

Case Study:

Freedom to Operate Analysis in the Field of Medical Devices

Tech Transfer
IP Consulting
IP Handling



Patents and patent applications give their owners or assignees the exclusive right to exclude others from manufacturing, using, selling, distributing or importing a product, process or application falling under the claimed features of the invention in its designated countries. As many technological fields are crowded with patent rights, companies that intend to commercialize high tech products are advised to perform a freedom to operate analysis, before running the risk being sued for patent infringement by a patent holder.

A Chinese producer of medical supplies (the “client”) has asked BDC - The Business Development Company GmbH (“BDC”), Switzerland, through its German distributor to perform a due diligence evaluation to clarify whether the client will be free to sell four medical product lines in view of any existing third party patent rights in the European market. In order to identify relevant third party patent rights for the client’s products in Europe, patent documents with valid claims protecting features that are likely to be implemented in the client’s medical products have been evaluated in three steps.

In a first step, related patents in the business field were identified. Based on the documents and product information provided by the client, a search strategy was mapped out and conducted in patent databases. More than 1’000 patent documents in the field were screened and related patent documents that claimed defined search features implemented in the client’s devices were identified.

Potentially critical valid patent claims were evaluated in a second step. Thereby, a legal status and patent family analysis of the related patent documents was performed in order to exclude patent documents that are not in force anymore. In addition, the legal status and the geographical coverage of the remaining patents and patent applications were determined. This step lead to 50 relevant third party patent rights.

In the last step, a detailed freedom to operate analysis was performed by comparing the claimed features of the relevant patents and patent applications with the features of the client's medical devices of each product line. The analysis yielded 11 third party patent rights in total that might be infringed by the client's devices, if marketed in certain European countries.

However, the client seems to be free to commercialize the devices of the first product line in due time, as two critical patents will expire within the next months. Only two patent applications were found for the devices of the second product line. Consequently, the prosecution of these patent applications was analyzed to determine the potential scope of protection, if they will be granted. Finally, three patents and four patent applications were evaluated in detail by the client and BDC to determine a strategy for designing the concerned devices around these patent rights. Now the client and its distributor have a solid basis for commercializing their products in Europe without running the huge risk of being sued for patent infringement.

BDC's representatives would be happy to assist you with evaluating the freedom to operate of your products or services.

Please contact us for further information.