

Chemical Selection Inventions in the EPO and in Germany: Continued Divergence in Legal Interpretation

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The 2007 decision of the Federal Patent Court of Germany ("FPC") invalidating the "Lipitor" patent is taken as a departure point for a review of the fundamental differences in how the European Patent Office ("EPO") and the FPC and Federal Supreme Court ("FSC") assess the novelty of chemical compound selection inventions. The article highlights EPO and German decisions pertaining to the novelty of specific chemical compounds (e.g. enantiomers) falling within but not individually described in a broader prior art disclosure (e.g. a racemate or a Markush formula).

This divergence in opinion in the EPO and Germany is largely due to differences in how the skilled person is assumed to interpret the prior art. Germany and the EPO each require that a substance disclosed in a prior art document can actually be made in order to be novelty-destroying. They also each interpret the content of a prior art document as extending beyond its literal disclosure, including what the skilled person takes from this disclosure. In chemical selection inventions, however, the German skilled person takes more from the prior art than his European counterpart. Consequently, the same prior art document may be seen to disclose more information in Germany than in Europe; a claim deemed novel in the EPO may lack novelty in Germany in view of the same prior art. A need for legal harmonization between EPC contracting states and the EPO has been acknowledged, but highest instance German case law has supported the German courts' deviation from the EPO's rulings, even given identical facts. Appreciating the differences in European and German views of novelty with regard to chemical compound selection inventions is crucial to developing successful strategies in enforcing as well as invalidating such inventions in Germany. In some cases these differences may be advantageously exploited.

Introduction

In fall 2007 the Federal Patent Court of

Germany ("FPC") handed down its decision 3 Ni 36/05 (EU)¹, invalidating the German part of Pfizer's European Patent EP 409 281 B1. The patent related to the active agent of Pfizer's anti-cholesterol drug Lipitor®² (for simplicity the case will be referred to in the following simply as the "*Lipitor* case", "the *Lipitor* decision" or "*Lipitor*"). The product claim of this patent was directed to the hemicalcium salt of a specific R(R*R*) enantiomer and was found to lack novelty in view of prior art describing the corresponding racemate. Although the claim had been found to be novel in Examining Proceedings as well as in Appeal before the European Patent Office ("EPO"), the FPC later denied the novelty of the claim in view of the same prior art.

The FPC decision is one of several illustrating the divergent evolution of substantive patent law in regional (EPO) and German jurisdictions with regard to chemical selection inventions. This article sketches this legal divergence as recently exemplified in the *Lipitor* case. While the holding of this decision is not groundbreaking in itself, the decision is interesting for certain statements which directly address the lack of harmonization between the EPO and the courts of contracting states to the European Patent Convention ("EPC"). We discuss these

1 Available in German at:
<http://juris.bundespatentgericht.de>

2 <http://www.lipitor.com/>

statements in the context of relevant German case law, and suggest general strategic responses to the lack of harmonization between the EPO and German courts in the interpretation of chemical selection inventions. The present article does not present an exhaustive account of all relevant regional and national decisions on this topic. Rather, the discussion will be limited to those decisions which illustrate the dominant trends which have evolved in the EPO and in Germany for selection inventions relating to chemical compounds.

The view in the EPO: "Photographic" interpretation

In the early decision **T12/81**³ ("Diastereomers") the case before the Board concerned a claim directed to a particular (threo) diastereomer of a compound described by a chemical formula, in which the claimed diastereomer was not defined by absolute configuration at each of the chiral centers but rather by a melting point range. The prior art disclosed a specific method, the inevitable product of which included the compound claimed. The applicant-appellant had argued that the claimed compound represented the result of a selection from one of over 20 disclosed starting materials and one of 5 alternative starting substances.

The Board denied the novelty of the claimed compound in T12/81, stating that

[t]he teaching of a cited document is not confined to the detailed information given in the examples of how the invention is carried out but embraces any information in the claims and description enabling a person skilled in the art to carry out the invention.

In the Board's view, it was crucial that the prior art document disclosed a process of manufacture resulting in the claimed compound, i.e. disclosed the claimed product, even if this disclosure represented the result of making a selection from numerous alternatives. The Board stated in this regard:

The concept of substance selection pre-supposes the choosing of a single compound or a specific sub-group from a group of substances. Thus the felicitous choice of the claimed threo compound from among the multiplicity of substances covered by Formula 1 in the cited document would, of course, be a genuine selection if the cited document did not supply any further information. The compound or sub-group chosen must, of course, also be new; but that is not the case here, as shown under 7 and 8 above [where the method of the prior art was shown to lead to the claimed compound]. ... A substance selection can come about in various ways, e.g. if an unmentioned compound or group of compounds having a formula covered by the state of the art is found, in the absence of any information as to the starting substance or substances. The present subject-matter does not involve a selection of that kind in an area which, although marked out by the state of the art, is nonetheless virgin territory. (underlining added for emphasis)

The simple fact that a claimed compound represents one of many possible compounds encompassed in the disclosure of the prior art thus cannot itself justify the novelty of a selection invention. If the prior art discloses a path to the claimed compound (i.e. specific starting materials fed into a specific method), this compound, though a selection out of many, will lack novelty. The converse constitutes the core

³ Available in English at: <http://legal.european-patent-office.org/dg3/biblio/t810012ep1.htm>

view of selection invention novelty established in this decision and still generally applied in the EPO: A specifically claimed compound falling within a broad structural formula of the prior art will be novel in the absence of specific information in the prior art relating to the claimed compound. At the same time, the disclosure of a process described specifically by reference to the starting materials and the working method includes the product which would inevitably result from this method.

The principles of T12/81 were applied in the later decision **T181/82**⁴ ("spiro-compounds"). Here, the Board had to determine what compounds were actually disclosed in a prior art describing "C1-C4 alkyl bromides". The Board saw this disclosure as conceptually encompassing methyl, ethyl, n-propyl, isopropyl, n-butyl, isobutyl (two forms) and tert-butyl forms thereof: a total of eight alkyl bromides.

It cannot be denied the eight conceivable alkyl bromides are covered by all these definitions; a strict distinction must be drawn between this purely intellectual content of the definitions and their information content in the sense of a specific teaching with regard to technical action.

Applying this distinction, the Board saw only the methyl (C1) and the family of four possible butyl (C4) substituents as specifically mentioned. Of these five alkyl moieties, only methyl bromide was individualized as a specific compound. Accordingly, "C1-C4 alkyl bromides" specifically disclosed only methyl bromide, since methyl is synonymous with "C1". The Board thus applied a "photographic" understanding of novelty in which the prior art disclosed (only) those compounds which are described as individualized entities.

4 Available in English at: <http://legal.european-patent-office.org/dg3/biblio/t820181ep1.htm>

In decision **T12/90**⁵ ("E-Enantiomers of N-alpha-(2-cyan-2-alkoximino-acetyl) amino acid derivatives and peptides") the case before the Board concerned a claim directed to a chemical substance defined by a generic formula. The Examining Division had rejected this claim in view of prior art disclosing a broader generic formula encompassing the claim. In the view of the Examining Division, this overlap prejudiced the claimed subject matter, even though the prior art lacked an individualized disclosure of specific compounds falling within and not removed by disclaimer in the claim. In the Board's view, the prior art highlighted certain preferred substituent combinations falling within the claimed range which precluded a selection invention:

*A selection from a known collective which justifies novelty ... requires it adds a new element to what is already known and thus contains a new teaching for technical activity. Simply copying of what is already known does not lead to a new technical teaching and does not enrich technology.*⁶

Regarding the question of what constitutes an individualization, the Board further stated:

... the concept of "individualization" only fits the notion of a structural definition of a single compound, but not that of a collective; according to the case law of the Board, a collective defined by general formula does not disclose the individual entities it encompasses.

In the end, the Board denied the novelty of the claimed general formula in view of the overlap with the broader general formula of

5 Available in German at: <http://legal.european-patent-office.org/dg3/biblio/t900012du1.htm>

6 All translations of passages from decisions are the authors' own unless indicated otherwise.

the prior art. However, in doing so, the Board distinguished between the disclosure of the broad general formula and that of preferred substituent combinations in the description of the prior art. In standing with the decisions already discussed above, the Board confirmed that a broad general formula does not disclose individualized structures. In the Board's view, however, preferred substituent combinations provided outside of the general formula represent an individualized disclosure which prejudices the novelty of the claim in total.

The above views were applied further in later decisions, all handed down by the same Technical Board of Appeal (3.3.1). In **T296/87**⁷ ("Enantiomers") the claim was drawn to the D-enantiomer of a known corresponding racemate. The difference between the claim and the prior art was that the claim recited the D-enantiomer, whereas the prior art made no mention of the enantiomers at all. In the Board's opinion, a chemical substance will be novel if it differs from a known substance in a reliable parameter. The stereochemical configuration is one such parameter, and this parameter must be disclosed in an individualized manner in the prior art to prejudice the novelty of a claim reciting a specific stereochemical configuration. From the reasons to the decision:

Given the asymmetrical carbon atom in the formula, the substances in question can indeed occur in many conceivable configurations (D- and L-enantiomers); that alone does not mean, however, that these configurations are disclosed in individualised form. The novelty of the D- and L-enantiomers is therefore not destroyed by the description of the racemates. ... The situation is different if the state of the art includes enantiomers - however designated (D,

d, L, l or + or -) - which are specifically named and can be produced [as set out in i.a. T12/81]. ... In taking this view the Board is aware that the two enantiomers, far from falling merely intellectually within the definition of the structure in question, actually exist unseparated in the racemate. Generally, the latter can also be separated by converting the enantiomers into a mixture of diastereomers, e.g. using optically active substances, then resolving the mixture and recovering the enantiomers from the resulting products. These considerations are immaterial to the question of novelty, however, and will be more usefully applied to the examination as to inventive step. (underlining added)

In other words, even though the skilled person could have separated the racemate into its constituent enantiomers using his general knowledge, the claimed enantiomer was still novel in view of the prediscovered racemate.

In the decision **T1048/92**⁸ ("Penem Derivatives") the claim was directed to a compound defined by absolute stereochemical configuration. The prior art encompassed two possible stereoisomers, one of which was the claimed compound, but did not mention the absolute configuration of the claimed compound. It did, however, mention "various optically active isomers" of the compounds as embraced by the invention. In rejecting the application leading to the appeal, the Examining Division had maintained that the prior art implicitly disclosed the compound claimed with absolute stereochemical configuration. Applying the concepts developed in its previous decisions, the Board overruled the Examining Division, stating that

7 Available in English at: <http://legal.european-patent-office.org/dg3/biblio/t870296ep1.htm>

8 Available in English at: <http://legal.european-patent-office.org/dg3/biblio/t921048eu1.htm>

... the novelty of such an individual chemical configuration can only be denied if there is an unambiguous disclosure of this very configuration in the form of a technical teaching It is thus not sufficient that the configuration in question belongs conceptually to a disclosed class of possible configurations, without any pointer to the individual member. ... The fact that the disclosure of [the prior art] does not embrace more than two possible steric configurations does not take away the novelty of the specific one which is claimed in the present application, because there is no unambiguous technical teaching directed to that configuration in the parts of [the prior art] relied upon by the Examining Division. (brackets serve merely to increase readability by removing references to specific documents mentioned in the decision)

This Board's holding in T1048/92 is especially noteworthy since the claimed stereoisomer represented one of only two possible stereoisomers encompassed by the disclosure of the prior art. The recognition of novelty of a single compound representing one of multiple compounds belonging to, but not individualized in a broader prior disclosure, thus cannot depend on the number of compounds from which the claimed compound is selected.

Similar circumstances existed in the decision **T1046/97**⁹ ("Enantiomer"). Here, the Examining Division had rejected a claim to a specific stereoisomer as lacking novelty in view of prior art disclosing the same compound without mention of any specific stereochemistry. Specifically, the Examining Division had been of the opinion that the prior art disclosed a mixture of enantiomers and the skilled person's general knowledge would allow him to separate this mixture into

its constituent enantiomers. In standing with its previous decisions in similar cases, the Board ruled that

... the novelty of an individual chemical compound can only be denied if there is a direct and unambiguous disclosure of this very compound in the form of a technical teaching It is thus not sufficient for denying novelty in the present case that the claimed enantiomer of formula ((+)-I) belongs conceptually to the group of possible optically-active forms mentioned in document (B) unless there is a pointer to the individual member of the group at stake, ie the specific (+)-enantiomer. ... In [the prior art] the term "optically-active forms" provides thus no information about any specific stereochemical form(s) of the chemical compound disclosed [there]. In other words, from a stereochemical point of view, the disclosure in [the prior art] must be regarded as undifferentiated, with the effect that the said term cannot be equated to an individualised disclosure of a specific enantiomer.

In summary, consistent jurisprudence of the EPO has held that a claimed chemical compound representing one species from within a broader predisclosed genus constitutes a chemical selection invention. As long as the prior art does not contain an individualized disclosure of the compound and does not disclose a particular method entailing specific starting materials which would inevitably lead to the claimed compound, such a chemical selection will be novel over the prior art. This approach is often referred to in the relevant literature as "photographic" in nature, since it is based on a literal (the FPC may say slavish) interpretation of the prior art. According to this interpretation, the skilled person's understanding of the prior art is limited to what is literally individualized, either by

⁹ Available in English at: <http://legal.european-patent-office.org/dg3/biblio/t971046eu1.htm>

name, formula or by a specific method of manufacture. The skilled person does not extend this literal individualization by applying his common general knowledge.

The Lipitor Decision and chemical selection inventions in Germany: The skilled person's view is broader than in the EPO

The case before the German FPC in the Lipitor case was similar to those facing the EPO Board above. The main claim in suit¹⁰ was directed to the hemicalcium salt of a specific enantiomer while the prior art disclosed the sodium salt of the corresponding racemate. By the standards of the EPO, the claimed compound should have been deemed novel for two reasons. First, the hemicalcium counterion recited in the claim was different than the sodium counterion disclosed in the prior art. Second, the claim specifically recited the R(R*R*) enantiomer, where the prior art disclosed only the racemate. Only this second aspect is relevant to the present discussion of chemical selection inventions. The following discussion thus ignores any considerations of the first aspect relating to the type of hemicalcium salt.

In fact, after initial rejection by the Examining Division the *Lipitor* case had gone to appeal in the EPO (T229/97¹¹) before the same appeal board (3.3.1) responsible for the EPO decisions discussed above. The appeal was directed against the Examining Division's rejection based on lack of inventive step, meaning that the Examining Division had already found the claimed subject matter novel. This finding was confirmed by the Board in T229/97, where it stated:

10 The claim as granted and later invalidated reads:
"The hemicalcium salt of [R-(R*,R*)]-2-(4-Fluorophenyl)-β,δ-dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)-carbonyl]-1H-pyrrole-1-heptanoic acid."

11 Available in English at: <http://legal.european-patent-office.org/dg3/biblio/t970229eu1.htm>

The Board is also satisfied that the subject-matter of the claims ... meets the requirements of Article 54 EPC¹² as already acknowledged by the Examining Division, since [the prior art] specifically discloses only a salt of the corresponding racemate using a different cation.

Given this confirmation of novelty in two separate instances before the EPO, why did the FPC invalidate the German part of the same patent in view of the same prior art? What different standard did the FPC apply to the assessment of novelty? The answer to this question goes to the heart of the difference in European and German standards for novelty of chemical selection inventions.

The FPC's statements in item II.1.a of the Reasons for the Decision explain why the FPC decided as it did in *Lipitor*:

*It is true that the hemicalcium salt of the R(R*R*)-enantiomer according to claim 1 of the patent in suit has not been prepared in the examples of the [cited prior art], nor is it named as a single compound in these documents. However, according to the jurisprudence of the Federal Supreme Court ... , the disclosure of a document belonging to the prior art is not restricted to the literal disclosure, but encompasses everything which the skilled person supplements in a self-evident or a nearly essential manner or which he directly recognizes in a careful study of the document and reads in his thoughts ("in Gedanken mitlesen"). These principles, which refer to the disclosure content of a prior publication in the field of mechanics are applicable in the field of product chemistry, provided that the novelty of*

12 Art. 54 EPC is the provision of the EPC governing novelty.

a chemical compound is to be viewed as prejudiced when a prior publication or a document with earlier priority date conveys to the skilled person a concrete indication to the compound in question, that is that the skilled person automatically reads this compound in his thoughts and, as a result of this indication, is directly put in the position of laying his hands on the compound in question. It is not necessary that the compound has actually already been prepared. The mere possibility of its preparation and, thus, of its being made available suffices [reference to specific decisions].

In the case of a stereoisomer to be assessed here, the particularity resides in the fact that compounds with one or more asymmetric carbon atoms – in contrast to natural products in biosynthesis – normally occur as a mixture of their stereoisomers with a higher or lower proportion of the individual isomers. The individual stereoisomers are thus already present in the reaction product. In the case that a prior art document discloses the preparation of a chemical compound with one or more asymmetric carbon atoms via a non-stereospecific reaction, the skilled reader immediately recognizes this circumstance without requiring a further indication, let alone an explicit mention of individual stereoisomers. The novelty of a stereoisomer (epimer, entantiomer, diastereomer) is thus already to be denied when the skilled reader clearly recognizes that it [the stereoisomer] is recognizably disclosed in the form of a mixture of its stereoisomers and is accessible to him from this mixture by routine measures using conventional separation methods. ... It is not necessary to indicate or explicitly name the relevant stereoisomer, nor is it necessary to

provide or describe a method for its isolation (underlining added for emphasis)

Both the EPO (see e.g. T12/81, above) and the FPC (see e.g. the *Lipitor* decision, above) interpret the disclosure of a prior art document as extending beyond its literal disclosure. Further, both the EPO and the FPC invoke the view of the skilled person in determining the extent of this disclosure. **However, where the EPO in most cases assumes that the skilled person's understanding is limited to a "photographic" reading the document's concrete technical disclosure, the FPC allows the skilled person more interpretative latitude to extrapolate a document's literal disclosure using his own general knowledge. This essentially broadens this disclosure of a prior art document in Germany for the purposes of assessing novelty.**

This distinction is crucial and warrants reiteration: In determining the content of the prior art when assessing the novelty of a chemical selection invention, the EPO effectively asks "What does the prior art literally and individually disclose?". The FPC asks this question too but goes a step further, extending the disclosure to embodiments that are not literally mentioned. The difference between the interpretation of prior art for the purpose of chemical selection inventions in the EPO and Germany thus comes down to the difference in how the skilled person is viewed and how far he is assumed to extrapolate literal content, with the skilled person in Germany "thinking further" than in the EPO. This is the reason that the same prior art as deemed non-prejudicial in the EPO may encompass novelty-destroying embodiments to the same claim in Germany.

Historical Development in Germany

The reasons for this difference may be largely historical. The German Patent Act ("GPA") in its present form took effect in 1981. The previous GPA was effective from 1968. One refers to "old law" meaning GPA of 1968 or "new law" meaning GPA of 1981. The provision governing novelty differs significantly between the old and new laws. Whereas the pertinent part of the section of the 1981 GPA relating to novelty matches that in the EPC¹³, Section 2(1) of the 1968 GPA (also governing novelty) incorporated the view of the skilled person *expressis verbis*, stating that an invention is deemed to lack novelty if, at the time of application, it has been described in published works of the previous one hundred years in such a way that its use appears possible to other persons skilled in the art¹⁴. The earlier legal requirement for novelty under the GPA thus took explicit account of the skilled person's reading of the prior art. The central article of the EPC governing novelty is completely silent with regard to the skilled person.

In view of these statutory differences, case law in Germany relating to the novelty of chemical selection inventions had already begun to develop with an emphasis on the skilled person's view before the EPC came into force. Further, many cases handed

down by German courts after the EPC came into force still related to older German patents for which the GPA of 1968 remained binding. By the time German courts were required to assess the novelty of chemical subject matter for the German parts of patents granted under the EPC, the skilled person's interpretation of the prior art for the purposes of novelty was already well engrained in German national jurisprudence. The German courts could not well depart from this view without contradicting the fundamental holdings of earlier highest-instance decisions and giving an impression of capriciousness which must be avoided in any constitutional state.

The development of the interpretation of novelty in Germany is illustrated below with a selection of relevant decisions.

In the 1972 decision "*Cholinsalicylat*" ("*Choline Salicylate*")¹⁵ handed down by the German Federal Supreme Court ("FSC"), the claim in suit was directed in pertinent part to a method of preparing "crystalline choline salicylate". The prior art (a British patent) disclosed the preparation of various choline salts as well as their isolation and characterization in solid crystalline form. However, the prior art did not explicitly disclose choline salicylate as a solid crystalline substance. The issue before the FSC therefore turned on the question of whether or not a prior art document which stopped short of explicitly describing the claimed subject matter was prejudicial to novelty. The FSC ruled:

[The prior art lacks] indications as to the preparation of crystalline choline salicylate. Nevertheless, this cannot form the basis of novelty of the teaching of the patent in suit, as this is contained in the British patent document to such an extent that the skilled person endowed with the

13 Both § 3(1) S.1 GPA-1981 and Art.54(1) EPC read, in German: "*Eine Erfindung gilt als neu, wenn sie nicht zum Stand der Technik gehört*". The corresponding English version of the EPC reads: "*An invention shall be considered new if it does not form part of the state of the art.*"

14 § 2(1) S.1 GPA 1968 reads: "*Eine Erfindung gilt nicht als neu, wenn sie zur Zeit der Anmeldung ... in öffentlichen Druckschriften aus den letzten hundert Jahren bereits derart beschrieben oder im Inland bereits so offenkundig benutzt ist, dass danach die Benutzung durch andere Sachverständige möglich erscheint.*" ("*An invention shall not be deemed novel if, at the time of the application, it is already described in public documents from the last hundred years or is already used domestically in such an evident manner that the use by other technical experts subsequently appears possible.*")

15 FSC 27 Jun 1972 Case No. X ZR 75/68. Available in German in GRUR 1974 (6), 332

general specialty knowledge at the time of the application could extract the teaching of the patent in suit from it [the prior art] alone without contributing anything of his own, meaning implicitly (without thinking about it). ... The lack of the literal and formal indication as well as the description of the choline salicylate in the cited British patent document did not prevent the skilled person from supplementing these indications ...

In this decision, the FSC went so far as to generalize this finding as the headnote of the decision:

The teaching of the patent in suit lacks novelty if, although not completely, it is still previously described to such a extent that the skilled person can implicitly extract it from the previous publication.

The "choline salicylate" decision thus clarified the fundamental principle that the disclosure of a prior art document is not limited to, but rather can extend beyond what the document in question explicitly discloses, and further that the amount of extension depends on the view of the skilled person reading the prior art in question.

The FSC later ruled in its 1978 decision " α -Aminobenzylpenicillin"¹⁶ that

[a] chemical compound is no longer novel if it is identified in a previous publication as a chemical individual and the skilled person was able to prepare it. It is irrelevant whether or not the compound has actually already been made.

The ability to prepare the compound in question indicates the basic criterium that a novelty-destroying disclosure must be

enabling. In principle, the EPO shares this view, but differs from the FSC in its assumption of the amount of information the skilled person requires in order to arrive at an individual chemical compound. In the FSC's view, the skilled person can draw more on his own speciality knowledge than the skilled person in the EPO, thus taking more from (and thus requiring less specific disclosure in) the prior art to arrive at the claimed chemical compound. Conversely, the skilled person in the EPO, who is not assumed to draw on his own knowledge to such a large extent as the German skilled person, requires a more literal disclosure to reach the same result.

In the FSC decision "*Flouran*" ("*Fluorane*")¹⁷, the question of novelty for a claimed chemical compound turned on the question of whether it is enough to prejudice the novelty of a claimed compound if this compound falls within the scope of a predisclosed general formula without being mentioned as such in the prior art. In section II.3.a of the reasons for the decision the FSC stated:

Thus, if a chemical compound has been described in a previous publication in such a way that a person skilled in the art could produce it on the basis of his general knowledge of the field, then the invention has been described in the previous publication. (IIC translation)

While the FSC then refers to the previously mentioned decision α -Aminobenzylpenicillin, it also generalizes its ruling in the headnote of *Fluorane* as follows, making it clear that the sole factor determining whether or not a prior art document discloses a particular compound is whether or not the skilled person could prepare it based on the document in question:

¹⁶ FSC 30 May 1978 Case No. X ZR 16/76. Available in German in GRUR 1978 (12), 696

¹⁷ FSC 26 Jan 1988 Case No. X ZB 18/86. Available in German (full text) in GRUR 1988 (6), 447; and in English (abridged form) in IIC 1989 (5), 736

The fact that a chemical compound falls within a previously published formula, of itself says nothing about the question of novelty. The only decisive factor is whether the information contained in a previous publication concerning a chemical compound can alone enable a person skilled in the art to perform the invention related to this chemical compound, i.e. to produce the substance in question. (IIC translation; underlining added)

Clearly, the question of whether or not the skilled person is able to prepare a compound based on a given teaching depends on the abilities of the skilled person himself. In allowing the skilled person to interpret into the disclosure of a prior art document, the FSC's standard effectively creates an area of ambiguity in what a prior art document discloses. The magnitude of this ambiguity depends on the extent of the specialty knowledge the skilled person is assumed to apply. The greater the knowledge the skilled person is assumed to have and apply when reading a given prior art disclosure, the more he will take from this disclosure, and the less literal this disclosure needs to be in order to prejudice a given claimed compound.

In the 1995 landmark FSC decision "*Elektrische Steckverbindung*" ("*Electrical plug-in Connector*")¹⁸ the FPC had based its ruling of lacking novelty on an interpretation of the prior art disclosure based on the view of the skilled person. The facts in this case are noteworthy in that the applicable law for the patent in suit was the "new" GPA of 1981. The FSC was thus effectively called upon to decide which standard should be applied in determining the disclosure of a prior art document for the purposes of novelty under the "new law". Should the interpretation be based on the principles

¹⁸ FSC 17 Jan 1995 Case No. X ZB 15/93. Available in German in GRUR 1995 (5), 330

already developed under the "old law" according to the GPA of 1968 (entailing a reliance on the skilled person's understand to "fill gaps" in the prior art disclosure), or something more akin to the "photographic" approach commonly applied in the EPO?

The FSC first summarized relevant aspects of the FPC's statements in the first instance, where the FPC emphasized the question of whether the language of the novelty provision in the GPA of 1981 should imply a departure from the novelty standard already developed under the "old" GPA of 1981:

The subject matter of claim 1 of the main request is not identically described in the sense of a "photographic conception of novelty". However, it emerges for the skilled person, whose understanding continues to be relevant even after the statutory introduction of "extended absolute conception of novel" [this refers to the new definition of novelty under the GPA of 1981, as discussed above] without having to think about it based on his specialty knowledge and his professional experience from the content of [the prior art]. ... Even if § 3(1) S.2 GPA 1981, in contrast to § 2(1) GPA 1968, no longer mentions the skilled person as the relevant reference person for the understanding of what knowledge has been made available to the public, it cannot be concluded from this that he is no longer relevant for the interpretation of the prior art and that the "public" should take his place.

In its own reasons for the decision, the FSC upheld the FPC's view as expressed above, reasoning as follows:

The legal appeal [i.e. the FSC instance here] concurs with the view of the FPC to continue to base the definition of novelty according to § 3(1)

S.1 GPA 1981 on the knowledge of the skilled person. [The legal appeal] allows that it cannot be decisive to base this view on the cognition possibilities of an uninformed and incompetent public.

... The FPC ... correctly ascribes no importance to the circumstance that § 3(1) S.2 GPA 1981 no longer mentions the skilled person as the carrier of relevant knowledge. One might first think that room should be made for another evaluation with regard to the assessment of novelty, since § 2(1) GPA 1968 deems "the use by other technical experts" relevant with regard to novelty, and § 3(1) S.2 GPA 1981 no longer mentions this "technical expert", i.e. the skilled person. This is not the case, as a comparison of § 2(1) GPA 1968 with § 3(1) S.2 GPA 1981 indicates. Both regulations are based in relevant part on the fact that the knowledge must be available to the public. From this it follows that that internal processes which have not become public do not prejudice the novelty of an invention. In mentioning "use by other technical experts" § 2(1) GPA 1968 recognizably pursued the aim of more clearly limiting when knowledge had become available or was (still) internal. Accordingly, the "use by technical experts" was not to be understood as meaning anything independent of or different than the "public".

It is thus obvious to base the measure of what has been made available to the "public" on the skilled person according § 3(1) S.2 GPA 1981 as well. ... The knowledge which has been made available to the public may only convincingly be determined in standing with the principles of a constitutional state if the "public" and

its understanding of the technical interrelationships is defined. Every disclosure is directed to a certain circle of addressees and is tailored to its needs and technical understanding. It need be understandable for this circle – and only this circle – and should be limited on the other hand to what is necessary for "those involved" to understand.

The FSC thus adhered to its previously developed principles in determining the content of a prior art document for the purposes of novelty, even though the novelty provision of the "new law" (equivalent to that in the EPC) lacks an explicit reference to the skilled person. For the purposes of novelty under the new GPA 1981 (equivalent in wording to the novelty provision of the EPC), the skilled person's knowledge should thus be factored into the question of what he will take from a prior art document and, thus, what the prior art document discloses for the purposes of novelty.

The later FPC decision of the same year, "*Herbizid wirksames Enantiomer*"¹⁹ ("*Herbicideally effective enantiomer*") continued in the same vein, explicitly referring to the previously discussed FSC decision *Electrical plug-in Connector*, and even making an *expressis verbis* break with corresponding EPO jurisprudence. Similar to the facts in certain of the EPO decisions discussed above, as well as the recent *Lipitor* decision from which our discussion started, in *Herbicideally effective enantiomer* the FPC had to determine whether the novelty of a claim directed to a specific enantiomer of a compound was prejudiced by prior art disclosing this compound as the racemate, and explicitly stating that

... the present invention also includes the individual stereoisomers of such

19 FSC 14 Sept 1995 Case No. 3 Ni 26/94 (EU). Available in German in GRUR Int. 1996 (7), 822

compounds, and mixtures of these stereoisomers in addition to the racemic mixture of stereoisomers.

In its reasons for the decision, the FPC explicitly mentioned past decisions of the EPO in cases with similar fact patterns, openly dissenting the holdings of the EPO Board of Appeal in these cases:

The Senate cannot accede to the view of the EPO Boards of Appeal [T12/81, T7/86, T12/90] that, as a rule, the specific compound is not encompassed by the disclosure of the structural formula under which it falls, at least not in this generality.

The EPO decision T12/81 has been discussed above. The FPC ruled that the description of the prior art was enough to disclose the only two conceivable enantiomers of the D- and L-form, and referred to the EPO T658/91²⁰ ("Enantiomère") in support of its opinion. This decision is admittedly a curious exception²¹ in light of the EPO's other case law relating to chemical product selections, especially since it is from the same appeal board (3.3.1) presiding in all other EPO decisions discussed above. Not only did the FPC clearly see itself free to interpret the novelty of an enantiomeric selection invention in the German part of a European

20 Available in French at: <http://legal.european-patent-office.org/dg3/biblio/t910658fu1.htm>

21 Even though the Appeal Board presiding in T658/91 was the same as in the other EPO decisions discussed hereinabove, and the facts were very similar to those of certain other cases discussed here (question of novelty of a specific enantiomer in view of prior art disclosing the corresponding racemate and specifically mentioning possible enantiomers), the Board ruled in T658/91 that the prior art disclosed the specific enantiomer in a non-equivocal manner. In the view of the board, the prior art put the skilled person in the position of preparing the specific enantiomer in question, thus destroying the novelty of a claim directed to the specific enantiomer. In the Board's opinion, the disclosure of the specific enantiomer in the prior was not "purely conceptual" in nature.

Patent differently than the preponderance of EPO decisions on similar topics; it even openly stated that it believes the EPO's view to be incorrect in its generality.

In summary, the *Lipitor* decision serving as the starting point for the present discussion illustrates the logical outcome of a long legal development in Germany. Due to the language of the relevant novelty provision under former German patent law, the flexible view of the skilled person has traditionally been accorded more weight, and thus the disclosure of a prior art document has been more open to interpretation, than has been or is the case in the EPO.

Legal Harmonization

But can such a situation exist? That is, must an applicant who has been granted a selection invention relating to a chemical product in the EPO expect that his patent may be ruled invalid in Germany in view of the same prior art as already considered in the EPO? The simple, if unsatisfactory answer to both of these questions is: Yes.

As mentioned above, the *Lipitor* decision is noteworthy in that it directly addresses the question of legal harmonization at EP-regional and German-national levels. The defendant in the *Lipitor* case had previously asserted that the EPC contracting states are obliged to harmonize their case law with regard to the assessment of patentability, and that it would be improper for a contracting state to deviate from the recognition of novelty already determined by an EPO Board of Appeal as well as in a legal opinion prepared by the EPO under Art. 25 EPC²² (such a legal opinion had

22 Art. 25 EPC reads: "At the request of the competent national court trying an infringement or revocation action, the European Patent Office shall be obliged ... to give a technical opinion concerning the European patent which is the subject of the action. The Examining Division shall be responsible for the issue of such opinions."

previously been prepared in the *Lipitor* case at the request of a Spanish court, and the EPO had found the subject matter novel). The FPC responded to this in *Lipitor* as follows:

The Senate cannot follow the view of the defendant that, in the interest of necessary harmonization of national and European patent law by as uniform an application of the law as possible (see also FSC GRUR 1987, 231, 233 – Rabies Virus), the patentability of the patent in suit may not be interpreted in a manner deviating from the decision of the Board of Appeal dated 20 July 2000 and the opinion of the Examining Division dated 19 October 2006. While the FSC has stressed the obligation, ... binding rules of interpretation for novelty and inventive step do not exist, despite the diverging practices of assessing these matters known to exist in the individual contracting states. It also cannot be determined that any one application of law consistent with that of the European Patent Office regarding the presently relevant question of novelty has been developed in the majority of the contracting states to the European Patent Convention, [to be applied under the Vienna Convention of 1969]. (underlining added)

The FPC thus acknowledges the theoretical need for an obligation to ensure harmony among EPC contracting states with regard to the legal interpretation applied in the EPO. The FPC even cites the FSC decision "*Tollwutvirus*"²³ ("*Rabies Virus*"), in which the FSC stated:

Since the alignment of national and European provisions of material patent law should be as consistent as

²³ FSC 12 Feb 1987 Case No. X ZB 4/86. Available in German in GRUR 1987(4), 231

possible in creating patent law, one must pay attention to interpret as uniformly as possible at the national and international levels.

Be this as it may, the FPC ultimately took the position in *Lipitor* that, in the absence of binding guidelines prescribing a particular legal interpretation of novelty (for example those set out in the Protocol to Art. 69 EPC²⁴), there remains no other option but to interpret in standing with national case law already developed for the novelty of compound selection inventions. Indeed, despite the FSC's general statement in *Rabies Virus*, the view of the FPC in the *Lipitor* decision is in standing with the holding of the FSC in another decision. The headnote of the FSC decision "*Zahnkranzfräser*"²⁵ ("*Gear rim cutter*") states:

A declaration of nullity can also be issued with respect to a European patent (solely) on the grounds of a state of the art that has already been taken into consideration in the opposition or opposition appeal proceedings before the European Patent Office concerning the same patent. (IIC translation)

However desirable or necessary legal harmonization of national and international interpretations of material patent law may be, the FSC thus provided the FPC with free license to decide as they see fit applying national considerations. The FPC is in no

²⁴ Art. 69 EPC governs the extent of protection of a European patent. Art. 69(1) EPC reads: "*The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.*" The corresponding Protocol on the Interpretation of Art. 69 EPC is an integral part of the EPC setting down binding guidelines as to how the extent of protection is to be determined.

²⁵ FSC 04 May 1995 Case No. X ZR 29/93. Available in German in GRUR 1996(10), 757 and (in abridged form) in English in IIC 1997(2), 235

way bound by a first or even second instance decision of the EPO in the same case considering identical facts.

The relevant literature contains numerous opinions on the need for harmonization of patent law practice between the EPC contracting states and the EPO. Of particular interest for its succinct treatment and specific suggestions presented is the recent contribution to IIC by Tilmann²⁶. This article was also cited by the defendant in support of its arguments in the *Lipitor* case, to no avail.

Consequences and Strategies

Appreciating in advance that the rulings of the FPC as to the validity of chemical compound selection inventions of European patents may in some cases be at odds with the legal practice applied by the EPO can be of great help in developing realistic strategies for both patentees (infringement plaintiffs/invalidity defendants) as well as infringement defendants/invalidity plaintiffs.

From the viewpoint of the patentee of a European patent to a compound selection invention in force in Germany, the would-be infringement plaintiff must expect that any infringement defendant will likely open an invalidity suit with the FPC relating at least to the enforced claims of the relevant patent. If the patentee is already aware during European examination that later enforcement of the patent in Germany is likely, he would do well to critically question the willingness of the EPO to allow claims directed to a chemical product encompassed by but not described in an individualized manner in the prior art. Specifically, he should ask himself whether it would be possible for a skilled person who "sees further" would be able to use his

knowledge to lay hands on the claimed product. If so, then it is possible that the FPC may invalidate the claim in Germany based on the same prior art, even though the EPO had previously allowed it. If at all possible, the patentee should actively pursue claims before the EPO conforming to both European and German novelty standards.

Especially in cases with similar fact patterns as in the *Lipitor* case, such a strategy may not be possible without unacceptably surrendering protection for the desired chemical compound altogether. In such cases, depending on the disclosure of the prior art, it may be advisable to pursue corresponding medical use claims which would also be acceptable in Germany, the novelty and inventive step of such claims deriving from the nature of the therapeutic use recited. We have discussed the divergence of European and German practice with regard to the allowability of second medical use claims as well as options for strategically confronting this divergence in a separate contribution²⁷.

From the viewpoint of a would-be invalidity plaintiff who has been or expects to be served with a German infringement suit based on a similar claim as described above, it may be prudent, depending on the timing of events and the cited prior art, to allow the time limit for European opposition to expire without filing opposition, saving arguments for a later invalidity suit in Germany where such arguments would be expected to have a better chance of success. Indeed, in a case with a fact pattern similar to that in the *Lipitor* case, filing opposition using the same prior art as cited in European examination might be expected to have the double disadvantage of failing to achieve the desired revocation

²⁶ See Winfried Tilmann: "The Harmonization of Invalidity and Scope of Protection Practice of the national Courts of the EPO Member States". Available in English in IIC 2006 (1), 62.

²⁷ See Franz-Josef Zimmer & Steven M. Zeman (2007) "Applicant-friendliness of the EPO for second medical use claims: A mixed blessing". *Biotechnology Law Report* 26(4), 341

(due to the EPO's view in assessing the novelty of selection inventions), and delaying possible lodging of an invalidity suit in Germany until after European Opposition Proceedings have been finally terminated²⁸.

Of course, the timing of events may not always allow such freedom of decision.

For example, in a first scenario, it is possible that another party than the would-be infringement defendant opposes the patent in question. Here, the only option for this defendant may be to wait until Opposition Proceedings in the EPO are terminated, possibly contributing to these proceedings as a third party observer²⁹ (even anonymously).

In a second possible scenario, the infringement action may be tactically served so as to restrict the defendant's ability to respond. Here, the infringement defendant may intervene³⁰ in ongoing opposition proceedings and, if the opposition is unsuccessful in revoking the patent, prepare an invalidity suit based on German national

standards for the prior art as discussed above. Sometimes, just a draft in itself can be inducement enough to force the patentee to the negotiation table, and possibly to withdraw any pending infringement action and settle out of court, thus avoiding the potential costs of a lost invalidity suit.

Conclusion

The divergence of the interpretation of the novelty of chemical compound selection inventions in the EPO and Germany is regrettable, and leads to legal uncertainty, but it is nonetheless a reality which has been confirmed by highest level German jurisprudence. Appreciating this reality and understanding the nature of the divergence may allow parties to develop corresponding strategies regardless of which side of the table they are on. As outlined above, certain fact patterns and timings may even allow a party to exploit this divergence to their advantage. At the very least, one should exercise caution when taking a chemical selection invention granted in the EPO to court in Germany.

28 § 81(2) GPA-1981 reads: "The suit for the declaration of invalidity of the patent may not be lodged as long as an opposition may still be lodged, or an opposition proceeding is pending."

29 Art. 115 EPC governs observations by third parties: "*In proceedings before the European Patent Office, following the publication of the European patent application, any third party may, in accordance with the Implementing Regulations, present observations concerning the patentability of the invention to which the application or patent relates. That person shall not be a party to the proceedings.*"

30 Art 105 EPC governs intervention in ongoing Opposition Proceedings by a putative infringer: "*(1) Any third party may, in accordance with the Implementing Regulations, intervene in opposition proceedings after the opposition period has expired, if the third party proves that (a) proceedings for infringement of the same patent have been instituted against him, or (b) following a request of the proprietor of the patent to cease alleged infringement, the third party has instituted proceedings for a ruling that he is not infringing the patent. (2) An admissible intervention shall be treated as an opposition.*"