

*ARTICLE:*

**THE EXPERIMENTAL USE EXCEPTION:  
A EUROPEAN PERSPECTIVE**

**Heinz Goddar\***

**I. INTRODUCTION**

When studying the extent to which experimental use of patented inventions may be permitted in Europe, one has to look into national patent laws. Art. 64 of the European Patent Convention (EPC) states in part (1) that the rights conferred by a European patent in all designated countries to which the European patent extends shall be the same as those conferred by a national patent granted in that state. Furthermore, part (3) of Art. 64 of EPC states that any infringement of a European patent shall be dealt with by national law.

All national patent laws contain clauses similar to Art. 11.2 of the present German Patent Act (in force since 1981), which in translation reads essentially as follows: "The rights conferred by the Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention."

A similar provision can be found in Art. 9 of the Draft Council Regulation on the Community Patent<sup>1</sup> of August 1, 2000, which will be the basis of the forthcoming Community Patent, possibly ready to come into force in 2003.

With regard to the Experimental Use Exception, most of the case law developed in European countries, and particularly in Germany, has been developed on the basis of pharmaceuticals. The big question here has been, and still is, whether during the duration (period of protection) of a pharmaceutical patent, pre-clinical and/or clinical tests may be conducted.

In principle, provided that a certain substance is protected as a pharmaceutical for a certain indication, two different kinds of testing can occur during the duration of a patent. First, tests with the aim of finding new indications of pharmaceutical substances that have been patented only for one indication. Second, tests for market approval of a patented substance for an already patented indication during the protection of a pharmaceutical patent. If the latter kind of test is permitted, a competitor of a patentee can prepare for market approval well ahead of the expiration of the respective patent. As a result, immediately

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\* German Patent Attorney, European Patent and Trademark Attorney, Boehmert & Boehmert/Forrester & Boehmert, Munich, Germany.

<sup>1</sup> COMM (2000) 412 final.

upon expiration of such patent, the pharmaceutical in question for the patented indication can be put onto the marketplace right away without risk of patent infringement.

In all other technical fields, the Experimental Use Exception has not caused any problems in case law. As long as tests/experiments are directed toward better understanding the content of a patent, or toward doing further research with regard to the invention, no essential problems have ever been observed. Only in relation to pharmaceuticals – given the enormous financial consequences of earlier or later market entry, particularly in the case of “blockbuster” pharmaceuticals – has case law developed rather slowly. But the result has been surprisingly clear, at least as far as Germany is concerned.

## **II. CASE LAW IN GERMANY BASED ON GERMAN PATENT ACT OF 1968**

In the German Patent Act of 1968, in force until the end of 1980, there was no specific provision excepting experimental use from the exclusivity rights of a patent. The decision of the German Federal Supreme Court (BGH) of February 21, 1989, well-known under the key word “*Ethofumesat*,” was based on the German Patent Act of 1968. In that decision, the BGH clearly stated that experiments or “trials” with a protected subject matter, like a pharmaceutical, would only be permitted insofar as such experiments were directed to the substance itself. For example, experiments were permitted in order to get more information regarding the substance’s inherent properties and to determine whether the substance could be manufactured at all, whether it was sufficiently pure, or whether it had the properties of the protected pharmaceutical. Clinical trials, however, were considered as being of a different nature and were not permitted. Accordingly, it was not possible to obtain approval for marketing a patented pharmaceutical in Germany immediately after expiration of a third party’s patent. Instead, the necessary governmental approval would have to be obtained after expiration of the patent.

## **III. CASE LAW BASED ON GERMAN PATENT ACT OF 1981**

The German Patent Act of 1981, which replaced the Patent Act of 1968, provides for experimental use being exempted from patent protection.<sup>2</sup> It took a while before the BGH issued a first decision regarding this issue. District court decisions to that point had held that nothing had changed with regard to clinical trials as discussed above. The BGH, however, changed the world, at least as far as Germany is concerned.

### **A. German Supreme Court Decision “Clinical Trials I” – 1995**

In 1995, the BGH issued its first decision based on the Patent Act of 1981. In *Clinical Trials I*, published in July 1995, the BGH stated that the experimental privilege allows one, during the lifetime of a patent, to conduct trials directed toward obtaining data for approval of a pharmaceutical for a second, not-yet patented indication of a protected pharmaceutical.

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<sup>2</sup> Art. 11.2.

In other words, the BGH held that using a protected pharmaceutical in experiments, including clinical trials, for the purpose of finding indications different from the patented one, would not infringe the respective patent. Accordingly, such experiments could be conducted during the lifetime of a third-party patent.

In *Clinical Trials I*, the BGH did not decide what the legal consequences would be if clinical trials were not directed toward a new indication, but were instead conducted to obtain government approval for a pharmaceutical having an indication identical to that of the protected substance. For example, the Court did not decide whether clinical trials could be conducted during the last few years of a third party's patent term for the purpose of obtaining early governmental approval – which would allow the party conducting the clinical trials to begin distribution of the respective pharmaceutical in Germany immediately upon expiration of the third party's patent.

Various authors expressed the opinion that the BGH, in *Clinical Trials I*, implicitly expressed that “normal” clinical trials – those to obtain early approval for patented substances in order to market such substances immediately upon expiration of a third party's patent – would not be permitted.

## **B. German Supreme Court Decision “Clinical Trials II” – 1997**

In 1997, in *Clinical Trials II*, the BGH explicitly stated that clinical trials are permitted in cases where one of their purposes is to obtain data for clinical approval, even if such clinical trials are conducted for the same indication as that of the protected product. The only restriction the BGH described in *Clinical Trials II* was that no trials could be conducted in a volume that would not be justified for the purpose of the experiments/trials or which were conducted for the purpose of interfering with the marketing efforts of the patentee.

## **C. Developments After 1997**

*Clinical Trials II* was heavily disputed after 1997. Some authors, including myself, concluded that clinical trials during the lifetime of a patent, even if for the same substance and the same indication as protected, could be conducted, so long as the purpose was not to use the respective substance in any infringing manner. For example, distribution or manufacture before the expiration of the patent was prohibited, but clinical trials for the purpose of obtaining early market approval was permitted.

Other authors, particularly from “Big Pharma,” heavily fought this opinion and trusted that the German Constitutional Court, to which this case had been taken, would reverse the opinion of the BGH.

#### **D. German Constitutional Court Decision “Clinical Trials II” – 2000/2001**

The German Constitutional Court, by decision of May 10, 2000,<sup>3</sup> affirmed *Clinical Trials II*, with the following results. The decision of the BGH was in full conformity with the German Constitution. According to German law, the experimental use exception applies whenever tests relate to the subject matter of the patented invention as such, and have the purpose of obtaining additional information. The BGH, as well as the Constitutional Court, will not distinguish between different uses of the information obtained through clinical trials. The only prerequisite is that experiments done with the protected matter must be directed towards the generation of information. Whether this information is further used for the registration of medications or for filing of use patents does not matter. The limitations that occur for the proprietor of the patent during its lifetime have to be accepted by its owner in view of the development of both the state of the art and the public interest; otherwise, an unjustified factual extension of patent protection would occur.

As a result of the above case law, Germany is viewed as being one of the most liberal countries in Europe with regard to the experimental use exception in general, and with regard to clinical trials conducted for the purpose of finding new indications for old substances or for getting market approval for patented indications that are still protected.

#### **IV. THE EUROPEAN SITUATION OUTSIDE OF GERMANY**

The situation in Germany is extremely liberal. In a sense, only a “commercial use under disguise” of the patented matter would be prohibited, which is clearly distinguishable from clinical trials to obtain information leading to market approval.

In other countries, very different conditions prevail. The case law with regard to permitting or prohibiting experimental use with regard to clinical trials in pharmaceuticals is not harmonized within the European Union. In most countries, including Sweden and the United Kingdom, clinical trials are regarded as patent infringement. In other countries, such as Denmark, the situation appears closer to the German “liberalism.”

Further developments will have to be observed. In due course, the central patent litigation procedures provided under the Draft Council Regulation on a Community Patent – the law inside the European Union – will become uniform, and the liberalized approach as defined by the German courts will prevail.

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<sup>3</sup> GRUR 2001, at 43 *et seq.*