

Germany: Clinical Trials In Pharmaceuticals

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Changes in law and recent decisions permit clinical trials, but they may not interfere with patent's marketing

Until mid 1995 license arrangements relating to Germany had to take into consideration the fact that, in accordance with the earlier jurisdiction of the German Federal Supreme Court (BGH), according to which clinical trials, which are a necessary condition for obtaining government approval to sell a pharmaceutical in Germany, were not permitted in view of the exclusivity right granted to a patentee by a patent protecting such pharmaceutical. The aforementioned jurisdiction was based on the old German Patent Act of 1969 being in force until 1998, in which there was no specific provision relating experimental use from the exclusivity rights of a patent.

Even the basic decision of the BGH of February 21, 1995, well-known under the key word "Bilbaostrasse," was based on the former German Patent Act of 1969 in which the experimental use was not explicitly regulated. Accordingly, in the aforementioned decision the BGH had 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, e.g. in order to gain more information in relation to its inherent properties, whether it can be manufactured at all, whether the substance is sufficiently pure, or whether a certain substance has the properties of the protected pharmaceutical. Explicitly, clinical trials, i.e. to obtain data for the pharmaceutical approval of such a substance were considered as being of a different nature and therefore not permitted.

The aforementioned legal situation had the effect that, until 1995, licensing agreements concluded with i.e. a licensee in Germany, who should be entitled to produce a certain pharmaceutical in accordance with a licensed patent which in itself was dependent from a third party's patent (expiry soon in e.g. two years after the conclusion date of such a license agreement) had to take care of the fact that during the life time of the third party's patent no clinical trials could take place in Germany. Accordingly, it was not possible to obtain approval for marketing the respective product in Germany immediately after expiration of the aforementioned third party's patent, rather only after a "waiting time" after the expiration of the respective patent of the third party, necessary to obtain government approval.

In 1995, the situation changed insofar as the BGH issued its first decision based on the Patent Act of 1998, which at that time replaced the Patent Act of 1969, and which provides in Article 11 No. 2 for experimental use being exempted from patent protection. The aforementioned first decision of the BGH, under the key words "Clinical Trials I," was published in July 1995 and stated that the aforementioned experimental privilege gives the possibility, even during the life time of a patent, e.g. protecting a pharmaceutical substance, to conduct trials of any kind, including clinical trials intended, among other goals, in obtaining data for approval of a pharmaceutical, as far as a second, not yet patented indication of the protected pharmaceutical was subject of the experiments.

In other words, the BGH at that time, i.e. in 1995, already declared that using a protected pharmaceutical in experiments, including clinical

trials, with the purpose of finding indications different from the patented one, would not infringe the respective patent. Accordingly, such experiments could already be conducted during the lifetime of a third-party patent.

In "Clinical Trials I" the BGH did not decide, however, what the legal situation would be if clinical trials were not directed to a new, second indication, rather conducted to obtain government approval for a pharmaceutical having the identical indication as a protected substance, e.g. clinical trials conducted during the last few years of the lifetime of a third party's patent with the aim of obtaining approval so early that immediately after the expiration of the aforementioned third party's patent distribution of the respective pharmaceutical in Germany by the party conducting the clinical trials could begin.

Various authors discussing the decision "Clinical Trials I" still expressed their opinion that in the aforementioned decision the BGH implicitly had expressed that "normal" clinical trials (namely e.g. to obtain early approval for patented substances in order to be able to market such substances immediately after the expiration of a third party's patent) would not be permitted.

In the meantime, however, in August 1995, a further decision "Clinical Trials II" of the BGH has been published by which the BGH explicitly has stated that clinical trials are permitted even in cases where one of their purposes, or even the main purpose, is to obtain data for clinical approval, and even if such clinical trials are conducted for the same indication as already known and protected, respectively.

For example, that means that

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since last year it is possible to conclude a license agreement affecting Germany on the basis that before the expiration of a third party's patent clinical trials with a patented substance, protected by a dependent patent, can start even during the lifetime of the superior patent of the third party, so that much-valued market entrance of the licensed pharmaceutical can take place.

The only restriction the BGH has described in "Clinical Trials II" as not permitted, as far as clinical trials are concerned, is that no trials can be conducted in a volume that is no longer justified because of the purpose of the experiments/trials or which are conducted with the purpose of interfering in a disturbing manner with the marketing efforts of the patentee.

The abovementioned restrictions and reservations, respectively, of the BGH have to be seen in the light only, however, of comparison with other decisions of similar subject in both The Netherlands and in the United Kingdom, discussed in the reasons of the BGH's abovementioned decision "Clinical Trials II," and at least for the time being it cannot be seen whether any practical conclusions can be derived from such restrictions.

As a conclusion, for the time being, licensees and licensors negotiating and concluding license agreements affecting Germany should just take into due consideration that even during the lifetime of a patent of another party clinical trials, even for the same substance and the same indication as protected, can be conducted, as long as

the purpose of such clinical trials is not to use the respective substance in any patent infringing manner during the lifetime of the patent, e.g. by distribution or manufacturing before the expiration of the patent, but only in order to get early market entrance as soon as the patent would have expired.

By this fact, a variety of reservation clauses otherwise to be provided in license agreements, e.g. as far as minimum royalties during the initial years of a license agreement etc. are concerned, should be duly modified, with the aim of making both the licensee and licensor in a well-balanced manner benefiting from the fact that early clinical trials can take place, even during the lifetime of an otherwise preventing third party's patent.