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Entrepreneurial Patent Management in Pharmaceutical Startups



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SUMMARY			
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Abstract

In the present paper, the authors examine patent management strategies pursued by startups in the pharmaceutical industry. Pharmaceutical startups face different challenges than large companies, the most prominent one being limited financial resources for filing, monitoring and enforcing patents. Based on a study on startup projects accompanied by the Swedish pharmaceutical partnership network PULS, the authors examine the benefits and risks attached with several patenting strategies, beginning with the pros and cons of patenting inventions at an early or at a later business phase of startups. The authors further present the so-called “*focus and surround*” and “*reposition and extend*” strategies, both based on patent portfolios combining different kinds of patents available in the pharmaceutical industry.

Summary

Over the last years, startups have gained increasing importance for innovation within the pharmaceutical industry. Innovation within the pharmaceutical industry is characterized by significant investments in research and development (R&D) as well as long R&D times. Patents are, therefore, one of the most important means for pharmaceutical companies to secure sufficient returns from investments in R&D. As a result, the propensity to patent is high within the pharmaceutical industry.

Compared to large companies, pharmaceutical startups have several special characteristics that require a unique approach to patent management, the most prominent one being limited financial resources for filing, monitoring and enforcing patents. Consequently, pharmaceutical startups pursue different patenting strategies than large companies, as a rule.

The authors examined patenting strategies followed by projects accompanied by the Swedish pharmaceutical partnership network PULS. PULS invests in early-stage pharmaceutical projects and contributes with scientific and business development services, ideally until exit. The study focused on three startup projects PULS successfully exited, namely Ambria Dermatology, DuoCort and LIDDS.

Regarding the right timing for filing for patents, pharmaceutical startups are confronted with the choice between patenting their innovations at an early or at a later business phase.

Given the limited financial resources usually available, startups often file for patents as late as possible, while, in the meantime, they rely on secrecy to prevent imitation of their inventions. Apart from limiting

costs, late patenting also extends the patent protection time, which can be very important considering the long R&D times common in the pharmaceutical industry.

On the other hand, several factors may require early patenting. Patents help startups raise venture capital much needed, particularly at their early stages. Early patenting also excludes the risk of being locked out by competitors undertaking R&D in the same field (through a patent granted prior to filing for an own patent). Furthermore, patents play a very important role in enabling exits. As practice shows, startups based on academic research also often need to patent early, in order to meet with their founders' wish to publish their results in academic journals as soon as possible (since publications eliminate novelty, and, consequently, hinder later patenting).

In order to secure the above benefits, while, at the same time, keeping costs at a moderate level, pharmaceutical startups often file for patents with a limited geographic coverage of protection (patents need to be filed in each country separately), focusing for example in the larger markets with the highest commercial potential.

Besides that, startups often pursue strategies based on patent portfolios combining different types of patents available in the pharmaceutical industry. In general, pharmaceutical companies can choose between (1) matter patents, claiming the active chemical substance, (2) method of use patents, claiming the use of the substance to treat one or multiple specific disease(s), (3) formulation patents, claiming the composition or method of application of the substance, and (4) process patents, claiming the process by which the substance is manufactured.

One of the strategies using patent portfolios that combine different types of patents is the so-called "*focus and surround*" strategy. This strategy consists in applying for an early broad patent (for instance, a matter or a method of use patent), which is then supported by a pipeline of related patent applications (for example, formulation and process patents), which can, for instance, be filed close to exit.

Another strategy using patent portfolios combining different types of patents is the so-called "*reposition and extend*" strategy. This strategy consists in repositioning an already patented substance to the use against a new disease (that is a disease not claimed before) through filing for an additional method of use patent, which, in case it is granted, will extend the patent protection time regarding the substance in question.

In conclusion, the authors suggest that improved patent management by pharmaceutical startups will benefit innovation in the industry as a whole. This would, particularly, take place by decreasing transaction costs in connection with interactions between startups and large companies (for instance, in cases of exits), as well as by making the repositioning of old substances to new diseases through additional method of use or formulation patents more attractive for companies.