

Healthcare industry BW

Technology Licensing Office (TLB): invention and patent management

Long-term clinical testing and expensive approval procedures with uncertain outcomes mean that medical technology, biotechnological and pharmaceutical inventions do not have an easy ride to market. The biotechnology sector has seen the highest increase in the number of products for which approval is sought (up 42.6 per cent; 7,400 registrations). The Technology Licensing Office (TLB) works in partnership with science and industry and is continuously coming up with new ways to ensure the economic success of inventions from all the key fields of technology. Dr. Frank Schlotter, head of Life Sciences at the Karlsruhe-based TLB, provides insights into the work that his office does, taking as examples innovations from the fields of regenerative medicine and diagnostics.



Dr. Frank Schlotter, Head of Life Sciences of TLB GmbH
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In 2010, the field of medical technology filed the largest number of patent applications with the European Patent Office than any other area: 10,500 applications were filed in this field, while drugs accounted for 6,700 applications (up 20 per cent). However at present, biotechnology is on the fast lane and has experienced the largest increase in the number of applications filed by any one sector. "However, the market has also undergone general changes over the last few years, in particular in so far as the handling of high-risk and early projects is concerned. This also changed the way we do our work," said Dr. Frank Schlotter, head of the Life Sciences department of the Technology Licensing Office (TLB). The specialists at the Karlsruhe-based agency support inventors and entrepreneurs in all phases of invention and patent management and develop made-to-measure solutions for their clients.

Only around six per cent of all active drug ingredients researched by pharmaceutical companies manage to obtain marketing authorisation. It usually takes between eight and 12 years to be granted a marketing authorisation. During this time, companies have to make huge investments at the same time as being unable to generate revenues with the new product candidates. "The work and expenditure associated with placing a drug on the market are continually growing due, amongst other things, to the benefit dossier that companies now need to submit. On the other hand, the number of marketing authorisations granted is decreasing," explains Dr. Frank Schlotter. University inventions are usually inventions in the early stage of development, which have not been clinically tested. This is because universities generally do not have the money to cover the costs of clinical trials. "Companies are therefore less interested in taking on the production and marketing of early-stage university inventions. And this represents a huge challenge for patent exploitation agencies like the TLB," said Schlotter.

A growing number of regulations and less readiness to take on risks

Companies have become more cautious and have considerably reduced the number of "early" projects. Big pharma is under increasing pressure as a result of stricter drug regulations, R&D expenditures are increasing and, at the same time, company budgets are decreasing, which is why fewer drugs are being placed on the market. "In addition, there is an enormous competitive pressure from generics producers," said Schlotter who, together with his team, provides support for 25-30 life sciences inventions per year. The fact that the patents of many blockbuster drugs have expired or are due to expire in the near future does not mean that the patent exploitation agencies "sell" inventions like hot cakes, far from it. Companies tend to work on the basis of minimising risk. "They make more effort with their existing product portfolio and product life cycle management, they try to keep their drugs "alive" for longer by expanding the application of a certain drug to other indications or filing new applications related to the altered dosage of drugs," said Schlotter.

The length of time it takes to turn life science inventions into marketable commodities cannot be reduced because of the need to assess the efficacy of drugs in clinical trials and apply for marketing authorisation. However, clinical or marketing authorisation studies is not the work of academic researchers or clinical doctors. "Financially strong companies that are able to take on the risk associated with uncertain outcomes need to be brought in to carry out clinical trials," said Dr. Frank Schlotter who knows from experience that researchers' attitudes towards the utilisation of their inventions has changed over the last few years. "University researchers are under increasing pressure to publish, as employment contracts are only renewed if, amongst other things, a candidate has demonstrated scholarship by having papers published in reputable scientific journals. This means that researchers now frequently publish their inventions as quickly as possible rather than focusing on more detailed elaboration," Schlotter points out, adding that a "patent is often less important for a researcher's career than a publication."

Successful exploitation needs a long breath

It usually takes several years for life sciences inventions to become marketable commodities. This is due to clinical testing and long application procedures. An invention related to the examination of chromosomes that was dealt with by the TLB clearly shows the length of time needed. This particular invention was the first of its kind in the world to use what is known as comparative genome hybridisation to produce accurate results in DNA examinations, including tumour diseases and prenatal diagnostics. The licensee brought on board by TLB is a global leader in the biotechnology market. TLB filed a patent application for the procedure in 1996 and a licensing agreement was signed in 2003. The product was placed on the market in 2006. It thus took 10 years from the time



Safe and gentle: The Fibuskop® enables the examination of the respiratory tract under continuous respiration. A medical technology invention by researchers from the University Hospital in Heidelberg.

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the patent was filed to the time that the first licensing fees generated the first revenues. Both the university and the inventors benefit from the financial return. "Major hurdles included the application procedures, the first tests, the reliability of the product, the consistency of the data and the ability to standardise the product. The market also needs to be ready for the product," said Dr. Frank Schlotter summarising the process.

Schlotter believes that the exploitation of intellectual property through a licensee has clear advantages: "When an established company manages the exploitation of a product, there is a greater chance of generating a financial return. In addition, the procedure that turns a product into a marketable commodity is easier and quicker. The company deals with all remaining stages up to marketability and marketing of a product. We are in charge of patenting and we negotiate the licensing agreements," said Schlotter. However, although a licensing company might be involved in the development of an academic invention right from the start, it nevertheless takes a long time to place a product on the market.

Understanding future markets

Great expectations are also being placed on the relatively young area of regenerative medicine, which deals with the restoration of defective cells, tissues and organs with biological substitutes. Increasing numbers of patent applications and a huge research dynamic boost prognoses of a rapidly growing market volume in the future. "The impact of regenerative medicine will become even more noticeable within the next three to five years, both in the pharmaceutical as well as the medical technology industry. Regenerative approaches are generally preferred over solutions that are either foreign to the human body or artificial. "We tend to file outstanding inventions in this area, despite the high patenting costs resulting from the length of time it takes to obtain marketing authorisation," said Schlotter. At present, the TLB is responsible for numerous inventions related to regenerative medicine, including a new intervertebrate disc implant. This invention is aimed at restoring the biomechanical stability of the vertebral column and tightening the disc ring, thereby reducing the risk of another herniated disc.

Emerging generics market

Frank Schlotter sees additional opportunities to exploit inventions in the fact that the patent protection of many drugs expires after 20 years. This opens up a huge market segment for generic

drugs. "In such cases, patented inventions such as a specific protein purification method for large-scale industrial use will play an important role," said Schlotter. This invention will help to produce important therapeutics with microorganisms a lot more efficiently and at much lower cost. The invention enables the necessary purification steps to be carried out up to ten times faster and it also generates a much higher product yield. "This particular method will be of great interest for generics producers who wish to conquer the biopharmaceuticals market," said Schlotter.

Company foundation based on patents

In many cases, inventors and technology transfer agencies consider the possibility of establishing a company to take a particular invention to marketability. The most important prerequisite is that the team of inventors includes people who are willing to take on the risk of company establishment. "The motivation for establishing a company must come from the inventors themselves. Only then will we help them set up a start-up company," said Frank Schlotter. In order to ensure that a start-up has an excellent start, the initial phase of company foundation needs to be financed with scientific funds or venture capital. "In principle, there are two possibilities: one involves establishing a company with the aim of developing a product into a marketable commodity and placing it on the market. The other possibility is to found a company to bring together know-how and patents, drive the development to a specific stage and then sell the company as a whole to an established company," said Schlotter. The second possibility is specifically suited for founders who wish to generate value beyond the filing of a patent, and attract the interest of big companies. "Founders also consider this possibility in cases when the cost of marketing authorisation and market placement is too high for a small company," said Schlotter.

Conflict: rapid publication or secrecy?

When university researchers and companies work together during the exploitation process, each group brings its own specific way of thinking to the issue. "Academic thinking focuses on the detection of problems and finding solutions for specific issues," explains Dr. Frank Schlotter. Researchers look for technical solutions, rather than concentrating on economic issues. On the other hand, potential licensees are interested in the product's benefit for customers and its market price. Innovation managers therefore take on the role of entrepreneurs when they assess inventions, which means they focus particularly on market-oriented aspects. "A conflict between the ambitions of academic researchers and entrepreneurs also arises due to the fact that scientists are interested in publishing their results as quickly as possible and are looking to discuss their invention with the greater scientific community. On the other hand, entrepreneurs like to keep the invention secret for as long as possible and use their knowledge advantage for the economic exploitation of the invention," summarised Dr. Frank Schlotter.

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Knowledge and technology transfer as a social responsibility