The Research Use Exemptions from Patent Law

– when patents do not cover the use of their products or methods

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When can you safely use patented products without infringing the rights of the Patentee? Selected case studies show you when.

A patent gives the Patentee the right to prevent others from making, using, importing, selling or marketing the patented product or method. However, there are exemptions from the patent law that makes it possible for others to use patented products and methods. The exemptions fall in two categories 1) the general experimental exemption that permits use of a product or method for further research and 2) the industry specific research exemption that permits tests with drugs for preparing regulatory approval e.g. with the EMA (European Medicines Agency).

The industry specific research exemption allows e.g. generic producers of medicaments to prepare generic or copy drugs for the market prior to expiry of a dominating patent. Hence this is the explanation for the overnight drop in price of blockbuster drugs following patent expiration. This research exemption is found in many jurisdictions and is known by a multitude of names[1]. Although this exemption generally gives the same rights to third parties in the most sought markets, the specific laws covering the particular jurisdiction wherein the trials are to be conducted should be scrutinized carefully. Care must be taken in relation to the goal of the trials to be conducted. As an example, in the EU the Directive (2004/27/EC) is implemented differently in the European countries giving variances in the scope of the exemption: in some EU countries you may conduct trials for submission to both EMA and the FDA (the American Federal Drug Administration) without infringing the rights of the Patentee, in others only for trials to be submitted to EMA. Likewise, in Germany trials should be *directly related* to a submission for regulatory approval in order to be exempted, whereas in the US they need only be *reasonably related* to such a submission to be exempted.

The Tool Rule:

In doubt whether you are infringing? Use the Tool Rule: If you are conducting experiments *with* a patented product or method, you are using the patented item as a tool and you are infringing. If you are conducting research *on* the patented item you are exempt.

The general experimental exemption is likewise found in many jurisdictions and allows the use of a product or method for further research. In all jurisdictions, this exemption is interpreted narrowly and in general the interpretation can be said to follow the "tool rule": If you are using the patented product or method as a tool, you *do not* fall under the exemption and thus you are infringing the rights of the Patentee. It is a common misconception that any scientific research conducted especially at public research institutions such as universities and hospitals are exempt – they are not. The experiments that are exempted are those where the experiments are conducted *on* the patented item, not when the experiments are conducted *with* the patented item.

[1] The research use exemption for obtaining regulatory approval is also known as the safe harbor exemption, the experimental use exemption in the EU, the §271(e)(1) or Hatch-Waxmann exemption in the US and the Bolar provision in Canada.

The following cases illustrate examples that fall within and without the exemptions:

Case 1 In Denmark MiniBio A/S synthesizes BigPharmas patented blockbuster drug and then conducts trials with the drug.

If the goal of the trials are to obtain regulatory / marketing approval with the EMA, then the make and the use of BigPharmas drug is exempted and thus does not infringe the right of BigPharma.

If the goal is to obtain regulatory approval with the FDA, the use of BigPharmas drug is also exempted in Denmark and thus does not infringe the right of BigPharma. In other EU countries, e.g. the UK and Germany, these trials would not be exempted.

If the purpose of the trials are to compare MiniBios own drug candidate with BigPharmas for marketing studies, MiniBios activities are most likely, but not for sure, exempt in Denmark and in the EU. The aim of the patent law in general is to further technological advancement and comparator studies can be said to demonstrate an advance. If the trials where conducted in the US they would most likely be deemed *reasonably related* to a submission for regulatory approval to the FDA, and therefore are likely to be exempted.

Case 2 MiniBio A/S uses a detection method patented by NovoTech to screen for novel drug candidates.

This case is not exempt as it breaks the tool rule: No matter whether a drug candidate is found that one day will be the basis of an application for regulatory approval with the EMA the detection method is used as a tool and thus the use of the method is infringing the rights of Novotech. This applies no matter whether the research is conducted in Denmark, the EU or in the US.

Case 3 The University of Knowhow uses a detection method patented by NovoTech to screen for novel drug candidates.

The same as above: The University is infringing the rights of Novotech: No entity whether public, private or non-profit is exempt from the (patent) law. The University is conducting research *with* the patented item.

Case 4 MiniBio A/S has outsourced drug screening and use of the detection method patented by NovoTech to a company in Norway. NovoTech has no patents in Norway.

MiniBio A/S is not liable for patent infringement, because the importation of data (from the 3rd party in Norway) is not infringement of NovoTech's patent.

Case 5 The University of Knowhow uses a detection method patented by NovoTech to understand and improve the method.

The activities fall under the general experimental exemption and the University is not infringing. The research is conducted to improve the method and thus the experiments are conducted *on* the patented item.

Case 6 MiniBio A/S hires WeMake to synthesize BigPharmas blockbuster drug, which MiniBio then uses for comparator studies with own drug.

In the US (and the UK) both the activities of MiniBio and WeMake are most likely exempt from the rights held by BigPharma as long as the activities are likely to be used for submission for regulatory approval. In other EU countries, e.g. Germany, WeMake are likely to infringe, as they are not themselves conducting experiments that provide exemption. In Denmark the situation is likely the same as in Germany.

If you are interested in learning more about research use exemptions and how they apply to your business you are always welcome to contact a patent attorney at Høiberg A/S.

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