

# The Olanzapine Patent Dispute: German court grants a preliminary injunction on a patent invalidated by the first instance

## Federal Patent Court

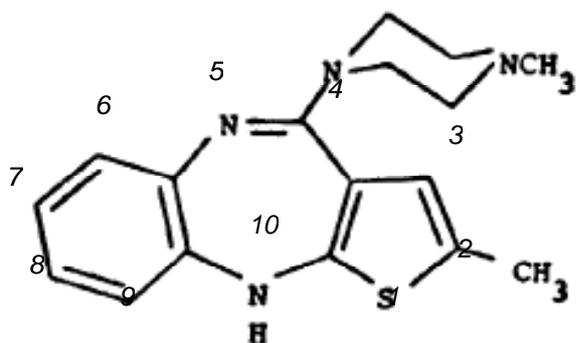
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The recent olanzapine case has caused a furor in Germany. For the first time in history, a German court allowed a preliminary injunction based on a patent that was found invalid by the first instance Federal Patent Court. The Olanzapine patent (DE 691 12 895) owned by Eli Lilly was attacked by several generic companies filing invalidation complaints with the Federal Patent Court. By decision 3Ni 21/04 (EU) combined with 3Ni 41/06(EU), the Federal Patent Court declared the Olanzapine patent invalid for lacking novelty. Nevertheless, the patentee filed a request for a preliminary injunction *inter alia* with the first instance Civil Court in Düsseldorf, which rejected the request; surprisingly, however, the second instance Appeal Court granted the preliminary injunction. This is all the more noteworthy since the infringement court of second instance, composed of “non-technical” judges found the underlying patent to be valid, contrary to the opinion of the Federal Patent Court having technical judges deciding on the case.

### The Decision of the Federal Patent Court to invalidate the Olanzapine Patent

The patent contains 22 claims *inter alia* directed to Olanzapine having the following formula:

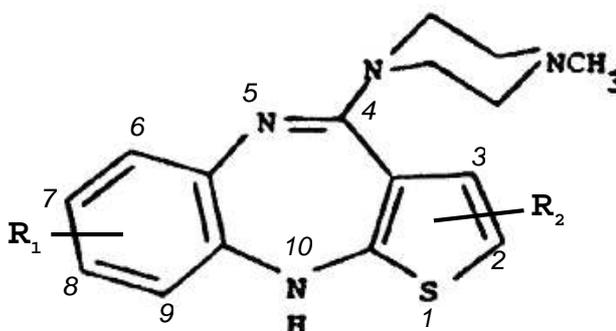
[Formula]



central nervous system such as for treating schizophrenia.

Among the prior art cited against the patent was a publication by Chakrabarti et al. in J. Med. Chem. 23 (1980), pages 878 ff of which disclosed a group of compounds allegedly having neuroleptic activity and being defined by the following lead structure:

[Formula I]



to said compound for use as a pharmaceutical, and to the use of said compound for treating disorders of the

In order to determine the content of Chakrabarti *et al.* the Federal Patent Court interpreted the prior art to disclose everything which, besides the literal wording, the skilled person would “read into” (read between the lines of) the literal disclosure<sup>1</sup>.

Applying the Federal Supreme Court case to the disclosure of Chakrabarti, the Federal Patent Court further considered, among other things, how the disclosure content of Chakrabarti should be defined.

In the Patent Court’s opinion, the compounds with lead structure of formula I were disclosed as preferred compounds with neuroleptic activity. Based on this starting point in Chakrabarti *et al.*, the Patent Court’s further considerations may be summarized as follows:

Chakrabarti would clearly disclose to the careful reader a group of compounds falling under formula I with R<sub>1</sub> occupying position 7 and being selected from H, Cl and F, and R<sub>2</sub> occupying position 2, and being selected from H, Me, Et, i-Pr.

Consequently, there would be a group of only 12 compounds clearly disclosed by the lead structure (R<sub>1</sub> being H, Cl, F; and R<sub>2</sub> being H, Me, Et, i-Pr). The residues R<sub>1</sub> and R<sub>2</sub> would be freely combinable because for all compounds the structure-function-relationship would be known (leading to 12 possible combinations, i.e. 12 compounds with the desired activity). Further, Chakrabarti would disclose 3 specific compounds immediately “neighbouring” Olanzapine, namely, compound 6 (R<sub>1</sub> is H and R<sub>2</sub> is Et), compound 8 (R<sub>1</sub> is F and R<sub>2</sub> is H), and compound 9 (R<sub>1</sub> is F and R<sub>2</sub> is Me). Based on the assumed structure-function relationships for all 12 compounds and the disclosed 3 specific compounds “neighbouring” Olanzapine, the Court concluded that the skilled person would

immediately also take from this specification that Olanzapine is a neuroleptic compound (R<sub>1</sub> is H, R<sub>2</sub> is Me). Since, according to the report of Chakrabarti, a skilled person would further obtain all information to synthesize Olanzapine, all requirements for a novelty-destroying disclosure of Olanzapine would be fulfilled.

Moreover, in the Patent Court’s opinion, Chakrabarti would also mention a neuroleptic activity of the compounds. This in turn would directly tell the skilled person that the compounds are useful for treating diseases such as schizophrenia. Therefore, also the use of Olanzapine for treating *inter alia* schizophrenia would lack novelty over Chakrabarti. Consequently, the Court invalidated the patent for lack of novelty.

### **The influence of validity questions in German patent litigation**

To understand the Olanzapine decision of the Düsseldorf Court of Appeal, it is helpful to understand the limited influence of validity questions in German patent infringement litigation.

A core feature of German patent litigation is the strict separation of the infringement court and the court dealing with the question of validity of a patent. The infringement court has to accept the patent as it is granted.<sup>2</sup>

The jurisdiction for all questions relating to infringement of a patent is vested with the so-called ordinary courts, i.e. the District Courts (Landgerichte) for the first instance level, and the Courts of Appeal (Oberlandesgerichte) for the appellate level. As a third instance, the Bundesgerichtshof (BGH) or Federal Supreme Court decides on questions of

<sup>1</sup> See Federal Supreme Court in “elektrische Steckverbindung” (electrical plug-in connector) GRUR 1995, 330.

<sup>2</sup> BGH GRUR 1959, 320, GRUR 1999, 914, 916 – Kontaktfederblock; BGHZ, 134, 353, 355 – Kabeldurchführung

law in infringement cases.<sup>3</sup> The infringement courts must accept the patent as it has been granted.

The jurisdiction for invalidity suits is vested with a special court on the first instance level, the Bundespatentgericht or Federal Patent Court. Decisions of the Federal Patent Court can be appealed to the Federal Supreme Court. The appeal is not limited to questions of law but, as an exception, also to the finding of facts. In fact, the Federal Supreme Court regularly appoints a court expert to assist the court in judging the skilled person's understanding and to deal with questions of inventive step. While at the Federal Supreme Court patent infringement cases and invalidity cases are dealt with by the same judicial panel, an infringement case in an invalidity suit concerning one and the same patent will not be tried as one case by the Federal Supreme Court even if both cases are pending before it simultaneously.

The system has obvious advantages, since the infringement cases are not delayed by questions of validity and in fact progress as rather swiftly, providing an enforceable decision in favor of the patentee, even after a first instance judgment. In other words, invalidity of the patent is not a defense in an infringement suit. On the other hand, the majority of all patent infringement suits run parallel to an invalidity suit filed by either the defendant of the infringement suit or a friendly company, for example the licensor or supplier of the defendant. The defendant of the infringement suit will of course bring an invalidity suit filed by itself or a third party to the attention of the infringement court. The infringement court may, under German procedural law, stay the infringement proceeding at its discretion if it comes to the conclusion, summarily weighing the pros and the cons of the invalidity suit, that the invalidity suit has a

<sup>3</sup> In law suits to the merit, there is only one appeal in preliminary injunction cases

strong likelihood of success<sup>4</sup>. As a general rule, the Court of Appeals of Düsseldorf requires that a patent either seems to lack novelty or that the inventive step has become so questionable in view of the prior art presented by the infringer that there is no reasonable argument in favor of validity left<sup>5</sup>. The infringement judge forms his opinion on the basis of the invalidity suit filed by the infringer, including all prior art references the invalidity suit relies upon.

If the infringement court stays the proceedings, it usually waits until a final decision has been handed down in the invalidity case. At their discretion, however, the courts may also stay up to a first instance decision in the invalidity case and resume the infringement suit if the patent has been upheld by a first instance decision of the Federal Supreme Court or, if an opposition is pending, of the Opposition Division of the European Patent Office or the German Patent Office.

The above rules are for lawsuits on the merits.

In preliminary injunction proceedings, the mechanism is somewhat different.

Notwithstanding the rule that the infringement court has to accept the patent as it has been granted or as amended by a final ruling in an invalidity case, it is common practice that a preliminary injunction can only be granted if

- the validity of the patent is clear beyond reasonable doubt
- the infringement is clear; and
- there is a need for an urgent ruling.

<sup>4</sup> BGH GRUR 1987, 284 – Transportfahrzeug; Court of Appeals Mitt., 97, 257, 258 - Steinknacker

<sup>5</sup> Court of Appeals Düsseldorf InstGE 7, 139, 146- Thermocycler

This requires that the interests of the parties are weighted against each other, taking into account doubts with respect to the validity of the patent and the swiftness of the patent owner in enforcing his rights.

Due to German case law, the stay of a preliminary injunction proceeding would be inconsistent with its character as a means of swift justice. Therefore, doubts with respect to the validity of a patent cannot, contrary to the practice in lawsuits to the merits, be resolved by staying the proceeding and waiting for the result of an invalidity suit or an opposition.

It follows that the request for a preliminary injunction will be denied if the validity of the patent is in doubt.

There is no strict standard as to when the validity of a patent can be regarded to be sufficiently clear to hand down a preliminary injunction against an infringer. The court of Appeals of Düsseldorf remarks in the Olanzapine decision that the validity can, as a rule, only be considered to be sufficiently clear if the patent has already been upheld in either an opposition or an invalidity suit, at least by a first instance decision. However, this rather strict standard, which would imply that preliminary injunctions cannot be granted on patents which did not go through an opposition or an invalidity procedure, is not even applied in all cases under the jurisdiction of the Court of Appeals of Düsseldorf. It is common ground that a preliminary injunction will not be granted if, according to the infringement court, the prior art cited in an opposition or invalidity suit comes so close to the patent that the court would stay a lawsuit on the merits.<sup>6</sup> If the prior art upon which the invalidity suit or opposition is based is not strong enough to warrant the stay of a lawsuit on the merits, the standards of different courts vary. In the

jurisdiction of the Karlsruhe Court of Appeals, there is a rule that a preliminary injunction can be denied even if the prior art would not be strong enough to warrant the stay of a lawsuit on the merits.

Even this does not mean that the existence of an invalidity suit or an opposition as such, or even any new type of prior art quoted against the patent, excludes a preliminary injunction. At least when the alleged infringer has had enough time to produce relevant prior art against the patent, even in the preliminary injunction proceeding the preliminary injunction will be denied only if the infringer demonstrates a strong likelihood that the patent will be invalidated. The likelihood would then be the same as it would be to convince a court in a lawsuit on the merits that it has to stay.<sup>7</sup>

From the above it becomes apparent that an infringement court can never judge with binding effect but can only give a forecast (prognosis) as to the result of an invalidity suit or an opposition. In view of this, infringement courts usually refrain from making their own prognosis if and when a first instance ruling took place on validity, either by the Federal Patent Court in an invalidity suit or by the EPO or German PTO in an opposition procedure. The reason behind this attitude is the principle that the infringement court should not interfere with the findings of the Federal Patent Court or the Patent Office which has, albeit only on a first instance level, sole jurisdiction to decide on the validity. However, first instance decisions of the Federal Patent Court and especially the EPO are not followed blindly where patents are upheld. The District Court of Düsseldorf decided repeatedly that a decision – even of the Federal Patent Court – upholding a patent can still leave doubts, for example if the Federal Patent Court failed to address a relevant legal

<sup>6</sup> OLG Düsseldorf 29.05.2008 – Olanzapine decision; Court of Appeals Düsseldorf Mitt. 96, 87; Court of Appeals Frankfurt, GRUR-RR 2003, 263.

<sup>7</sup> District Court Düsseldorf 15.04.2005, InstGE 5,231,233.

question or if conflicting decisions existed to parallel intellectual property rights, for example a branched off German utility model<sup>8</sup>. Other courts have handed down similar decisions.

It seems to be unique, however, that a court replaces a first instance decision declaring a patent invalid by its own prognosis to the contrary as the Court of Appeals of Düsseldorf chose to do in the Olanzapine decision, especially in a preliminary injunction proceeding. Simple logical considerations underscore just how unique this decision is: Since a preliminary injunction is granted only if there is no reasonable doubt with respect to validity, one is more apt to conclude that a decision **upholding** a patent still leaves some doubts than that a decision invalidating a patent is so clearly wrong that no reasonable doubts as to its validity remain.

### **The Decision of the Appeal Court Düsseldorf to grant a Preliminary Injunction**

The Appeal Court in principle acknowledged the well-established practice that a preliminary injunction requires that the underlying patent is valid and, in general, that this validity has been affirmed at least by one first instance decision in a contentious proceeding such as opposition or nullification proceedings. This in turn would mean that in general a preliminary injunction has to be refused if opposition or nullification proceedings are still pending and rely on prior art which leads to concerns regarding the validity of the underlying protection right. This holds all the more so if the first instance has invalidated the protection right. The Appeal Court emphasizes that as a rule the infringement judge may not disregard the nullification of a patent, even if only in the first instance, since this would be tantamount to a de facto supervision of the

decision of the Federal Patent Court which would be inconsistent with the appellate jurisdiction of the Federal Supreme Court. However, the Düsseldorf Court of Appeal emphasized that, in an **exceptional case**, where the nullification of the patent by the Federal Patent Court is **evidently wrong** in the view of the infringement Court, this court is free to make its own assessment of the validity and consequently would also be free to grant a preliminary injunction. Moreover, the Düsseldorf Court of Appeal pointed out that one must consider that if the underlying patent were to expire in the near future, it would constitute a refusal of rights if the court did not enforce the (wrongly invalidated) patent. In the Olanzapine case, the Appeal Court was convinced that the first instance decision of the Federal Patent Court was wrong and, moreover, that the claimed invention is based on an inventive step.

Specifically, the Appeal Court concluded that the Federal Patent Court applied too many considerations ultimately allowing the skilled person to take the compound Olanzapine from the Chakrabarti art.

The Appeal Court saw the multiple considerations applied by the Patent Court in interpreting the teaching of Chakrabarti as extending far beyond those relevant for the assessment of novelty. In addition, the Appeal Court clearly rejected some of the findings of the Federal Patent Court, in particular, that residues R<sub>1</sub> and R<sub>2</sub> would be freely combinable without losing the desired pharmaceutical activity, and that there would be a structure-function relationship known for the compounds falling under formula I. This, in turn, would mean that predicting the function based on a change of the compound's structure would be possible only by "trial and error". Moreover, contrary to the Federal Patent Court's opinion, the Appeal Court saw the Chakrabarti art as teaching the skilled person that a halogen substitution for R<sub>1</sub> is mandatory in position 7 in order to achieve the desired pharmacological activity. Therefore, the skilled person would have to depart from the teaching of Chakrabarti

<sup>8</sup> District Court Düsseldorf decisions 1996, 51; Court of Appeals Düsseldorf InstGE 8, 122.

in order to arrive at Olanzapine as a useful compound.

Consequently, the Appeal Court rejected the Federal Patent Court's finding that Chakrabarti destroys the novelty of Olanzapine. The Appeal Court was also convinced of the inventive step underlying the claimed invention, in particular, in view of the replacement of the halogen atom in position 7 by hydrogen in Olanzapine. In the court's view, the skilled person would not have expected the observed activity as a result of such a replacement. Moreover, the Appeal Court was of the opinion that several other indications would support the patentability of the Olanzapine patent, *inter alia*, the fact that it took more than ten years from the disclosure of the publication date of Chakrabarti to the priority date of the Olanzapine invention would speak against the obviousness of Olanzapine. Therefore, since the Appeal Court was convinced that the claimed invention, Olanzapine, would be patentable and there were only a few years left before the patent expired, they decided not to wait for a second instance following the invalidation proceedings but rather issued the preliminary injunction.

### **Further Considerations**

The latter consideration is in compliance with the principle that in preliminary injunction cases the interests of both parties have to be balanced. The Düsseldorf Court of Appeals took specific account of the long duration of German invalidity cases, especially in the second instance. In the Court's opinion, it would be unlikely that the Federal Supreme Court would hand down its decision on the appeal of the patent owner before the patent expires. In view of this, denial of the preliminary injunction would be, in the view of the Düsseldorf Court of Appeals, refusal of justice (Rechtsverweigerung).

### **Conclusion**

The Olanzapin case is certainly an exceptional case concerning the

mechanism of preliminary injunctions. One cannot conclude from the decision of the Düsseldorf Court of Appeals that in the future it will be easy, much less the rule, to obtain a preliminary injunction where the validity of the patent is doubtful or has even been denied by a German court or an opposition division. The exceptional character of the case was even emphasized by the judge presiding in the Düsseldorf Court of Appeals decision. On the other hand, the decision is a signal that the patentee must not give up if he feels that there really exists clear and convincing evidence that the decision in an invalidity procedure is wrong. The same is of course true in appropriate cases where the validity of the patent has been confirmed.

Note: an English translation of the Olanzapine decision is available under <http://www.grunecker.de/download/publications/olanzapine.pdf>