HOFFMANN EITLE

D17A

Translation of the Judgment of the Higher Regional Court Dusseldorf, as pronounced on 19 February 2016

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I - 2 U 55/15
4c O 62/15
Regional Court Dusseldorf

Pronounced on 19 February 2016
according to the Minutes
Krüger
Court Clerk
as Registrar of the Court Registry

HIGHER REGIONAL COURT DUSSELDORF

IN THE NAME OF THE PEOPLE

JUDGMENT

In the provisional injunction proceedings

AstraZeneca AB, represented by the Vice President Mats Peter Berglund, 15185 Södertälje, Sweden,

Petitioner and **Appellant**,

Attorneys of Record: Attorney at Law Dr. Schüßler-Langeheine, Attorney at Law Dr. Steins and all other attorneys at law of the law firm Hoffmann Eitle, Arabellastrasse 30, 81925 Munich, Germany,

versus

Hexal AG, represented by its Board Members Dr. Andreas Eberhorn, Sandrine Piret-Gérard, Wolfgang Späth, Matthias Weber and Dieter Ziebold, Industriestrasse 2, 83607 Holzkirchen, Germany,

Attorneys of Record: Attorney at Law Tellmann-Schumacher, Attorney at Law Dr. Rißе and all other attorneys at law of the law firm Arnold Ruess, Königsallee 59A, 40215 Dusseldorf, Germany,

Respondent and **Appellee**,

following the Hearing of 19 February 2015 [sic], the Second Civil Panel of the Higher Regional Court Dusseldorf, composed of the Presiding Judge at the Higher Regional Court Dr. Kühnen and the Judges at the Higher Regional Court Fricke and Thomas

held:

I. Upon the appeal, the Judgment of Civil Panel 4c of the Regional Court Dusseldorf pronounced on 19 November 2015 is amended.

Respondent is ordered, by way of a provisional injunction,

1. to cease and desist, in avoidance of a disciplinary fine of up to EUR 250,000 to be determined by the Court for each instance of non-compliance, alternatively thereto detention, with detention to be enforced on the respective Board Members of Respondent,

   a) from evidently preparing in the Federal Republic of Germany by recommending in the patient information leaflet the use in the treatment of breast cancer by intramuscular injection,

   a pharmaceutical formulation comprising fulvestrant, a pharmaceutically acceptable alcohol being a mixture of 10% weight of ethanol per volume of formulation and 10% weight of benzyl alcohol per volume of formulation, and the formulation contains 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a ricinoleate vehicle so as to prepare a formulation of at least 45mgml^{-1} of fulvestrant, wherein the ricinoleate vehicle is castor oil, and wherein the total volume of the formulation is 6 ml or less,

b) and from offering, putting on the market or using or importing or possessing for the aforementioned purposes in the Federal Republic of Germany medicaments adapted in this manner.

2. to surrender the evidently prepared products designated in item 1. that are in the possession or ownership of Respondent to a bailiff with local responsibility who is to be appointed by Petitioner for the purpose of provisional sequestration until the parties have reached an out-of-court settlement or until a final decision has been rendered regarding Petitioner's claim to destruction established with the ordered sequestration,

II. Beyond that, the request for the issuance of a provisional injunction is rejected.

III. The execution of the provisional injunction is made dependent upon the Petitioner providing a security of EUR 1,500,000 beforehand.

IV. The costs of the first-instance proceedings are imposed on Respondent. Petitioner is to bear one fifth and Respondent is to bear four fifths of the costs of the appeal proceedings.

V. The value in dispute of the appeal proceedings is fixed at EUR 1,750,000.

Grounds:

I.

A presentation of the facts is foregone pursuant to Sec. 540 (2), Sec. 313a (1), sentence 1, and Sec. 542 (2), sentence 1, German Code of Civil Procedure.

II.

The admissible appeal is successful. Since Petitioner has rendered both the right to an injunction and the ground for an injunction credible, the contested Judgment is to be amended and the requested provisional injunction is to be issued to the extent set out in the operative part.

(1)

The Injunction Patent (EP 2 266 573) relates to a sustained-release pharmaceutical formulation adapted for administration by intramuscular injection containing the compound 7α-[9-(4, 4, 5, 5, 5-pentafluoropentylsulfinyl)nonyl]estra-1, 3, 5(10)-triene-3, 17β-diol (hereinafter referred to as "fulvestrant") in solution in a ricinoleate vehicle which additionally comprises at least one alcohol and a non-aqueous ester solvent which is miscible in the ricinoleate vehicle, the formulation being used in the treatment of breast cancer.

According to the introductory remarks of the Injunction Patent, one therapeutic approach for the treatment of many benign and malignant diseases of the breast and reproductive tract is based on oestrogen deprivation, i.e. oestrogen withdrawal (paragraph [0002]). The endogenous production of oestrogen is prevented, and thus the cancer cells lack oestrogen. As a result, tumor growth is prevented or at least inhibited.

An alternative approach to such a therapy is to antagonize oestrogens with antioestrogens. These are drugs that bind to and compete for oestrogen receptors (ER) present in the nuclei of oestrogen-responsive tissue (paragraph [0003]). When taking such an approach, oestrogen receptor (ER) antagonists occupy the binding sites (receptors) of hormone-dependent tumor cells. If the receptor is blocked in this manner, oestrogen can no longer bind thereto and thus cannot unfold its effect. As further stated in the specification of the Injunction Patent, conventional nonsteroidal antioestrogens, such as tamoxifen, compete

efficiently for ER binding. However, their effectiveness is often limited by the partial agonism they display, which results in an incomplete blockade of oestrogen-mediated activity (end of paragraph [0003]). Moreover, substances like tamoxifen or toremifene have an oestrogen-like stimulatory activity (paragraph [0008]). The potential for nonsteroidal antioestrogens to display agonistic properties prompted the search for novel compounds that would bind oestrogen receptors (ER) with high affinity without activating any of the normal transcriptional hormone responses and consequent manifestations of oestrogens. Such molecules are "pure" antioestrogens, clearly distinguished from tamoxifen-like ligands and capable of eliciting complete ablation of the trophic effects of oestrogens. Such compounds are referred to as Estrogen Receptor-Downregulators (E.R.D.) (paragraph [0004]). One example of such a compound without oestrogenic activity is fulvestrant, as disclosed in the European patent application 0 138 504 (paragraph [0010]), which binds to ER with an affinity similar to that of oestradiol and completely blocks the growth stimulatory action of oestradiol on human breast cancer cells *in vitro*. Owing to the lack of oestrogen-like stimulatory activity, fulvestrant may offer improved therapeutic activity as compared to tamoxifen or toremifene, characterized by more rapid, complete, or longer-lasting tumour regression; a lower incidence or rate of development of resistance to treatment; and a reduction of tumour invasiveness (paragraph [0007] *et seq.*). Moreover, fulvestrant does not block hypothalamic ER. Oestrogen ablation also causes or exacerbates hot flushes and other menopausal symptoms. Fulvestrant will not cause such effects because it does not cross the blood-brain barrier (paragraph [0009]).

However, fulvestrant shows certain physical properties which make formulation of these compounds difficult. For instance, fulvestrant is a particularly lipophilic – i.e. fat-soluble – molecule, even when compared with other steroidal compounds. Moreover, its aqueous solubility is extremely low (paragraph [0011]). As further stated in the specification of the Injunction Patent, currently there are a number of sustained-release injectable steroidal formulations which use oil as a solvent and wherein additional excipients such as benzyl benzoate, benzyl alcohol and ethanol may be used. Examples of such formulations are apparent from Table 1 of the specification of the Injunction Patent (paragraph [0012] *et seq.*). As apparent to the skilled person from Table 2 of the specification of the Injunction Patent, fulvestrant has a significantly better solubility in castor oil than in other tested oils. However, even when using this solvent alone it is not possible to dissolve fulvestrant so as to achieve a high enough concentration to dose a patient in a low volume injection and achieve a therapeutically significant release rate (paragraph [0015] *et seq.*). To achieve a therapeutically effective release rate the amount of fulvestrant needed would require the formulation volume to be large, at least 10 ml. Currently guidelines recommend that no

more than 5 ml of liquid is injected intramuscularly in a single injection. Pharmacologically active doses required for a one month long acting depot formulation of fulvestrant is around 250 mg. Therefore, when dissolved in just castor oil, fulvestrant would need to be administered in at least 10 ml of castor oil (paragraph [0017] et seq.).

Against this background, the Injunction Patent is based on the object (which is not explicitly stated in the specification of the Injunction Patent) of providing a pharmaceutical formulation, which does not have the above-stated disadvantages, which can be administered intramuscularly and which achieves a depot effect.

To solve this problem, patent claim 1 provides a combination of the following features:

1. A pharmaceutical formulation

    1.1. for use in the treatment of breast cancer

    1.2. by intra-muscular injection.

2. The pharmaceutical formulation comprises

    2.1. fulvestrant;

    2.2. a pharmaceutically-acceptable alcohol being a mixture of

        2.2.1. 10% weight of ethanol per volume of formulation and

        2.2.2. 10% weight of benzyl alcohol per volume of formulation,

    2.3. 15% weight of benzyl benzoate per volume of formulation, and

    2.4. a sufficient amount of a ricinoleate vehicle so as to prepare a formulation of at least 45 $mgml^{-1}$ of fulvestrant,

        2.4.1. wherein the ricinoleate vehicle is castor oil.

3. The total volume of the formulation is 6 ml or less.

2.

The validity of the Injunction Patent is sufficiently established for granting the requested injunctive order to cease and desist (including the associated sequestration).

a)

According to the established case law of the Panel, the issuance of a provisional injunction is only possible if both the question of patent infringement and the validity of the injunction IP right are to be answered so clearly in favor of the petitioner that an erroneous decision to be revised in potential subsequent main proceedings cannot be seriously expected (Panel judgments "*Olanzapin*", as published in InstGE 9, at 140; "Harnkatheterset", as published in InstGE 12, at 114 ; "*Gleitsattelscheibenbremse II*", as published in GRUR-RR 2011, at 81; "*Kreissägeblatt*", as published in Mitt. 2012, at 413 [LS]; "*Adapter für Tintenpatrone*", as published in Mitt. 2012, at 415; Judgment of 6 December 2012, court docket: I-2 U 46/12; also: Higher Regional Court Karlsruhe, GRUR-RR 2009, 442 = InstGE 11, 143). As a rule, this can only be assumed if the injunction patent has already survived first-instance opposition or nullity proceedings (Panel judgments "*Olanzapin*", as published in InstGE 9, at 140, 146; "*Harnkatheterset*", as published in InstGE 12, at 114; Judgment of 18 December 2014, court docket: I-2 U 60/14; Judgments of 10 December 2015, court dockets: I-2 U 35/15 and I-2 U 36/15; Higher Regional Court Karlsruhe "*Ausrüstungssatz*", as published in GRUR-RR 2015, at 509; different opinion Higher Regional Court Brunswick, as published in Mitt. 2012, at 410). In order that an injunction IP right may be the subject of provisional injunction proceedings, a positive decision by the technically competent courts responsible for the opposition and nullity proceedings is therefore necessary.

However, the requirement of a validity decision in adversarial proceedings in favor of the petitioner can be foregone in exceptional cases.

Such an exceptional case is given, for example, if – as here – the request for issuance of a provisional injunction is directed against generics companies. The reason for this is that in such cases, it cannot even be reasonably expected from patent proprietor to wait for the outcome of opposition or nullity proceedings owing to the imminent disadvantages if the infringing acts are continued. While the damage brought about by generics companies is often enormous and cannot be compensated in view of the decline in prices caused by a corresponding determination of fixed prices, if the patent is maintained later, an injunction that is unjustified due to a later destruction of the patent only has the consequence that the

generics company is for some time unjustly kept away from the market, which can be fully compensated by corresponding claims for damages against the patent proprietor. When considering moreover that the generics company generally does not take any economic risks of its own for its market presence since the preparation has been sufficiently tested medically and is established on the market thanks to the patent proprietor, an injunctive order to cease and desist has to be issued even if the infringement court cannot gain final certainty regarding validity, but if more speaks for than against it in the opinion of the infringement court (Panel judgment "*Flupirtin-Maleat*", as published in GRUR-RR 2013, at 236, 240; Kühnen, "*Handbuch der Patentverletzung*", 8th edition, section G marginal no. 56 *et seq.*). An injunctive order to cease and desist thus even has to be issued without a previous decision in opposition or nullity proceedings if the infringement court (based on the assessment it is able to provide in view of the respective technical matter) gains the conviction by way of sufficient presumptive proof that the injunction IP right is valid since the lack of patentability of the subject matter thereof cannot be established. To this end, from the perspective of the infringement court, either better arguments have to indicate patentability so that it can be confirmed, or the question of patentability at least has to remain unclear taking into account the distribution of burden of proof applying in validity proceedings so that the infringement court, if it had to decide on its own instead of the Patent Office or the Federal Patent Court, would have to confirm validity thereof (Panel judgment "*Desogestrel*", as published in BeckRS 2014, at 04902; Kühnen, "*Handbuch der Patentverletzung*", 8th edition, section G marginal no. 57).

Another exception from the requirement of an adversarial opposition decision or nullity decision is to be taken pursuant to the case law of the Panel ("*Harnkatheterset*", as published in InstGE 12, at 114) if third parties participated in the grant proceedings relating to the Injunction Patent – as was the case here. Such an involvement of third parties in the examination proceedings as a rule elevates the decision of grant to a validity decision in adversarial proceedings so that, as an exception, no (further) decision confirming validity in adversarial proceedings is necessary for the issuance of an injunctive order to cease and desist.

Irrespective thereof, if a parallel patent has already been confirmed in opposition proceedings or nullity proceedings, the court also has to take this decision into account when answering the question of whether validity is sufficiently established, where the corresponding statements can be applied to the injunction patent. If this is the case – although the infringement court is obliged to seriously examine the chances of success of attacks on validity, even after the conclusion of first-instance validity proceedings, in order

to comply with its own responsibility of getting a picture of the patentability of the invention (Panel, "*Medizinisches Instrument*", as published in InstGE 8, at 122; Judgment of 18 December 2014, court docket: I-2 U 60/14) – the infringement court as a rule has to accept the decision issued by the responsible technical instance (German Patent and Trademark Office, European Patent Office, Federal Patent Court) after a technically competent examination as regards the maintenance of the parallel patent and, unless there are particular circumstances in the individual case, has to draw the appropriate conclusions also with regard to the injunction patent by issuing the necessary orders to cease and desist to protect the patent proprietor (Panel, Judgment of 10 November 2011, court docket: I - 2 U 41/11). A reason to doubt a parallel decision regarding validity and to abstain from an order to cease and desist is only given if the infringement court does not regard the line of arguments of the opposition instance or nullity instance to be tenable, or if an attack on the injunction patent is substantiated by (e.g. new) aspects promising success, which have not yet been considered and decided upon by the authorities dealing with the matter (Panel, Judgment of 6 December 2012, court docket: I - 2 U 46/12). As long as the statements in the opposition proceedings or nullity proceedings can be applied to the injunction patent and the injunction patent does not have any deviating features justifying another assessment, it is as a rule not permissible to reject the request for issuance of a provisional injunction despite the parallel patent having been maintained in the first instance for the reason alone that the infringement court replaces a tenable assessment by the responsible opposition or nullity instance with its own assessment of the technical facts (Panel, Judgment of 10 November 2011, court docket: I-2 U 41/11; Judgment of 18 December 2014, court docket: I - 2 U 60/14). This is impermissible in particular if a technically complex matter (e.g. from the field of chemistry or electronics) is at issue, with regard to which the infringement court that does not have the technical knowledge has only limited insights and assessment possibilities *a priori*. If the problem is not that, for instance, passages of a citation have been overlooked by the Opposition Division and have therefore not been considered when taking the decision, but if the dispute between the parties relates to the problem of which technical information can be gathered – from the skilled perspective – from the text acknowledged in validity proceedings, and which conclusions can be drawn from this by the average skilled person based on his general knowledge, the members of the validity instances are clearly in a better position to judge this owing to their technical knowledge and their professional experience in the pertinent field. Therefore, it is generally excluded that the infringement court with its own considerations (which are inevitably made by technical laypersons) overrules the decision of the technical specialists and denies a cease and desist order. If the respondent does not base its attack on the injunction patent on new aspects, which have not yet been considered by the authorities dealing with the matter and

which also promise success, a rejection of the request for issuance of a provisional injunction under the aspect of insufficiently established validity could only be considered if the infringement court becomes convinced that the decision issued in the validity proceedings is obviously incorrect and the infringement court can reliably recognize that the decision is incorrect since the arising technical questions are comprehensible to the infringement court and can be answered conclusively by the infringement court due to sufficient experience in the assessment of technical aspects and aspects of patent law. In individual cases, this may be different owing to the fact that the provisional injunction has particularly severe consequences – beyond what is generally the case – for the respondent and/or the public (e.g. for patients that depend on the infringing embodiment) which, when weighing interests, precludes as an exception the granting of an order to cease and desist at that point, which order may lose its basis with a reasonable chance of success in the further validity proceedings.

b)

Based on these principles, in the present case the validity is sufficiently established for granting the requested injunctive order to cease and desist (including sequestration).

(1)

Mention of grant of the Injunction Patent was published as recently as 17 June 2015, and therefore the Injunction Patent so far has not survived opposition proceedings or nullity proceedings. However, the Injunction Patent was granted in consideration of the essential citations presently used by Respondent to cast doubt on validity. Since several third parties participated in these grant proceedings, the decision of grant is thus comparable to a validity decision in adversarial proceedings – as already explained in detail by the Panel – and therefore this can exceptionally be foregone as a condition for the issuance of a provisional injunction.

Apart from that, the Injunction Patent is part of the same patent family as EP 1 250 138 B2 (hereinafter referred to as "parallel patent") which constitutes the subject matter of the parallel proceedings before the Panel having the court docket I-2 U 54/15. In an opposition decision of 11 February 2015, the Opposition Division of the European Patent Office considered the parallel patent in the version in dispute in the parallel proceedings to be valid, providing extensive and plausible reasoning for both novelty and inventive step. The maintained patent claim 1 of the parallel patent is worded as follows:

> "Use of fulvestrant in the preparation of a pharmaceutical formulation for the treatment of a benign or malignant disease of the breast or reproductive tract by intra-muscular administration, wherein the formulation comprises fulvestrant in a ricinoleate vehicle, a pharmaceutically acceptable non-aqueous ester solvent, and a pharmaceutically acceptable alcohol, and wherein the formulation is adapted for attaining a therapeutically significant blood plasma fulvestrant concentration for at least 2 weeks."

Moreover, patent claim 4 of the parallel patent, which was also maintained, has the following wording:

> "Use of fulvestrant in the preparation of a pharmaceutical formulation for the treatment of a benign or malignant disease of the breast or reproductive tract by intra-muscular administration, wherein the pharmaceutical formulation comprises fulvestrant, 30 % or less weight of a pharmaceutically-acceptable alcohol per volume of formulation, at least 1 % weight of a pharmaceutically-acceptable non-aqueous ester solvent miscible in a ricinoleate vehicle per volume of formulation and a sufficient amount of a ricinoleate vehicle so as to prepare a formulation of at least 45 $mgml^{-1}$ of fulvestrant."

The patent claim constituting the subject matter of the present proceedings differs from the claims regarded as valid by the Opposition Division essentially in that the claims of the parallel patent are worded in the so-called Swiss-type claim version, while the present claim in dispute is worded as a purpose-restricted product claim within the terms of EPO 2000 (cf. Art. 54 (5) EPC). Precisely this purpose restriction is what also distinguishes the patent claim in dispute from the claims to which the Opposition Division still objected on 7 November 2011 with regard to the parallel patent (cf. Exhibits AR 4/AR 4a in the parallel proceedings), in which the treatment of breast cancer was contained as a mere statement of purpose ("for the treatment of a benign or malignant disease of the breast or reproductive tract"). Since both the Injunction Patent as well as the parallel patent essentially protect a formulation comprising fulvestrant in a ricinoleate vehicle, a pharmaceutically acceptable alcohol and a pharmaceutically effective [sic] ester solvent for use in the treatment of breast cancer by intramuscular administration, the statements of the Opposition Division regarding the parallel patent can also be easily applied to the Injunction Patent.

Thus, the essential documents on which Respondent presently relies to substantiate that validity is not sufficiently established in Respondent's opinion have not only been considered already during grant of the Injunction Patent, but also constituted the subject matter of the opposition proceedings relating to the parallel patent that essentially has the same content. This applies in particular to the article by McLeskey et al. "Tamoxifen-resistant fibroblast growth factor-transfected MCF-7 cells are cross-resistant *in vivo* to the antiestrogen ICI 182,780 and two aromatase inhibitors", Clinical Cancer Research 4, 1998, 697-711 (= Exhibit D 13 in the opposition proceedings) as well as EP 0 346 014 (= Exhibit D 1 in the opposition proceedings). With regard to both citations, the Opposition Division – in a completely different composition of examiners than the Examining Division – did not only set out comprehensibly why it does not regard these as detrimental to novelty. Rather, the Opposition Division subsequently also acknowledged these citations under the aspect of inventive step and still maintained the parallel patent in the scope in dispute in the parallel proceedings. In this regard, the Opposition Division did not only consider McLeskey (D 13) in isolation, but also provided comprehensive reasoning regarding the question of whether the invention might be rendered obvious by a combination of D 13 with the article by Howell et al., "Pharmacokinetics, pharmacological and anti-tumour effects of the specific anti-oestrogen ICI 182780 in women with advanced breast cancer", British Journal of Cancer 74, 1996, 300 - 308 (citation D 15 in the opposition proceedings). Also in this respect, the Opposition Division confirmed the validity of the claims of the parallel patent in the version in dispute in the parallel proceedings.

In the present case, this means that two consistent votes of technical experts exist regarding the relevant objections against the validity of the Injunction Patent, and said votes cannot be ignored by the infringement court without an absolutely compelling reason. The communications issued by the first examiner in the divisional application EP 2 286 818 (Exhibits AR 15, AR 16) do not stand in the way of this conclusion. Leaving aside the fact that they represent the opinion of one single technical expert, who prepares the decision of grant, and that they only express an opinion promoting the proceedings and thus do not have the same quality as a final decision of grant or refusal, let alone an opposition decision, all communications date before 2015. While it is true that the first examiner responsible for EP 2 286 818 was also involved in the grant of the Injunction Patent, the only conclusion that can be drawn from the sequence of decisions in time is that the first examiner has changed her opinion in regard to lack of novelty and inventive step. Thus, the status of the examination proceedings in EP 2 286 818 does not allow any conclusions on a lack of validity of the Injunction Patent.

(2)

The opposition decision of the European Patent Office of 11 February 2015, which is favorable for Petitioner, cannot be excluded as a reliable basis for the assessment of validity for the sole reason that the opponent Gedeon Richter Ltd. had previously withdrawn its opposition by letter of 30 December 2014 so that the opposition proceedings were *ex parte* at the time when the opposition decision was issued.

Respondent correctly points out that, according to the established case law of the Panel, a decision in adversarial proceedings is necessary for validity to be sufficiently established (Panel judgments "*Olanzapin*", as published in InstGE 9, at 140, 146; "*Harnkatheterset*", as published in InstGE 12, at 114; Judgment of 18 December 2014, court docket: I-2 U 60/14; Judgments of 10 December 2015, court dockets: I-2 U 35/15 and I-2 U 36/15; Higher Regional Court Karlsruhe "*Ausrüstungssatz*", as published in GRUR-RR 2015, at 509). The requirement of adversarial proceedings regarding validity is, however, no end in itself. Taking into account that attacks on validity are typically launched by competitors of the IP right proprietor on the respective market, which have an overview of the relevant prior art owing to their own business activities and application activities and which moreover have sufficient search options and use these accordingly, the requirement of adversarial proceedings ensures that the opposition or nullity decision in favor of patent proprietor is on a secure basis, since it considers all opposition or nullity grounds and has been issued against the background of the entire relevant prior art. Thus, the deficit regarding search and examination in (e.g. grant) proceedings that are performed *ex parte* is supposed to be compensated, since said deficit can result in that certain relevant citations are overlooked in the proceedings or certain objections (e.g. lack of disclosure or added matter) are either not assessed at all or not evaluated under all relevant aspects. The involvement of third parties in the presentation and assessment of the facts to be decided thus increases the reliability of the decision made. In view of this, it is irrelevant whether the adversarial dispute about the validity was carried out between the parties involved in the provisional injunction proceedings or between third parties (e.g. the previous proprietor of the Injunction Patent and/or another competitor). It is also irrelevant that the opposition proceedings, which had started as adversarial proceedings, were concluded *ex officio* (and hence formally *ex parte*) due to the withdrawal of the opposition, as long as the purpose of the aforementioned adversarial character of the proceedings has been safeguarded since the opponent – during its active involvement in the proceedings – set forth serious attacks on validity which were dealt with in the opposition decision. Therefore, it is as a rule also insignificant whether the finally maintained claim category has already been pursued in the stage of the proceedings

when the opponent was still participating in the proceedings, or only at a later point in time when the opponent has already withdrawn the opposition.

This is the case here. As already explained, the essential citations used by Respondent to support the alleged lack of validity of the Injunction Patent were already the subject matter of the opposition proceedings relating to the parallel patent, in which the Opposition Division considered the parallel patent to be valid, with an overall detailed and comprehensible reasoning both in regard to novelty and inventive step, and accordingly maintained it. It is not apparent that the Opposition Division would have conducted the proceedings without due care in the *ex parte* proceedings following the withdrawal of the opposition. Not only the comprehensive reasoning of the opposition decision speaks against this, but also the fact that the opposition proceedings had already been going on for 8 1/2 years when the opposition was withdrawn. On 7 November 2014 (cf. Exhibits AR 4 and AR 4a in the parallel proceedings), the Opposition Division still regarded the claims originally worded as product claims to be anticipated by citation D 13. As Petitioner thereupon filed new main and auxiliary requests by letter of 2 January 2015 (i.e. after the withdrawal of the opposition), the Opposition Division also objected to these requests (cf. Exhibit HE 2a, bottom of page 4). This already shows that even after the withdrawal of the opposition the Opposition Division thoroughly dealt with the question of validity of the claims to be decided upon. Moreover, the Opposition had all the more reason to do so since third-party observations were received with the Brief of 26 January 2015 (cf. Exhibits HE 26 and HE 26a). In its decision, however, the Opposition Division does not focus on the question arising in this context of lack of inventive step in view of a combination of D 15 and D 13, but discusses validity in detail and extensively both under the aspect of lack of novelty as well as lack of inventive step. Furthermore, the third-party observations expressly pointed the Opposition Division also to the issue now discussed between the parties, i.e. of the subcutaneous administration disclosed in D 13, so that the Opposition Division had every reason to comprehensively discuss the citation D 13 that forms the core of the validity attack of Respondent.

(3)

Where the Opposition Division confirmed novelty and inventive step of the parallel patent, the Panel holds the carefully reasoned deliberations as justifiable, also in view of the attacks set forth in the appeal by which – putting aside the allegation of a prior public use – no new prior art has been brought up.

(a)

First of all, this applies with regard to the objection of lack of novelty (Art. 54 EPC) raised by Respondent.

(aa)

Where Petitioner invokes the above-stated article by McLeskey et al. in this regard, the Opposition Division of the European Patent Office stated the following with respect to this citation available as Exhibit D 13 in the opposition proceedings:

> "Document D13 is a scientific article reporting on a study that aimed at elucidating one possible mechanism of tamoxifen resistance. For this purpose, tumour-bearing mice injected with fibroblast growth factor (FGF)-transfected MCF-7 breast carcinoma cells were s.c. treated i.a. with ICI 182,780 (fulvestrant). D13 discloses a pharmaceutical formulation containing ICI 182,780 (i.e. fulvestrant, the patent: paragraph [0006]) in an amount of 50 mg/ml preformulated in a vehicle of 10% ethanol, 15% benzyl benzoate and 10% benzyl alcohol brought to volume with castor oil (D13: page 698, second column, under the heading "Materials and Methods", sub-heading "Drugs"). This composition is the same composition as disclosed in the only example in paragraph [0060] of the contested patent. Therefore, the same plasma level as claimed will be attained. [...]
>
> The mice were treated by s.c. injection.
>
> It was found that ICI 182,780 did not affect the *in vivo* growth of the particular breast cancer cells (see the abstract; Discussion, first §)
>
> The Opposition Division is of the opinion that D13 does not disclose the use of the formulation for the treatment of a benign or malignant disease of the breast or reproductive tract by intra-muscular injection.The subject-matter of the present claims is therefore considered novel in the light of D13."
>
> (cf. Exhibit HE 2a, page 10).

Basically nothing needs to be added to this. This evaluation by the Opposition Division appears comprehensible and justifiable to the Panel, and thus validity under the aspect of lack of novelty is sufficiently established for granting a provisional injunction in regard to cease and desist and sequestration claims. It is not apparent that the citation discloses the claimed use of fulvestrant according to feature group 1 for the treatment of breast cancer by intramuscular administration.

The assessment of whether the subject matter of a patent is anticipated by a prior publication demands that the overall content of the prior publication be ascertained. The decisive factor is the technical information disclosed to the person skilled in the art. The concept of disclosure in this context does not differ from that applied otherwise in patent law (Federal Court of Justice judgments "*Olanzapin*", as published in BGHZ 179, at 168 = GRUR 2009, at 382; "*Fahrzeugleitsystem*", as published in GRUR 2004, at 407, 411). What needs to be ascertained therefore is not in which form the skilled person, for instance with the help of his expertise, can reproduce a given general teaching or how he can modify this teaching if necessary, but exclusively that which is "directly and clearly" apparent to the skilled person from the prior publication as the content of the given (general) teaching (Federal Court of Justice judgments "*Luftverteiler*", as published in BGHZ 148, at 383, 389 = GRUR 2002, at 146 ; "*Elektronische Funktionseinheit*", as published in GRUR 2004, at 133, 135; "*Betonstraßenfertiger*", as published in GRUR 2008, at 597; "*Mementain*", as published in GRUR 2011, at 999, 1001).

In this context, it is to be considered that the patent claim in dispute is no longer directed generally at a formulation containing, *inter alia*, fulvestrant. Rather, the Injunction Patent grants purpose-restricted substance protection for the second medical indication within the terms of Art. 54 (5) EPC.

Against this background, novelty is given if the substance was already known as medicament, but the invention teaches a new and inventive specific use (Schulte/Moufang, "*Patentgesetz*", 9th edition, Sec. 3 marginal no. 144).

This is the case here. The reason for this is that the skilled person does not take any hint from the citation that the formulation described in feature group 2 is to be used in the treatment of breast cancer by intramuscular administration. As already clarified by the Abstract of the article, the tests described therein deal with elucidating a possible mechanism of tamoxifen resistance (cf. Exhibit HE 2a, page 2, "to elucidate a possible mechanism of tamoxifen resistance ..."). For this purpose, ovariectomized tumor-bearing mice injected with fibroblast growth factor (FGF)-transfected MCF-7 breast carcinoma cells were treated with fulvestrant or one of two aromatase inhibitors, wherein the administration was carried out subcutaneously into the breast fat layer (and hence not intramuscularly) (cf. Exhibit HE 2a, page 2 and top of page 8). McLeskey et al. found in the course of their tests that the oestrogen-independent tumor growth was not inhibited by treatment with pure antioestrogen or with aromatase inhibitors (cf. Exhibit HE 2a, page 2 and page 14, as well as the headline "Tamoxifen-resistant fibroblast growth factor-

transfected MCF-[7] cells are cross-resistant *in vivo* to the antiestrogen ICI 182,780 and two aromatase inhibitors"). They conclude from this that in this tumor oestrogen as a mitogenic stimulus has possibly been replaced by the autocrine activity of the transferred FGF (cf. Exhibit HE 2a, bottom of page 2). If this is the case, therapies directed at this mechanism of action might enable a second antioestrogen-therapy treatment (cf. Exhibit HE 2a, top of page 3). The fulvestrant formulation described on page 7 of the citation thus served as a tool in examining a possible signaling pathway in tamoxifen resistance (cf. also Exhibit HE 24a, page 2). Where fulvestrant is designated in the citation as treatment alternative to tamoxifen (cf. Exhibit HE 2a, bottom of page 3), there is no hint in the article that this relates to the formulation according to feature group 2 of the patent claims in dispute that was subcutaneously injected to mice in the tests. Against the background of the prior art submitted by Respondent, it is – correctly – not disputed between the parties that fulvestrant *per se* was known as active ingredient at the priority date of the Injunction Patent. The tests described on page 17 of the translation of the citation only generally served to determine the fundamental activity of fulvestrant, wherein the experiments were carried out in intact (and hence apparently healthy) female mice (cf. Exhibit HE 2a, page 17).

Against the background of that stated above, it is not apparent either that the skilled person would "read in" the features not explicitly disclosed. A disclosure may also include that which is not expressly mentioned in the patent claim or the description, but which, from the point of view of the person skilled in the art, is quite evidently required to carry out the protected teaching, and therefore does not need to be specifically disclosed, but will be "read in". The inclusion of plainly evident subject matter does not, however, permit the disclosure to be supplemented by expert knowledge. Just as when the literal meaning of a patent claim is ascertained, such an inclusion is only for the purpose of full ascertainment of the content and its meaning, i.e. the technical information the expert reader, based on his expertise, will find in the source (Federal Court of Justice judgments "*Olanzapin*", as published in BGHZ 179, at 168 = GRUR 2009, at 382; "*Proteintrennung*", as published in GRUR 2014, at 758). However, as already stated, since the skilled person does not gather any hint as to the use of the fulvestrant formulation, as disclosed on page 7 of the citation, for the treatment of breast cancer by intramuscular administration, such "reading in" would be equivalent to complementing the disclosure with expert knowledge.

The "*Proteintrennung*" decision of the Federal Court of Justice (as published in GRUR 2014, at 758), which was used by Respondent to substantiate its deviating opinion, does not justify any other assessment. According to this decision, a measure that was the means generally used in practice on the priority date is comprised by the disclosure of a prior

publication if it is apparent to the skilled person from the description of a method for preparing a protein concentration suitable for therapeutic use that further method steps are necessary to bring about the therapeutic replaceability [sic]. Such hints are, however, not to be found in the citation in dispute here in view of the fulvestrant formulation injected subcutaneously to mice, as disclosed on page 7 of the citation.

(bb)

Respondent cannot successfully invoke prior public use either.

(aaa)

If the alleged invalidity of a patent – as here – is based on a prior public use, then a stay of the proceedings in a main action firstly requires a conclusive and detailed presentation of the facts of the prior use together with the corresponding offer to provide evidence in the nullity proceedings. Moreover, to substantiate the additionally required probability of a positive proof of prior use, additional objective clues have to be set forth indicating that the allegation of prior use is correct. Although it is as a rule only essential in proceedings regarding provisional legal protection to make the submissions by the parties credible and affidavits are admissible as means for making something credible, this also has to have effects on the handling of provisional injunction proceedings if the objection of prior public use of the invention is raised. In proceedings regarding provisional legal protection, the standards are the same in this regard. It must not be ignored in provisional injunction proceedings that the infringement court only has limited examination competence for a disputed prior public use, which excludes its own determination of evidence. On the contrary, this must be considered in that the validity can only be affected to a relevant extent if prior public use, which anticipates or renders obvious the invention, is proven in a manner that would justify a stay in parallel main proceedings. Another standard could only be applied if the infringer can plausibly assert to be dependent on witnesses and their affidavits since it has been impossible for said infringer due to the brevity of time in provisional injunction proceedings to substantiate the prior use by solid evidence (Panel, Judgment of 19 March 2009, court docket: I-2 U 55/08; Kühnen, "*Handbuch der Patentverletzung*", 8th edition, section G marginal no. 65).

bbb)

Based on these principles, the submission on prior public use is unable to cast any doubts on the validity of the Injunction Patent.

Respondent is correct in pointing out that the authors of citation D 13 had already been provided by Petitioner with a pre-formulated fulvestrant formulation in accordance with the embodiment example described in paragraph [0059] *et seq.* of the Injunction Patent (cf. in this regard Exhibit HE 20; page 7). However, there are no specific indications submitted or apparent that Petitioner, as alleged by Respondent, would have disclosed in this context, without a corresponding confidentiality agreement, the use of this formulation for the treatment of breast cancer by intramuscular administration. The mere allegation that such a verbal exchange is common is not enough, nor is it sufficient to point out that a confidentiality agreement is allegedly missing. Specific indications that it was discussed to use the fulvestrant formulation provided by Petitioner in the form of intramuscular administration for the treatment of breast cancer cannot be derived from the submissions of Respondent who has the burden of substantiating the conditions of prior public use and making these credible. A conclusive presentation of the facts of prior use is therefore missing.

The US discovery proceedings to which Respondent referred in this context does not justify any other assessment. The principles of good faith that are also to be applied in patent law may result in an obligation of the party not bearing the burden of proof to provide the adversary with certain information to facilitate its burden of proof, which may include the specification of facts in particular if these facts are not or only with considerable difficulties available to the party bearing the burden of proof, while it is possible without difficulties for the adversary to lay these facts open and this can also be reasonably expected (Federal Court of Justice judgments "*Blasenfreie Gummibahn*", as published in GRUR 2004, at 268; "*Kunststoffbügel*", as published in GRUR 2006, 927). However, it is not apparent that such circumstances apply here. Firstly, Petitioner set forth undisputedly that the central documents had already been provided at the beginning of February 2015, and therefore Respondent or Sandoz Inc. had sufficient time to inspect the relevant documents and possibly to identify a particularly relevant document and request its release for the present injunction proceedings. It is not apparent that Respondent or Sandoz Inc. had done this. Secondly, Petitioner invoked that it would not be able to disclose the deposition of Dr. McLeskey since it related to confidential information of third parties. Specifically for the purpose of protecting such information, the corporate group of Respondent had in the U.S.

proceedings agreed to the Protective Order according to which such information must be used exclusively for the U.S. proceedings. Based on this agreement, Dr. McLeskey and others were deposed by the attorneys of Sandoz Inc. without any restrictions and regard to any non-disclosure obligations vis-à-vis third parties which are not involved in the proceedings. In view thereof it is not sufficient that Respondent only sweepingly denies the lack of discretion of Petitioner for disclosure and the content of the deposition in respect of the interests of possible interests of third parties. It would rather be incumbent upon Respondent, in order to substantiate a secondary burden of proof, to show why Petitioner, despite the protective order according to which the content of the deposition of Dr. McLeskey may undisputedly be used in the U.S. proceedings only, should have been in the position to disclose the deposition of Dr. McLeskey. Since Dr. McLeskey was undisputedly deposed by Sandoz Inc., and thus a company associated with Respondent, the Panel is unable to determine that this information is not or only with considerable difficulties available to the party bearing the burden of proof, i.e. Respondent, or that it is possible without difficulties for Petitioner to lay this information open and that this can also be reasonably expected. Therefore, the burden of substantiation has to remain with Respondent.

(b)

The assessment of the Opposition Division that the subject matter of the patent claims in dispute in the parallel proceedings I-2 U 54/15 was not obvious to the average skilled person based on the cited prior art (Art. 56 EPC) seems comprehensible and justifiable to the Panel, and therefore this assessment is also maintained in the present provisional injunction proceedings.

(aa)

Where Respondent relied on a combination of citation D 15 (Howell et al., "Pharmacokinetics, pharmacological and anti-tumour effects of the specific anti-oestrogen ICI 182780 in women with advanced breast cancer", British Journal of Cancer 74, 1996, 300 - 308) with the article by McLeskey et al. (citation D 13) to substantiate obviousness, the Opposition Division first of all correctly assumes (cf. Exhibit HE 2a, bottom of page 13) that the treatment of patients with fulvestrant is described, with fulvestrant being present in a long-acting formulation contained in a castor oil-based vehicle. However, a formulation within the terms of feature group 2 which also comprises in addition to fulvestrant a pharmaceutically acceptable non-aqueous ester solvent and a pharmaceutically acceptable

alcohol is not disclosed (cf. Exhibit AR 8a, page 301, right column). On this basis, it is comprehensible that the Opposition Division formulates the technical problem so as to provide an alternative formulation of fulvestrant for intramuscular administration.

The Opposition Division further stated that in order to find such a formulation a skilled person would not resort to the article by McLeskey available as Exhibit D 13 in the opposition proceedings, since this does not *a priori* relate to the treatment of individuals but reports on a study to examine the sensitivity of FGF-transfected MCF-7 breast cancer cells vis-à-vis, *inter alia*, fulvestrant.

That this is the case has already been set out by the Panel when examining novelty. In particular, it is already clarified by McLeskey et al. in the Abstract that the intent is to elucidate one possible mechanism of tamoxifen resistance (cf. Exhibit HE 20, page 2). That fulvestrant as provided by Zeneca is, among other substances, only used as a tool to examine a possible signaling pathway, is not only apparent from the description of the investigations where it is stated, *inter alia*:

> "Estrogen-independent growth of tumors produced by FGF-transfected MCF-7 cells is not inhibited by treatment with a pure antiestrogen or with aromatase inhibitors. [...] To test the hypothesis that growth of the FGF-transfected cells in ovariectomized or tamoxifen-treated nude mice is due to increased sensitivity to the small amounts of estrogens still present in ovariectomized nude mice, we tested the ability of a pure antiestrogen, ICI 182,780, and two aromatase inhibitors, 4-OHA and letrozole, to inhibit the estrogen-independent tumor growth produced by these FGF-transfected cell lines."
>
> (cf. Exhibit HE 20, top of page 6; middle of page 14)

In fact, this is explicitly confirmed again by the author of the article in the declaration submitted as Exhibit HE 24/HE 24a (cf. Exhibit HE 24a, middle of page 2). In this connection, the author of the article also clarifies that the formulations of these active ingredients were intended for research purposes for subcutaneous administration to mice (and not for the treatment of humans) (cf. Exhibit HE 24a, bottom of page 2). Finally, the author of the article concluded at the end of said declaration that a scientist interested in developing a fulvestrant treatment for humans would not have looked to the publication available as Exhibit D 13 in the opposition proceedings for guidance given that this is directed to exploring a signaling pathway of cancer growth which is different from the mechanism of

action of fulvestrant and does not provide any information about how to formulate an intramuscular sustained-release preparation for use in humans (cf. Exhibit HE 24a, bottom of page 4).

Similar statements are also to be found in the private expert opinion by Dr. Schaupp submitted by Petitioner as Exhibit HE 30. Also in her opinion D 13 is a biochemical basic research paper dealing with the elucidation of a cellular resistance mechanism rather than treatment of breast cancer. The cellular resistance mechanism would be in the field of breast cancer research in the widest sense, but D 13 does not deal at all with the question of whether and under which conditions fulvestrant could actually be used successfully in the treatment of breast cancer in humans. The mice experiments of McLeskey did not aim at their cure by a medicament, but were an attempt to elucidate a mechanism of action using fulvestrant as a tool in this experiment. She further stated that fulvestrant was known for its antioestrogenic effect and was therefore used as a tool in an experiment to elucidate a possible mechanism of action regarding the development of or overcoming the tamoxifen resistance. The use of the preformulated fulvestrant formulation as a therapeutic agent in the treatment of breast cancer could by no means be derived therefrom or from any other information in the citation (cf. Exhibit HE 30, bottom of page 3 to top of page 4). Against this background, the private expert even doubts that a skilled person, either from the medicinal or from the pharmaceutical side, would even have seriously studied the basic research paper by McLeskey, since it was not of interest for the objective of developing a fulvestrant formulation in humans (cf. Exhibit HE 30, bottom of page 5).

Since the opinion of the Opposition Division, i.e. that the skilled person would not combine D 15 with the article by McLeskey since the latter did not even relate to the treatment of individuals but reported on a study relating to treating the sensitivity of FGF-transfected MCF-7-breast cancer cells vis-à-vis fulvestrant, was confirmed in two private expert opinions with a comprehensive and plausible reasoning, it cannot be said that the decision of the Opposition Division is not tenable. This applies all the more since the private expert Dr. Schaupp also discussed, in the supplementary expert opinion submitted in the hearing before the Regional Court, the private expert opinion by Prof. Lehr presented by Respondent as Exhibit AR 18 that included a deviating view, and nevertheless remained of her original opinion with comprehensible reasons.

(bb)

This applies in analogy to a combination of EP 0 346 014 B1 (citation D 1 in the opposition proceedings) with the article by McLeskey (citation D 13 in the opposition proceedings).

The Opposition Division rightly started from the fact that the formulation disclosed in D 1 does not contain a pharmaceutically acceptable non-aqueous ester solvent in contrast to feature 2.3 of the disputed claims of the Injunction Patent (cf. Exhibit HE 2a, middle of page 11). Since the addition of such a non-aqueous ester solvent, in particular benzyl benzoate, undisputedly results in compositions having a better solubility of fulvestrant (cf. also Injunction Patent, paragraph [0045], Table 3), the Opposition Division further assumed correctly that the skilled person starting from D1 was faced with the problem to increase the solubility of fulvestrant in an intramuscular formulation.

The Opposition Division plausibly argued further that adding such an ester solvent to the castor oil-based formulation comprising fulvestrant and benzyl alcohol, as disclosed in D 1, was not obvious to the skilled person in view of D 1, since the addition of fatty acid esters was described in the citation only in the context of oil-in-water emulsions that were only disclosed as oral formulations. Therefore, the addition of a non-aqueous ester solvent to the formulation for intramuscular use was not rendered obvious by D 1.

On the other hand, D13 was stated to be a scientific article reporting on a study aiming at determining the sensitivity of particular tamoxifen-resistant breast cancer cells vis-à-vis, *inter alia*, fulvestrant. The Opposition Division further stated that the formulation was administered subcutaneously to mice, and therefore the skilled person did not have any reason to consult the citation when looking for a solution to increase the solubility of fulvestrant in an intramuscular formulation (Exhibit HE 2a, middle of page 12).

Also in this regard, the Opposition Division also views the character of D 13 as a scientific article on the examination of the sensitivity of particular tamoxifen-resistant tumor cells as the main reason why the two citations cannot be combined. As mentioned before, this appears well justifiable, considering the expert opinions presented by Petitioner.

3.

Respondent has also made a right to an injunction credible.

a)

Respondent rightly did not deny that the Contested Embodiment (*Fulvestrant Hexal 250 ml Injektionslösung*) makes literal use of the technical teaching of the Injunction Patent. Respondent is therefore obliged vis-à-vis Petitioner to cease and desist in the requested scope pursuant to Art. 64 EPC in conjunction with Sec. 139 (1) German Patent Act.

b)

Where Petitioner asserted for the first time in the appeal instance claims for provision of information and sequestration, the admissibility of the associated extension of the request for issuance of a provisional injunction is governed by Sec. 533 German Code of Civil Procedure. The requirements of this section are fulfilled. Respondent did not agree with the extension of the request for issuance of a provisional injunction. However, the Panel regards it as appropriate within the terms of Sec. 533, no. 1, German Code of Civil Procedure since the inclusion of the additionally asserted claims for information and sequestration helps to avoid second provisional injunction proceedings imminent in view of the distribution of the Contested Embodiment which has meanwhile started, and since the content of the dispute of the first instance can be used in its entirety to assess the question of whether Petitioner is also entitled to these claims (cf. Panel judgment "*Haubenstretchautomat*", as published in GRUR-RR 2013, at 1, 2). Moreover, the extended request for a provisional injunction can also be based on facts that have to be considered by the Panel anyway pursuant to Sec. 529 German Code of Civil Procedure (cf. Sec. 533, no. 2, German Code of Civil Procedure).

c)

The sequestration ordered on this basis serves to secure the claim to destruction to which Petitioner is entitled vis-à-vis Respondent pursuant to Art. 64 EPC in conjunction with Sec. 140a (1) German Patent Act (cf. Kühnen, "*Handbuch der Patentverletzung*", 8th edition, section G marginal no. 32).

d)

In contrast, an obligation of Respondent to provide information is not given in the present provisional injunction proceedings.

Where Petitioner requested information regarding the names and addresses of *non-commercial* customers as well as rendering of accounts regarding individual deliveries, specified according to delivery amounts, delivery dates, delivery prices, this is due to the fact that this does not constitute the type of information pursuant to Sec. 140b (3) German Patent Act. The other requirements for an obligation to provide information are not given either. The reason for this is that the assertion of a claim for information in provisional injunction proceedings requires pursuant to Sec. 140b (7) German Patent Act that the infringement of the right has not only been made credible, but is obvious. This is the case if both the actual circumstances and the legal assessment are so clear with regard to the product for which information is due that patent infringement has already been established to such an extent that an incorrect decision and thus unjustified burdening of the respondent appears to be impossible (cf. *Bundestag* document 11/4792, section BIII 4 d; Higher Regional Court Hamburg, "*Transglutaminase*", as published in InstGE 8, at 11; Schulte/Kühnen/Voß, "*Patentgesetz*", 9th edition, Sec. 140b marginal no. 14). This means that an erroneous assessment in terms of fact and law must be excluded with a probability bordering to certainty (cf. Higher Regional Court Hamburg, "*Transglutaminase*", as published in InstGE 8, at 11; Benkard/Grabinski/Zülch, "*Patentgesetz*", 11th edition, Sec. 140b marginal no. 4). The condition for this is not only a sufficiently established assessment of the question of patent infringement. On the contrary, there may not be any doubt as to the validity of the injunction patent either (cf. Kühnen, "*Handbuch der Patentverletzung*", 8th edition, section G marginal no. 386; Schulte/Kühnen/Voß, "*Patentgesetz*", 9th edition, Sec. 140b, at the end of marginal no. 14). Only if it can be assumed with high probability that the injunction patent is valid (cf. Panel judgment "*Mehrfachkleiderbügel*", as published in GRUR 1993, at 818, 821; Busse/Kaess, "*Patentgesetz*", 7th edition, Sec. 140b marginal no. 25), it is justified to order the respondent to finally fulfil the obligation to provide information, as specified in Sec. 140b (3) German Patent Act, already in provisional injunction proceedings. In contrast, it is not sufficient that the court considers it probable that the injunction patent will be maintained in the validity proceedings. It must rather be a clear and unambiguous case in every respect (as also set out by Benkard/Grabinski/Zülch, "*Patentgesetz*", 11th edition, Sec. 140b, at the end of marginal no. 4).

This is by no means the case here. It is true that the Opposition Division of the European Patent Office confirmed validity of the parallel patent that essentially has the same content as regards the questions decisive here – as already stated – in consideration of the relevant citations, to which Respondent has now also referred to substantiate the lack of validity alleged by Respondent, with a comprehensive and comprehensible reasoning so that

validity is sufficiently established for granting an injunctive order to cease and desist (including the requested sequestration). Whether the Injunction Patent will also prove valid in the pending nullity proceedings under the aspect of obviousness (Art. 56 EPC) cannot be conclusively assessed by the Panel due to a lack of its own expertise, although the decision by the Opposition Division is very convincing. This precludes obliging Respondent to provide information right now, since the provision of information cannot be reversed if the Injunction Patent were to be destroyed later.

The answer to the question of whether inventive step is to be confirmed requires an evaluating decision (Federal Court of Justice judgment *"Elektrische Steckverbindung"*, as published in GRUR 1995, at 330) considering the prior art and the technical knowledge of the average skilled person (Panel judgment *"Desogestrel"*, as published in BeckRS 2014, at 04902). The evaluation is based on circumstances of fact, i.e. the determination of the invention, the prior art and the knowledge and skills of the relevant skilled person. An inventive step can only be acknowledged for a performance that stands out above the level of that which a skilled person with an average education, knowledge and skills is able to achieve when proceeding as usual (cf. Panel, *loc. cit.*).

Whether the claims at issue satisfy these requirements cannot be evaluated with final certainty by the Panel, which is not composed of technical judges. As already stated, Petitioner submitted two private expert opinions (cf. Exhibits HE 24a and HE 30) as well as a supplementary expert opinion which comprehensively show, just as the decision of the Opposition Division (Exhibit HE 2a), why it was not obvious to the skilled person to combine the article by McLeskey (citation D 13 in the opposition proceedings) with either D 15 or D 1. However, Respondent also presented a private expert opinion as Exhibit AR 18 in which Prof. Lehr, who is a professor at the department of biopharmacy and pharmaceutical technology at Saarland University, extensively set forth why in his view the use of the fulvestrant formulation disclosed by McLeskey as extravascular – subcutaneous or intramuscular – injection for breast cancer therapy was already at the disposal of the skilled person, but at least provided a promising starting point for his considerations regarding the formulation of fulvestrant for use in humans (cf. Exhibit AR 18, page 5, section 18). Prof. Lehr arrived at the result that neither toxicological nor biopharmaceutical information from the general technical knowledge of the skilled person would have stood in the way of using the formulation from the McLeskey publication in humans for the treatment of the indication in question. The skilled person would rather even have been encouraged by his general technical knowledge to consider this formulation for use in humans, since he would have assumed that the formulation would have properties such as a good tolerability as

compared to a solution in pure vegetable oil due to a reduced viscosity as well as a local anaesthetic effect due to the content of benzyl alcohol, which properties would be considered as advantageous for the application in humans. The tests of the formulation from the McLeskey publication in humans still necessary to confirm the above considerations and to investigate the question how long a therapeutically significant blood plasma level of fulvestrant could be achieved with such a formulation, would only represent routine works for the skilled person (cf. Exhibit AR 18, page 11).

Whether this is the case cannot be conclusively assessed by the Panel on the basis of its own knowledge. This question, the answer to which also depends to a great extent on general technical knowledge, will ultimately have to be clarified in opposition proceedings regarding the Injunction Patent. This precludes an obligation of Respondent to provide information in the provisional injunction proceedings, which would be irreversible if the Injunction Patent were to be destroyed later. In any case, against the background of the statements by Prof. Lehr, there is no obvious infringement of a right within the terms of Sec. 140b (7) German Patent Act.

III.

The decision on costs is based on Sec. 92 (1) in conjunction with Sec. 97 German Code of Civil Procedure.

It is not necessary to declare the present Judgment provisionally enforceable since it is a second-instance decision in provisional injunction proceedings, and is thus no longer appealable (Sec. 542 (2), sentence 1, German Code of Civil Procedure) and is finally enforceable without it being explicitly declared so.

The court has made the execution of the provisional injunction dependent on the provision of a security by Petitioner beforehand pursuant to Secs. 925, 936 German Code of Civil Procedure. The security is ordered to secure damage claims of Respondent pursuant to Sec. 945 German Code of Civil Procedure. Since it cannot be excluded owing to the limited means for fact determination in summary proceedings that the provisional injunction turns out to be unjustified in the main proceedings, and that Petitioner has to pay damages to Respondent pursuant to Sec. 945 German Code of Civil Procedure, the execution of an injunctive order to cease and desist on the grounds of patent infringement cannot be subject to lower requirements than the enforcement of a first-instance judgment ordering injunction. In regard to the amount of the security, the Panel has taken as a basis the value

in dispute attributed to the cease-and-desist request. By contrast, Respondent requested in its Protective Brief of 27 August 2015 that a security to the amount of EUR 5,000,000 be set, but it has neither been submitted nor is it evident that Respondent is threatened with a damage exceeding the security now ordered. In this regard, Respondent only refers to the value in dispute fixed in the nullity proceedings regarding the parallel patent to an amount of EUR 6,750,000 which is also the basis for the Panel for fixing the value in dispute. When fixing the value in dispute, the Panel has also taken into account that two parallel, patent infringement proceedings conducted as provisional injunction proceedings are at issue here, which justifies corresponding deductions from the value in dispute fixed in the nullity proceedings (cf. Federal Court of Justice judgment "*Streitwertfestsetzung im Nichtigkeitsverfahren*", as published in GRUR 2011, at 757; Higher Regional Court Rostock "*Moonlight*", as published in GRUR-RR 2009, at 39; Kühnen, "*Handbuch der Patentverletzung*", 8th edition, section J marginal nos. 125 and 132).

Dr. Kühnen Fricke Thomas