



BENEFITS OF THE PCT ROUTE FOR PHARMACEUTICAL CORPORATIONS

PATENT PORTFOLIO OF EGIS

Between 1980 and 2006, Egis based their patenting activities on filing national patents. This generated a significant workload with following the divergent local legal provisions and filing 60 patent applications annually, on average. The company used an extended network of patent attorneys that required significant financial resources. The system was also a gateway to potential errors in translations and transcriptions with serious consequences on patenting.

The single advantage of following the individual national patent application route was having independent applications, so any issues with one application did not stop the patenting process of others.

PATENTING STRATEGY OF EGIS

I. Preparation

Egis prepares the ground thoroughly before the patent application is made. Based on their research and development activities, Egis identifies patentable inventions including drug substances, drug products and any miscellaneous activities such as packaging, diagnostic methods or product and testing apparatus.

The identification of patentable inventions is done through the detailed and regulated workflow capture, based on which disclosures are made. This is followed by an assessment based on which the decision to file for patent can be made.

II. Assessment

Since patents are considered business assets, the assessment investigates the potential commercial need for the invention and the viability of the patent based on cost and geographical business relevance considerations as well as potential regulatory issues. Egis also assesses the licensing potentials of an invention before filing for patents.



Introducing Egis Pharmaceuticals PLC

The foundation stones of Egis are tradition, expertise and quality. The company's legal predecessor was founded by a Swiss and a Hungarian genius over a century ago in 1913 and the company grew into one of the leading pharmaceutical corporations in the CEE region with 634 products available in 61 countries around the globe.

Egis is a vertically integrated pharmaceutical company which means that the whole pharmaceutical value creation chain is covered by their activities. 76% of their products go for export in the CEE region, Russia, the CIS countries, and Western Europe. The remaining 24% sales are made in Hungary.

The turnover of Egis was 542 million EUR in 2020, and the R&D expenditure exceeded 40 million EUR. The company was able to grow and expand even in tough market conditions with the help of its products protected by a solid patent portfolio.

III. PCT route

If the assessment concludes with a positive decision, the company moves forward in a fairly traditional way with patenting. In most cases, Egis files a Hungarian patent application to secure priority. The PCT application is made with claiming this priority 12 months after the first filing. In case of countries which are not members of the PCT convention, Egis goes for a national patent filing within the priority year.

Egis rarely files demands for chapter II, and usually waits until the end of the 30 months period to enter the national phase and file for national or regional patents, because this serves the business interest of the company best.

IV. Using regional routes

Besides the PCT, Egis also uses the European and Eurasian regional patent systems as much as possible to reduce complexity and costs of patenting since this way most of the target countries of the company can be covered by a handful of applications. This strategy helped Egis to significantly cut their workload and cost of patenting reducing the average number of patent filing to 13 a year including first filings after 2006. This approach not only reduced the resource requirements of patenting, but also significantly increased the success rate of patents granted in the target countries. 61% of their patent application closed with a granted patent, in 12% of the cases the company eventually did not file a national application and approximately one-quarter of the applications closed with objections to patentability.

At the beginning, Egis chose ROSPATENT and the Austrian Patent Office as International Searching Authority, then switched to the European Patent Office for quite a long time. However, when it was established, the Visegrad Patent Institute became the company's choice for international searching authority.

Fun fact: The first international application in which the Visegrad Patent Institute was chosen as International Searching Authority was filed by Egis when the VPI started its operation in 2016.

EXAMPLE OF A TYPICAL PATENTING PROCEDURE AT EGIS

Invention: fix-dose combination antihypertensive and antihyperlipidemic medicines for the treatment of vascular diseases (4 product lines total)

The combination of medications that are usually prescribed together makes it possible for the patient to use one product instead of two. This simple idea provides convenience of administration and handling of the medications for the patient, and results in a better compliance to the therapy.

Egis filed several patent applications related to the subject matter including salt and crystal forms of the ingredients, methods of manufacturing and also for pharmaceutical compositions. Egis used the traditional method of filing a Hungarian patent application first, followed by a PCT application and by national patent applications at the end of the 30th month. Egis mainly works with patents since utility models in case of pharmaceutical inventions are rarely applicable. However, as a result of this application, Egis managed to obtain 52 patents and 4 utility models worldwide.

IMPORTANT CONSIDERATIONS FOR EGIS REGARDING THE PCT ROUTE

With the ever-evolving national patent regulations in mind, it is important to assess if the written opinion of the international searching authority or the international preliminary examination report provides sufficient indication that the intended scope of protection provided by the patent can be obtained in the target country.

The added cost of the IPER must be justified in order to enter the national phase with an application that has a higher potential for a favourable patentability decision.

Although Egis usually waits until the end of the 30th month with national patent applications, choosing the accelerated prosecution may be justified in certain cases in the economically important territories. Experiences of Egis are quite positive with the European Patent System where the acceleration scheme is available and with the USPTO where prioritized examination can be chosen.

BENEFITS OF THE PCT ROUTE FOR THE PHARMACEUTICAL INDUSTRY IN A NUTSHELL

- 1.** The 30 months before entering the national or regional phase provides ample amount of time to decide on business considerations.
- 2.** The filing and the procedure regulated by the PCT are straightforward with such benefits as no need for multiple translations, or the possibility of e-filing.
- 3.** The ISA-WO and IPER provide a comprehensive impression about the patentability of the invention and indicate potential points where the claim needs to be amended.
- 4.** PCT provides a possibility to further define the patentable subject matter based on the international preliminary examination report as well as an optional supplementary international search.
- 5.** The PCT process protects the applicants from certain errors with the help of the restoration of priority right, incorporation by reference and review-excuse procedures.

+1 TIP

from Egis:

Choosing the VPI as international searching authority provides certain cost reductions and the possibility of a search fee refund when the VPI can make use of the search report of the priority application.