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The Patent Lawyer Editorial Board looks back at 2023 to summarize key cases and developments by jurisdiction.

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Annual 2024

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Rapid development and market introduction of new technologies: why Freedom to Operate analysis is essential

Maciej Fajkowski, patent specialist at Patpol, evaluates the necessity to perform Freedom to Operate analysis to ensure the protection of new technologies from R&D through to introduction to the market, even with a product protected by exclusive rights.

reedom to operate (FTO) may not be the first thing that comes to mind for an entrepreneur when developing a new solution, but it is a very important direction that should always be considered, especially for startup entrepreneurs who want to commercialize their products. Launching a product, technology, or invention onto the market is associated with the risk of potential infringement of earlier exclusive rights of third parties. Infringement occurs when a technical solution is offered, introduced on the market, or used for profit without due authorization and it is revealed that it was already protected by a particular exclusive right of someone else. Moreover, the lack of awareness of the existence



Maciej Fajkowski

of an earlier exclusive right cannot be used as a justification for infringement of that right.

The risks resulting from not having carefully examined patent clearance include damaged relationships with partners, a risk of incurring financial penalties, and a possibility of the loss of a promising technical solution. The advantages of conducting profound patent clearance in the process of product development are security, better opportunities to attract investors, and a higher probability of commercial success. This is especially important now when entrepreneurs are looking at how to save the costs that they incur due to the current market situation and when more and more newly developed technologies are appearing on the market. Infringement of third parties' exclusive rights may involve the payment of a certain sum of money, the amount of which depends on the losses incurred by the right holder. Thus, taking care to minimize the probability of infringement of someone else's exclusive rights is an important factor in safeguarding against exposure to capital losses, which is especially important in situations of economic crisis. Therefore, Freedom to Operate (FTO) analysis is an effective tool for safeguarding one's own interests and giving oneself the opportunity to make the appropriate changes to a newly developed solution even before it is introduced on the market, or it may also be used to protect oneself against infringement from other parties.

In view of the above, let us have a look at two basic questions: why is awareness about the need for FTO analysis so important? And what is patent clearance by itself?

Résumé

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What is patent clearance and patent clearance examination?

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One may claim patent clearance of a solution when the examined solution does not fall within the scope of legal protection defined by a specific exclusive right. On the other hand, patent clearance examination, known as a Freedom to Operate (FTO) analysis, is an examination that results in an analysis determining whether manufacturing, using, selling, or importing a particular product, technology, or invention in the territory of a particular country will not involve infringement of the exclusive rights of third parties. Thus, a patent clearance examination provides an entrepreneur with information that the research, development, and marketing of a technical solution may proceed with either a low or high risk, depending on the outcome of the examination itself, of falling within the scope of protection of the patent granted to third parties. It should be noted at this point that the patent clearance examination does not provide a clear answer defining one hundred percent certainty regarding freedom to operate in the market. Rather, it should be considered as a risk assessment tool, on the basis of which decisions are made on further action on the commercialization of specific solutions. In an era of technological developments that result in the presence of a growing number of exclusive rights, such risk assessment tools are one of the essential things for entrepreneurs. In the case of a negative result of a patent clearance analysis, i.e., in the case of finding already existing exclusive rights, which would be infringed if one started to operate on the market with a given solution, entrepreneurs can develop a strategy to obtain the aforementioned freedom to operate on the market. Such strategy may include, among others, the following actions:

 Developing changes to the solution in order to stay out of the field of protection of the patent;

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- Attempting to invalidate the patent;
- Obtaining a license for a solution protected by a patent;
- Purchasing a technical solution from the right holder or with the right holder's consent;
- Purchasing a conflicting patent (a patent is a transferable right, so the patent holder can transfer it to another person/ other entity).

If the result of a patent clearance analysis is very unfavorable, it may be necessary to abandon further activities seeking to manufacture, use, sell, or import a particular solution.

How is the patent clearance analysis conducted?

The Freedom to Operate analysis for technical solutions should be carried out by the patent attorney appropriate for a particular country. This is important because a national patent attorney is familiar with the legal interpretation of the scope of protection of exclusive rights in a particular country. Thus, they will best assess the risk of patent infringement in their territory. The examination of patent clearance is the analysis carried out for a well-defined technical solution, so the first step is to determine in detail what the examination is to be about, that is, to clearly define the technical features of the examined solution. In the next step, the relevant criteria of the examination regarding the field of technology or the duration and scope of protection are determined. Then, a search is carried out in the patent literature to select the patent documents in force, closest to the examined solution, which are potentially subject to infringement. After selecting the aforementioned documents, the patent attorney conducts a detailed analysis, based on which they prepare an opinion on the patent clearance of the examined solution. Based on the received opinion on patent clearance, entrepreneurs can adjust the previously mentioned strategy to further actions on commercialization or application of specific solutions.

The rapid development of new technologies and the increasing number of intellectual property rights

Technological development is accelerating along with economic development. Large companies are expanding and producing new solutions. Moreover, more and more new companies working on their own solutions are appearing on the market, resulting in an increase in the number of patent applications. The chart below shows the upward trend in the number of patent applications on a year-to-year basis at the European Patent Office (EPO). As the number of patent applications is increasing, the number of granted exclusive rights is increasing as well. Thus, every entrepreneur, when introducing their new solutions on the market, must take into account the growing number of existing third-party rights that are potentially subject to infringement. Thus, year after year, entrepreneurs should put more and more emphasis on examining the patent clearance of the solutions that they intend to commercialize. At this point, it should be noted that there is a very important role here for patent attorneys, but also for IP practitioners, who should try to raise awareness among their clients about taking care of their interests and protecting themselves against possible infringements. Companies are more and more willing to examine their solutions, as they are more aware of the growing size of competition and the potential dangers of neglecting their own IP rights.



Why conduct the Freedom to Operate analysis?

In the times of rapid development of new technical solutions, no company, especially startups, wants to undertake costly and unpredictable legal actions, which is exactly what may happen if a patent clearance examination is not performed. In the case of infringement, the most optimistic scenario may be the need to pay licensing fees and legal costs, as well as the loss of trust of potential partners. In the worst-case scenario, in addition to incurring high costs, there may also be major disruption to the company's business due to the need to withdraw the solution from its offerings. In some jurisdictions, if the infringer was aware of existing third-party intellectual property rights, the compensation increased significantly.



In particular, startups that invest their resources in developing their new solutions risk legal consequences by failing to conduct a comprehensive patent clearance examination. These companies usually have less funding, and the legal consequences can cause huge barriers to the development and marketing of their products.

Consequently, the above demonstrates how many positive reasons emerge for conducting patent clearance examinations. Assuring partners that the company takes intellectual property rights seriously and does not want to risk infringement is one of those positive reasons. In addition, it is crucial to show that the company cares about its own solutions, by which it can gain the confidence of investors.

It should also be remembered that having an exclusive right for your own solution does not mean that the solution does not infringe others' exclusive rights! Therefore, conducting a patent clearance examination is crucial and is recommended when launching any solution, even one protected by your own exclusive right.

When to conduct the Freedom to Operate analysis?

As a general rule, a patent clearance examination should be conducted before a solution in the form of a product or technology is launched on the market, and when the solution is already clearly defined by the technical features describing it. However, patent clearance examination can also be carried out both at the early conceptual stages and after the solution has been introduced to the market. Conducting a patent clearance examination at the conceptual stages allows for

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the determination of whether it is worth investing further resources in the development and research of a particular project, or in which direction a project should go. Performing the Freedom to Operate analysis in the early design stages, however, may result in the need to perform the examination again when the company wants to enter the market, as the solution may have changed significantly by that point.

How can we help?

If you incur high costs for a new solution and want to bring it to the market, the Freedom to Operate analysis should be prepared by a law firm specializing in such services, especially because of the broad experience of patent attorneys employed in the firm and their high professional liability insurance.

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