of people across the world, but also a commercial value, which is realised when the products are introduced across the pharmaceutical industry."

To help support research and progression in this field, Mr Robertson and commercial director Jayne Nation have put together some key considerations when creating an effective intellectual property strategy, along with suggestions on how to develop it to ensure maximum protection and commercial reward.

On why an IP strategy is particularly vital to the biotechnology and medical industry, he said: "An IP strategy is vital to helping a company identify its strengths and weaknesses, the opportunities and threats that exist in the marketplace and from competitors, creating a framework for creating and managing the IP portfolio going forward so that it helps the company achieve its goals, and so that the company gets best value and quality for money.

"Part of this is typically identifying what intellectual property it possesses, why and how it should be protected, and where it needs to be protected.

"In the case of the biotech/pharmaceutical industry, intellectual property can protect a product, such as a drug, enzyme or antibody, or a method, such as a synthetic pathway, an enhanced manufacturing process, or a diagnostic test method or equipment."

To ensure the product is most effectively utilised within the pharmaceutical industry to ensure the optimal care of patients worldwide, but also to protect researchers' intellectual property rights, Mr Robertson has offered his opinion on how best to construct an IP strategy to drive success across both the health and commercial aspects.

He said: "With endless potential for innovation in this field and increasing collaboration between industry and academia, and between individual companies, a well-structured and effective strategy is vital in ensuring ownership of the rights to a discovery, and how the information can be utilised for maximum future success.

"In order to attain the greatest results through an IP strategy, it should be aligned with the aims of the business. This will allow inventors to pinpoint exactly which features they feel warrant protection, and potentially achieve the most lucrative results for the business.

"Having a considered IP strategy in place also allows companies to focus on the most commercially lucrative aspects of their technology and brand, consequently helping to hone and further their market potential.

"For larger companies and groups, some with sprawling IP portfolios, or those who have previously worked with multiple IP suppliers, a first major step can simply be understanding what patents, trade marks and registered designs they own and how they fit in with the IP strategy and the current commercial products.

"Doing this can simplify management, streamline decision-making, and reduce costs, particularly where the number of outside suppliers can be reduced and the quality of service increased at the same time."

Many, however, forgo investing in intellectual property during the initial stages of development, failing to recognise the purpose and value of an IP strategy. Their failure to appreciate the unparalleled importance of an intellectual property strategy could be attributed, in part, to the initial cost.

On why researchers and those developing products in the pharmaceutical industry need an effective strategy, Mr Robertson said: "A professionally crafted IP strategy is a wise investment in terms of protecting your initial development, and achieving success and longevity.

"Researchers will be all too aware of the expense of investing in creating a viable asset, carrying out research to enhance its marketability, and finally launching it into a competitive industry. This requires an ongoing financial commitment.

"A significant initial investment in research and development is required across the pharmaceutical and medical industries, where millions of pounds are spent on creating industry-leading techniques or treatments to revolutionise patient care.

"As such, we cannot emphasise the importance of a strong and targeted IP strategy in this industry enough. Having this in place will ensure those in the medical profession receive the deserved rights to their intellectual property and also enjoy the eventual commercial benefits.

"Putting a strategy in place also highlights the value of intellectual property as a commercial tool. In doing so, key decision-makers are better informed about where to allocate vital funding for research and development to better achieve ongoing business goals.

"Recognising the importance of IP and adequately protecting it can also have a beneficial impact on the value of the company which has established the drug, treatment, or equipment, which could encourage further investment by enhancing the reputation of the business.

"This is particularly positive for the medical industry which is reliant on attracting external funding and grants to support the continuation of extensive research.

"Ultimately, having a good and well managed IP strategy

demonstrates to potential investors that the business is worth investing in.

"One of the first roles to undertake when developing an IP strategy is to conduct an audit of the company's existing intellectual property, including any patents, trademarks, copyrights or designs, and comparing this against new inventions which are to be commercialised.

As well as having a top-level IP strategy in place, companies need to have a strategy for each technology or product sector which focuses on the specific issues it encounters, for example protecting inventions, dealing with potential infringement of other people's patents, directing future R&D, branding and so forth.

Mr Robertson said: "Having an effective plan in place from the beginning helps to reduce the likelihood of infringement of an existing patent, and reduces the risk of facing a dispute further down the line.

"It can also help to prevent an invention from being targeted by potential competitors keen to profit from it, without incurring the costs of the initial financial investment.

"Developing a product or drug, at great expense, and then discovering it has breached an existing patent could result in the abandonment of an invention without realising its commercial potential; finding out that the brand you have committed to selling under infringes an existing registered trademark could lead to significant and unnecessary costs."

"As part of the initial plan, an intellectual property expert will conduct thorough research, and, as appropriate, perform a freedom to operate search to help prevent this eventuality and reduce the associated risks. In the medical industry, a strategy can also help to sharpen the focus in what can often be a multi-faceted approach.

"For example, the administration of a particular drug could be revolutionised through the use of a newly discovered technique, a new dosage regime, or a new piece of equipment. As a result, it is vital that the rights to this are protected as part of an IP strategy, particularly if it has significantly added value and profitability."

Dr Jayne Nation agreed. She said: "Having an effective plan in place from the beginning helps to negate the likelihood of infringement and the threat from competitors. Robust protection of these assets is needed because the investment can run into hundreds of millions of pounds, money which could be potentially wasted if someone can just copy the invention."

Mr Robertson warned, however, that lines can often become blurred as drug development travels through different channels, with external collaborators including chemists, researchers, scientists, and developers all potentially involved in the process. As a result, consideration must also be given to intellectual property rights in relation to third parties.

He said: "The plan or strategy should address collaboration to ensure that the rights to the intellectual property are clearly defined in commercial agreements with third-party researchers, suppliers and collaborators, in order to avoid consequent conflicts at a later stage. The strategy should also clearly address the issue of confidentiality in working alongside outside parties, including - where and how the confidential information can be used; and who owns the rights to any subsequent discoveries.

"When compiling an IP strategy, prior art should also be considered to ensure the creation has space to evolve while protecting the inventor's initial investment and market exclusivity. Prior art is anything relevant to an invention which is already in the public domain.

"This can be anything from a published historic invention to discussions surrounding a use of technology that is very similar to a previous invention. By understanding the relevant prior art, patent applications can be crafted to provide the best possible protection for new inventions, whilst stepping around protection provided by prior art patents."

Dr Nation said that alongside patents and trademarks, another consideration for those creating an IP strategy is whether to keep trade secrets. "A trade secret is a form of intellectual property too but is more difficult to manage. It is an invention, knowhow or other unique creation that is considered so sensitive commercially it may be best managed by not making it transparent to the wider business community, unlike patents, where the details of the invention are published for anyone to see. However, using trade secrets to protect IP comes with significant, associated risks.

"If you are planning to keep your invention or other unique creation as a trade secret, you will need a rigorously defined management process within the company that restricts access to only the most strategically important personnel. If you are considering trade secrets, it is vitally important that you seek legal advice from a specialist IP attorney and discuss the risks with your investors, management board or other senior decision-makers."

In conclusion, Mr Robertson said: "It is imperative that the biotech/pharmaceutical industry recognises the importance of adopting effective intellectual property strategies, which can evolve with the development of world-leading products.

"Continued research and development must be given support to flourish and progress unhindered; this will undoubtedly safeguard the future of the pharmaceutical industry as a whole."

REFERENCE

1. https://www.mrc.ac.uk/about/what-we-do/spending-accountability/facts/ visited on October 2, 2017

Jim Robertson

Patent attorney and partner at Wynne Jones IP, whose primary technical fields are based in life sciences – specialising in bio-technology, pharmaceuticals, diagnostics and medical devices.

Jayne Nation

Commercial director at Wynne Jones IP. She has over 25 years' experience in creating and developing technical innovations and managing strategic business relationships.