I-2 U 62/18
4b O 39/18
Düsseldorf Regional Court

Pronounced on 15 March 2019 Krüger, judicial officer as Registrar of the Court

DÜSSELDORF HIGHER REGIONAL COURT

IN THE NAME OF THE PEOPLE

JUDGMENT

In the proceedings for the issuance of a preliminary injunction

Merck Sharp & Dohme Corp., 126 East Lincoln Avenue, 07065 Rahway, N.J., United States of America, legally represented by its CEO Kenneth Frazier, at the same address,

Injunction Plaintiff and Appellant,

Attorneys of record: Law Firm Hogan Lovells LLP in Düsseldorf,

versus

ratiopharm GmbH, Graf-Arco-Strasse 3, 89079 Ulm, represented by its managing directors Christoph Stoller, Andreas Burkhardt and Dr. Miran Denac, at the same address

Injunction Defendant and Appellee,

Attorneys of record: Law Firm Bird & Bird in Hamburg,

the 2nd Civil Division of the Düsseldorf Higher Regional Court, through the Higher Regional Court Presiding Judge Dr. Kühnen, and Higher Regional Court Judges Fricke and Thomas, following the oral proceedings on 15 March 2019

has adjudged as follows:

I. The appeal of the judgment of Civil Division 4b of the Düsseldorf Regional Court pronounced on 1 October 2018 is dismissed.

II. Injunction Plaintiff shall bear the costs of the appellate proceedings.

III. The judgment is enforceable.

IV. The value in dispute is assessed at [redacted].

Grounds:

I.

A presentation of the facts of the case is dispensed with in accordance with Sections 540 para. 2, 313a para. 1 sentence 1, 542 para. 2 sentence 1 of the German Code of Civil Procedure (ZPO).

II.

The admissible appeal remains unsuccessful on the merits.

The Regional Court rightly rejected the injunction application based on the supplementary protection certificate of injunction DE 12 2004 000 026.1 because of doubts as to the legal validity of the certificate of injunction.

1.
In order to reduce the risk of an erroneous decision with grave consequences, the issuance of a preliminary injunction in patent matters generally only comes into consideration if both the validity of the property right in suit and the issue of patent infringement are ultimately to be deemed so clearly in favour of the applicant that an erroneous decision that might have to be revised in subsequent main proceedings is not seriously to be expected (Division, InstGE 12, 114 – Harnkatheterset; Karlsruhe Higher Regional Court, InstGE 11, 143 – VA-LCD-Fernseher; Hamburg Regional Court GRUR-RR 2015, 137 – Hydraulikschlauchgriffteil). Conversely, the clearer the two factors can be assessed in favour of the holder of the property right, the less justified it is to nonetheless refrain from granting interim relief in view of potential competition interests of the respondent. In cases involving a clear legal validity and infringement situation, further considerations as regards a balancing of interests are superfluous as a rule (Division, judgment of 27 October 2011 – I-2 U 3/11; judgment of 10 November 2011 – I-2 U 41/11) and the need for interim relief in individual cases can result from the unambiguous legal position as such (Division, judgment of 10 November 2011 – I-2 U 41/11). In the present case, a preliminary injunction order – as the Regional Court rightly held – is ruled out.

2.
True, it is common ground between the parties that Injunction Defendant's challenged preparation makes literal use of the technical teaching of the certificate of injunction and that Injunction Defendant cannot claim any justification, so that the question of infringement must clearly be answered in favour of Injunction Plaintiff.

3.
However, the Regional Court rightly regarded the validity of the certificate of injunction that has been challenged by various nullity actions as inadequately secured, which is why, despite the given situation of use, an order for a prohibitory injunction cannot come into consideration.

a)
In principle, adequate legal validity can only be assumed if the property right of injunction has already survived contentious opposition or nullity proceedings at first instance (Division, InstGE 9, 140, 146 – Olanzapin, InstGE 12, 114 – Harnkatheterset, Karlsruhe Higher Regional Court, GRUR-RR 2015, 509 – Ausrüstungssatz), irrespective of whether the validity dispute was conducted between the persons involved in the preliminary injunction proceedings or between third parties. Nevertheless, the requirement of a contentious legal validity decision in favour of the applicant can be waived – but not the need to convince the infringement court dealing with the request for injunction of the legal validity of the property right of injunction (Division, judgment of 10 December 2015 – I – 2 U 35/15) – in special cases, for example, if there are "exceptional circumstances" which make it unacceptable for the applicant to await the outcome of the opposition or nullity proceedings due to the disadvantages which threaten him from the imminent commencement or continuation of acts of infringement (Division, InstGE 12, 114 – Harnkatheterset).

Such circumstances are generally given when acts of infringement of a generics company are involved (Division, GRUR-RR 2013, 236 – Flupirtin-Maleat). While the damage caused by them in the event that the patent is upheld later on is often enormous and (in view of the decline in prices caused by the corresponding fixing of fixed amounts) irreparable, the only consequence of an injunction that is unjustified (because the patent is later on destroyed) is that the generic drug company was kept out of the market unjustly for a period of time, which however can be fully compensated through corresponding claims for damages against the patentee. It should also be borne in mind that the generics company generally does not assume any economic risks of its own, because the preparation has been subjected to sufficient medical testing and is established in the market thanks to the IPR holder. For this reason, a prohibition order must be handed down even if the infringement court is unable to attain final certainty as to validity in the absence of an expert vote on the legal validity, provided the infringement court (on the basis of the assessment it is capable of in view of the technical matter concerned) arrives at the conviction (in the sense of sufficient substantiation) that the property right of injunction is valid due to the fact that the lack of patentability of the subject matter of its invention will not be able to be established (Division, judgment of 10 December 2015 – I-2 U 35/15; Düsseldorf Higher Regional Court, judgment of 11 January 2018 – I-15 U 66/17). To that end, this means that from the perspective of the infringement court, either the better arguments are *in favour* of patentability such that it may be positively affirmed, or the question of patentability (in consideration of

the distribution of the burden of proof applicable in validity proceedings) must at least remain unclear, so that the infringement court, if it were to decide the matter itself in place of the Patent Office or the Federal Patent Court, would have to affirm its validity (Division, BeckRS 2014, 04902 – Desogestrel).

"Exceptional circumstances" can arise further – and independently – from the fact that the expiry of the property right of injunction is imminent, so that a main action can no longer lead to success for reasons of time (cf. Düsseldorf Higher Regional Court, judgment of 11 January 2018 – I-15 U 66/17). If the applicant's reference to a first-instance decision in the ongoing legal validity proceedings would mean that no further legal protection would be granted at all against the alleged acts of infringement before the end of the term of protection, the infringement court itself must take up the challenge to legal validity and grant the requested injunction if it affirms the patentability (because no ground for revocation or nullity can be established) (Division, BeckRS 2014, 04902 – Desogestrel; Düsseldorf Higher Regional Court, judgment of 11 January 2018 – I-15 U 66/17).

b)
In the case in dispute, both of the aforementioned aspects suspend the requirement of a positive contentious decision on the legal validity of the certificate of injunction. The subject of the infringement attack are offering and distribution acts by a generic company; the certificate of injunction is moreover a few days from its expiry (02 April 2019). The Division is therefore obligated to assess the probable success of the nullity attacks against the certificate of injunction.

c)
The necessary review leads to the conclusion that the legal validity of the property right of injunction is countered by grave concerns. In concordance with the Regional Court, the Division is convinced that the ground of nullity of Article 15(1)(a) of Regulation No. 469/2009 (hereinafter: SPC Regulation) is given, because the SPC of injunction was not issued in accordance with the provisions for its grant under Article 3 of the SPC Regulation. Admittedly, when the SPC was filed on 22 June 2004, the certificate-protected product "*ezetimibe ... in combination with simvastatin*" was protected by the basic patent EP 0 720 599 B1, which was in force until 14 September 2014 (Article 3(a) of the SPC Regulation; however, a supplementary protection certificate had already been granted for the product of the certificate of injunction in the form of DE 102 99 001.1, thereby excluding the granting of a further, second certificate pursuant to Article 3(c) of the SPC Regulation.

aa)
The basic patent EP 0 720 599 B1, filed on 14 September 1994, relates to the treatment and prevention of atherosclerosis (colloquially also known as arteriosclerosis), which – among other factors – is mainly caused by an elevated

blood cholesterol level. For this reason, this should be reduced in order to reduce the risk of atherosclerotic disease, especially of the coronary arteries.

The basic patent takes two paths to achieve this, as already been clearly in the wording of its claims.

- Claim 1 provides protection for a particular chemical compound group, namely hydroxy-substituted azetidinones, which – as is apparent from the specification of sub-claim 8 – includes the compound ezetimibe. Said azetidinones inhibit the absorption of dietary cholesterol in the intestine, which, in turn, results in less cholesterol being available in the liver that is processed into hepatic lipoprotein there, which (after metabolisation to low density lipoproteins) can cause increased atherosclerosis.

- Claim 9 additionally protects a pharmaceutical composition comprising (in an effective amount) the described hydroxy-substituted azetidinone, especially ezetimibe, (alone or) in combination with a cholesterol biosynthesis inhibitor, in a pharmaceutically acceptable carrier. As indicated by sub-claim 17, the cholesterol biosynthesis inhibitor to be combined with ezetimibe may be simvastatin (besides other chemical compounds also mentioned in sub-claim 17). The additionally used cholesterol biosynthesis inhibitors act – as the term already indicates – to the effect that the body's own production of cholesterol in the liver is inhibited.

The sole starting point – scil. reduced dietary cholesterol absorption by means of hydroxy-substituted azetidinones (claim 1), notably ezetimibe (claim 8) – or the dual starting point for a reduction in blood cholesterol – scil. 1) reduced dietary cholesterol absorption by means of hydroxy-substituted azetidinones, notably ezetimibe, and (2) decreased synthesis of harmful cholesterol in the liver by means of the use of biosynthesis inhibitors such as simvastatin (claims 9, 8, 17) – is also clearly indicated to those skilled in the art in the descriptive text. Thus, it already mentions at the outset (translation into German, top of page 1) that the invention "*relates to hydroxy-substituted azetidinones useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis, and to the combination of a hydroxy-substituted azetidinone of this invention and a cholesterol biosynthesis inhibitor for the treatment and prevention of atherosclerosis.*" Under the heading "Summary of the invention" (translation into German, page 7) it further states: "*The present invention also relates to a method of reducing plasma cholesterol levels, and to a method of treating or preventing atherosclerosis, comprising administering to a mammal in need of such treatment an effective amount of a combination of a hydroxy-substituted azetidinone cholesterol absorption inhibitor … and a cholesterol biosynthesis inhibitor. That is, the present invention relates to the use of a hydroxy-substituted azetidinone cholesterol absorption inhibitor … for combined use with a cholesterol biosynthesis inhibitor (and, similarly, use of a cholesterol biosynthesis inhibitor for combined use with a hydroxy-substituted azetidinone cholesterol*

absorption inhibitor…) to treat or prevent atherosclerosis … In yet another aspect, the invention relates to a pharmaceutical composition comprising an effective amount of a hydroxy-substituted azetidinone cholesterol absorption inhibitor…, a cholesterol biosynthesis inhibitor, and a pharmaceutically acceptable carrier." The further text of the specification (translation into German, page 33) then provides more detailed dosage instructions as follows: "*For the combinations of this invention wherein the hydroxy-substituted azetidinone is administered in combination with a cholesterol biosynthesis inhibitor, the typical daily dose of the cholesterol biosynthesis inhibitor is 0.1 to 80 mg/kg of mammalian weight per day ...*"

bb)
Under the given circumstances, the Regional Court rightly concluded that the basic patent "protects" the active ingredient composition of the certificate of injunction (scil. ezetimibe + simvastatin) within the meaning of Article 3(a) of the SPC Regulation.

How said provision should be interpreted follows – conclusively, finally, and without exception – from the preliminary ruling of the CJEU of 25 July 2018 in Case C-121/17 (Teva v. Gilead). It may well be that the preceding case law of the Court of Justice of the European Union gave rise to ambiguities relating to the interpretation of Article 3(a) of the SPC Regulation, which – as can be inferred from the Commission's own description of the "main proceedings and the question referred for a preliminary ruling" in paras. 24-28 of its judgment of 25 July 2018 – were the motivation and the reason, even according to the CJEU's understanding, to again turn to it in the context of a request for a preliminary ruling. That the question referred was not handled in the composition of the single chamber – like the preceding decisions – but in the special plenary session of the Grand Chamber (which only sits when a Member State or a Union institution, that is a party to certain proceedings, so requests, or in particularly complex or important cases) quite clearly takes account of the lack of clarity of the jurisprudence described above and pursues the obvious purpose of providing final clarity with the renewed referral for a preliminary ruling and clarifying with binding effect – beyond the previous, potentially not entirely consistent decisions of various chambers – how the CJEU case law is to be understood in its entirety and with what exact content Article 3(a) of the SPC Regulation is therefore to be applied by all authorities and courts of the Member States – and thus also by the German Federal Patent Court and, if applicable, subsequently by the German Federal Court of Justice in the pending nullity proceedings against the certificate of injunction. The intention to bring about overarching legal clarity is evident not least from the fact that the Grand Chamber, in its considerations, extensively discusses the previous case law of the CJEU in order to finally establish the rules under which it is to be determined whether the product of the certificate is "protected" by the basic patent.

According to this, it does not suffice for the protection conferred by the basic patent that the active ingredient or combination of active ingredients of the certificate falls under the scope of protection of the basic patent (paras. 33, 53). Instead, the certificate product must represent the (narrower) subject matter of the basic patent. This is the case if the active ingredient/active ingredient composition claimed with the certificate application is expressly mentioned in the claims of the basic patent as a suitable means for the solution of the invention with the specificity (i.e. as such) corresponding to the certificate application (judgment, paras. 37, 53). If the active ingredient/active ingredient combination filed for the certificate does not find specific mention there, for example because the claim merely contains a functional feature or an overarching class of active ingredients under which the active ingredient/active ingredient combination can be subsumed in view of its inherent effects and/or properties, then it is necessary that the claims of the basic patent (e.g. with their functional definition) relate necessarily and specifically to the active ingredient/active ingredient composition filed for the certificate (judgment, paras. 37, 53). Whether the general (e.g. functional) feature in this sense focuses implicitly on the active ingredient/active ingredient combination in question is to be assessed from the point of view of the skilled person with the knowledge of the priority date, on the basis of the prior art as well as the patent description and the patent drawings (if any) (judgment, paras. 48-49, 51-53).

In the case in dispute, this means that the active ingredient combination of the certificate of injunction (ezetimibe + simvastatin) already enjoys the protection of the basic patent simply because sub-claim 9 is directed to a combination pharmaceutical product, preferably containing ezetimibe (sub-claim 8) as the first active ingredient and simvastatin (sub-claim 17) as the second active ingredient. The composition of the active ingredient of the certificate is therefore explicitly mentioned in the sense of the CJEU case law – processing because of its concrete designation in claims 9, 8 and 17 of the basic patent – and is consequently "protected" by the basic patent within the meaning of Article 3(a) of the SPC Regulation.

cc)
However, the active ingredient combination of the certificate of injunction (ezetimibe + simvastatin) is the subject of a previously issued certificate, namely DE 102 99 001.1 for the active ingredient "*ezetimibe or a pharmaceutically acceptable salt thereof*," so that the granting of a further certificate is no longer possible (Article 3(c) of the SPC Regulation).

(1)
According to Article 2 of the SPC Regulation, a supplementary protection certificate may be granted for any product protected by a patent whose distribution is authorised under medicinal product law. If a basic patent protects several products that differ from each other, it is possible to obtain several certificates on the basis of

one patent, namely a certificate for each of the different products protected by the basic patent (CJEU, judgment of 12 March 2015 – C-577/13 (*Actavis v. Boehringer*), para. 33; CJEU, judgment of 12 December 2013 – C-443/12 (*Actavis v. Sanofi*), para. 29). This is also in line with the purpose and purpose of the certificate protection, which is designed to re-establish a sufficient period of effective protection of a basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of his patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his patented invention by reason of the time which has elapsed between the date on which the application for that patent was filed and the date on which the first marketing authorisation in the European Union was granted (CJEU, judgment of 12 March 2015-C 577/13 (*Actavis v. Boehringer*), para. 34; CJEU, judgment of 12 December 2013 – C-443/12 (*Actavis v. Sanofi*), para. 31). This does not actually mean that the medicinal product-specific delays in exploitation must be compensated for in their entirety, i.e. in relation to all possible aspects of the invention. In particular, an extension of the period of protection does not have to take place with respect to all the different pharmaceutical compositions that are possible or expedient with the patented active ingredient (CJEU, judgment of 12 March 2015 – C-577/13 (*Actavis v. Boehringer*), para. 35; CJEU, judgment of 12 December 2013 – C-443/12 (*Actavis v. Sanofi*), para. 40). If the basic patent has several different subject matters, however, the concept of an extended period of protection for the subject of the invention of the basic patent applies to each individual one of the various subjects of the invention of the basic patent, and not just to an individual one of them (indeed which?).

(2)

In circumstances comparable to the disputed case with regard to the formal property right situation, the CJEU nevertheless prohibited the granting of a second SPC for a combination of active ingredients in the above-cited decisions *Actavis v. Boehringer* and *Actavis v. Sanofi*, after a first SPC had already been granted for the patented active ingredient. As in the case decided, there as well, the single active ingredient (in this case ezetimibe) was protected as *one* component of the active ingredient composition and in addition the active ingredient combination (in this case ezetimibe + simvastatin) by corresponding claims of the basic patent, while the second active ingredient of the active ingredient combination (in this case simvastatin) was not the subject of protection of the basic patent as such (CJEU, judgment of 12 December 2013 – C-443/12 (*Actavis v. Sanofi*), paras. 26, 30, 32, 36, 41-43; CJEU, judgment of 12 March 2015 – C-577/13 (*Actavis v. Boehringer*), paras. 26, 36, 37).

- In the *Actavis v. Sanofi* case, claim 1 of the basic patent related to the active ingredient irbesartan, and claim 20 to a pharmaceutical composition containing irbesartan in association with a diuretic – which was not specified in the patent (judgment, para. 11). A first SPC was granted to the patent proprietor for the active ingredient irbesartan, and a second SPC subsequently

for a medicinal product composed of irbesartan and the diuretic hydrochlorothiazide (judgment, paras. 13-14).

In the description of the facts (judgment, para. 15), it is stated that the combination of the active ingredients is associated with a merely additive effect, and therefore no other therapeutic effects are achieved with the active ingredient composition when compared with the effects obtained as a result of the separate administration of those two active ingredients.

- In the *Actavis v. Boehringer* case, claims 5 and 8 of the basic patent related to the active ingredient telmisartan. The patent proprietor had obtained a first SPC for this same active ingredient; it then sought another SPC for a combined preparation containing the active ingredients telmisartan and hydrochlorothiazide (judgment, paras. 10-11, 13). The certificate application had been granted after the patent proprietor subsequently included an additional claim 12 in the basic patent, which related to a pharmaceutical combination of telmisartan and hydrochlorothiazide (paras. 16, 18-20).

  Regarding the latter compound, the preliminary ruling (judgment, para. 26) states that hydrochlorothiazide is a molecule whose discovery the patent proprietor did not contribute to and whose use is in the public domain, because hydrochlorothiazide did not constitute the subject matter of the invention.

In both constellations, which are consistent with the conditions of the case in dispute in this respect, the CJEU criticised the granting of the further certificate for the combination of active ingredients due to violation of Article 3(c) of the SPC Regulation.

- In the earlier decision *Actavis v. Sanofi*, the CJEU presumed in favour of the certificate holder that the grant requirement of basic patent protection pursuant to Article 3(a) of the SPC Regulation was given, because the active ingredient combination irbesartan + hydrochlorothiazide was fulfilled due to its (partly[i] only functional) mention in claim 20 ("*pharmaceutical composition containing irbesartan in association with a diuretic*"). From the standpoint of Article 3(c) of the SPC Regulation, the Court nevertheless denied the conditions for granting an SPC as follows:

  "However, in circumstances such as those in the main proceedings, even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied, for the purpose of the application of Article 3(c) of that regulation, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC ... each time he places on the market in a Member State a medicinal

[i] With respect to hydrochlorothiazide.

product containing, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient[ii] which is not protected as such by that patent."

(judgment, para. 30, footnotes and underlining added)

The guiding principle of the preliminary ruling reads accordingly:

"In circumstances

... where, on the basis of a patent protecting an innovative active ingredient and a marketing authorisation for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained a supplementary protection certificate for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients,

Article 3(c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding that patent holder from obtaining – on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second supplementary protection certificate relating to that combination of active ingredients."

- In the *Actavis v. Boehringer* case that was decided later, the CJEU's considerations were no different on the merits, and it certainly did not indicate that intended with its decision to depart in any way from the legal position taken by another chamber with the previous preliminary ruling in *Actavis v. Sanofi*. Since every preliminary ruling of the CJEU binds all the authorities and courts of all Member States in their application of the law – as will be explained in more detail below – it appears to be ruled out a priori that in a decision by a (single) chamber, an interpretation of the law is ordered – and at best "between the lines" – which contravenes the previous preliminary ruling of another CJEU chamber regarding the same provision. It would be completely unclear in such a case which guidelines for the interpretation of the law should now be followed in legal relations, which is obviously untenable. In the case of divergent views on the interpretation of the law, only one scenario is conceivable and realistic, namely that the chamber later seised of the matter would have appealed to the CJEU's Grand Chamber due to its doubts as to the correctness of the preliminary ruling of another chamber, in order to achieve definitive clarity on the disputed question of interpretation. This did not occur here, though, which in itself makes it seem impossible to conclude that

[ii] Hydrochlorothiazide.

the CJEU's observations on the merits in the *Actavis v. Boehringer* case were intended to take a deviating position in the interpretation of Article 3(c) of the SPC Regulation than that which can be found on the merits in the preliminary ruling in the *Actavis v. Sanofi* case.

Furthermore, the *Actavis v. Boehringer* decision also expressly states – fully consistently with the considerations in the earlier *Actavis v. Sanofi* decision:

"... [I]f it were accepted that all subsequent marketing of an active ingredient in conjunction with an unlimited number of other active ingredients which do not constitute the subject-matter of the invention covered by the basic patent would confer entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs ...

Accordingly, ... it cannot be accepted that the holder of a basic patent in force may obtain a new SPC ... each time he places on the market in a Member State a medicinal product containing, on the one hand, an active ingredient, protected as such by the holder's basic patent and constituting the subject-matter of the invention covered by that patent, and, on the other, another substance which does not constitute the subject-matter of the invention covered by the basic patent."

(judgment, paras. 36-37)

The legal consequences to be drawn from this with respect to a case constellation such as that in dispute are presented even more clearly:

"In the light of the foregoing considerations, ... Article 3 ... (c) of Regulation No 469/2009 must be interpreted as meaning that where a basic patent includes a claim to a product comprising an active ingredient[iii] which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance[iv], that provision precludes the holder from obtaining a second SPC for that combination."

(judgment, para. 39 and guiding principle; footnotes added)

(3)

Whether the above considerations are accurate or convincing is not up for debate. This is because preliminary rulings of the CJEU are binding (unlike judgments of the German Federal Court of Justice (BGH)) beyond the individual case in which the preliminary ruling is handed down – precisely because they are intended to enforce a uniform application of the EU provisions in all Member States of the Community. It is therefore utterly immaterial which application of Article 3(c) of the

[iii] telmisartan (claims 5, 8).

[iv] telmisartan + hydrochlorothiazide (claim 12).

SPC Regulation the parties or the Regional Court consider to be correct, just as it would be completely meaningless which understanding of the provision the Division would prefer. The only factor that is decisive are the considerations on the interpretation of the law undertaken by the CJEU. If they are applicable to the case in dispute because it is the same as or sufficiently similar to the main proceedings in factual respects on which the preliminary rulings are based, the granting of a second certification must be omitted with regard to the secondary protection of the active ingredient combination ezetimibe + simvastatin. It can only come into consideration if the facts in the case in dispute diverge so strongly from the circumstances in *Actavis v. Sanofi* and *Actavis v. Boehringer* that there are legitimate reasons to presume that the CJEU would have reached a different decision under *such* (deviating) conditions, namely in favour of the granting of a second certificate.

The CJEU preliminary ruling in the *TEVA v. Gilead* case does not alter this in any way. It was adopted exclusively in respect of Article 3(a) of the SPC Regulation, and is therefore inconsequential for the interpretation of Article 3(c) of the SPC Regulation for this reason alone. Injunction Plaintiff's contrary legal position fails to recognise that CJEU preliminary rulings – as will be explained in more detail below in another context – have an absolute binding effect, and that effect prohibits the drawing of conclusions from considerations regarding the interpretation of a provision that is not discussed at all in the grounds of the preliminary ruling in question (in this case *TEVA v. Gilead*) which contravene a preliminary ruling of the CJEU that was adopted on this very provision (in this case *Actavis v. Sanofi* and *Actavis v. Boehringer*).

(4)

Two things follow quite clearly from the two preliminary rulings of the CJEU in *Actavis v. Sanofi* and *Actavis v. Boehringer* – which are thus solely relevant in the context of Article 3(c) of the SPC Regulation: First, although the mere fact that in addition to the actual active ingredient of the invention, a combination of active ingredients is protected in the claims of the basic patent which contains the patented active ingredient combined with another chemical compound, suffices with respect to Article 3(a) of the SPC Regulation, it is not yet allowed the presumption that the combination of active ingredients separately protected in the basic patent gives rise to a *different* product for which a further certificate can be obtained following a SPC already granted for the single preparation. If only the separate claiming of the combination of active ingredients in the basic patent were to be critical, there would have been no reason to refuse the certificate for the combination of active ingredients, as the CJEU did, given the fact that the composition of the active ingredient in the two patent applications was expressly mentioned in the two patent applications (or this was presumed by the CJEU). Secondly – and on the other hand – a situation is conceivable in which a basic patent protects several distinct "products," which means that separate SPCs can be granted for each of the different "products" of the same basic patent.

(a)
What makes up the decisive qualitative difference between those case constellations for which the CJEU has rejected the repeated granting of certificates, despite separate basic patent protection for active ingredient combinations, and those case constellations in which it considers this to be possible, has not been formulated in detail in the preliminary rulings of the CJEU thus far. Nor do they comment on the legal standard applicable in connection with Article 3(c) of the SPC Regulation for identifying factual constellations in which several products are to be presumed, rather than the existence of just *one* product. The CJEU will need to make a binding specification in a future preliminary ruling as to what the decisive demarcation criterion should be, although it is currently scarcely possible to foresee in advance how this decision will turn out, as this is largely a "discretionary decision" as to where exactly the boundary should be drawn from which the granting of a second certification should be permissible.

(b)
For proceedings for interim relief, the currently uncertain legal situation means that an injunction order can in principle only be considered under circumstances in which, despite all of the imponderables, it can already be reliably assumed at the present time that the possibility of a further grant of a certificate will be acknowledged. Conversely, such a measure will generally have to be excluded within the putative grey area between permissible and impermissible granting of certificates, which is consistent with the fact that the certificate holder would not be able to enforce judicial relief in main proceedings, either, because the infringement case would reasonably have to be stayed under the circumstances described until a preliminary ruling could be obtained from the CJEU in the proceedings on the validity. Put another way, interim relief is only possible if the case in dispute already deviate so greatly from the cases already negatively decided by the CJEU that, taking into account the considerations of the CJEU, a different assessment (in the sense of the admissibility of the granting of a second certificate) can reliably be presumed.

(c)
Indications as to what constitutes the relevant criteria for the determination of an additional product protected by the basic patent can at present be developed predominantly from the known circumstances of the cases which may have led the CJEU to refuse to issue the granting of a renewed certificate for the combination of active ingredients, and which are as follows:

- In the *Actavis v. Sanofi* case, a mere additive effect was associated with the additionally combined active ingredient hydrochlorothiazide, which is why no other therapeutic effects were achieved with the active ingredient composition than with the separate administration of the two active ingredients telmisartan and hydrochlorothiazide. Furthermore, the CJEU argued that the core

inventive advance of the basic patent is the provision of the active ingredient telmisartan and not – as one must conclude – the active ingredient hydrochlorothiazide.

- In the *Actavis v. Boehringer* case, the CJEU mentions that the hydrochlorothiazide to be combined with the actual and inventive active ingredient of the basic patent, irbesartan, is a molecule whose discovery the patent proprietor did not contribute to and whose use is in the public domain.

In the understanding of the Division, the overriding commonality of both case configurations is that from the point of view of the person skilled in the art, nothing is revealed in the active ingredient combination – proposed in addition to the inventive single active ingredient – that would go beyond the obvious modification of the inventive single active ingredient. Rather, the technical contribution justifying the patent protection lies in the provision of the single active ingredient, having regard to which (possibly including its mode of action and/or therapeutic usefulness) no further creative considerations were required in order to recognise the usefulness of an active ingredient combination containing the patented active ingredient.

Viewed thusly, the question of whether one or two SPCs can be granted on the basis of the same basic patent is determined by whether the basic patent contains *one* invention or *two* of them. If only the provision of the single active ingredient deserves the predicate of an invention because the combination of active ingredients containing it is a familiar modification to a person skilled in the art, only the granting of a single certificate – specifically for the solely inventive single active ingredient – comes into consideration. In contrast, if the combination of active ingredients itself, in addition to the inventive single active ingredient, constitutes a further invention because it was only discoverable for the skilled person through independent creative considerations, then the basic patent covers two inventions, which is why two certificates are also possible, one for each of the two inventions.

A consideration to this effect is not precluded by the fact that the single active ingredient does not represent prior art for the active ingredient combination, because both share the same priority date. Notwithstanding this matter of course under patent law, it is readily conceivable that in addition to the single active ingredient, the active ingredient composition treated in the same patent also represents an independent invention, for example, because the proposed combined administration of the active ingredients is associated with surprising effects that are unforeseeable for the skilled artisan and therefore inventive . A differentiation according to the number of inventions contained in the basic patent is accordingly not only practically possible and realisable; it is also supported in other respects by the fact that, in the view of the CJEU, the extension of the term sought with the SPC is intended only for *that* invention, but not for all possible forms of this invention

provided to the public by the basic patent (CJEU, judgment of 12 March 2015 – C-577/13 (*Actavis v. Boehringer*), para. 35; CJEU, judgment of 12 December 2013 – C-443/12 (*Actavis v. Sanofi*), para. 40). If the combination of active ingredients does not constitute a separate invention in addition to the single active ingredient, but merely represents a variation (embodiment) of the inventive active ingredient, the term with the SPC for the single active ingredient, even to the extent it concerns the specific embodiment of its use in an active ingredient combination. There are no grounds for the granting of a second SPC, which is also objectively justified insofar as the certificate holder can take action with his SPC granted for the single active ingredient not only against single preparations, but also unrestrictedly against active ingredient combinations containing the certificate-protected active ingredient – among others. On the other hand, if the active ingredient combination represents a further, independent invention in addition to the single active ingredient and independently thereof, the granting of the certificate for the single active ingredient in relation to this further invention has not yet effected an extension of the term, which is why it is possible to grant a second certificate.

(d)
Whether the question of the existence of one or more inventions is contingent solely on the contents of the basic patent or whether later findings which result in a surprising effectiveness or usefulness of the combination of active ingredients are instead to be taken into account, cannot be reliably deduced from the preliminary rulings of the CJEU.

Since the SPC is intended to extend patent protection for the technical subject matter which the basic patent has made available to the general public by virtue of the invention (which is linked to the protection conferred by the basic patent as granted and not that protection which could instead have been claimed more broadly), it would seem more appropriate, in principle, not to perform, for the purpose of assessing the question of what constitutes the subject matter of the basic patent for which an extension of the term of protection is to be pronounced once, a retroactive (re-)evaluation of the individual claims against the background of the prior art on the priority date; rather, the focus should be on what the person skilled in the art would identify as those – one or two – invention(s) for which the basic patent was granted in light of the text of the specification and the patent drawings, if any, with reference to his knowledge of the art on the priority date. A second active ingredient to be combined, which was known per se from the study of the basic patent in the view of the skilled person and for which no unexpected effects are disclosed within the active ingredient combination, thus represents a possibly advantageous and preferred modification of the subject matter of the invention, but nothing more than that, namely a variation of that active ingredient and its use that is foreseeable for those of skill in the art and characterises the actual subject matter of the invention of the basic patent (cf. *Actavis v. Sanofi*).

Conversely, a patented combination of active ingredients, alongside a patented single active ingredient, represents a separate, further product (invention) of the basic patent where the contents of the patent, when read with the requisite technical knowledge, indicates to the skilled person that not only the provision of the single active ingredient was filed and recognised as an inventive achievement, but that this is also the case in isolation for the second, combined active ingredient (cf. *Actavis v. Boehringer*). With the same consequences, it is conceivable that, although the second active ingredient of the protected combination is not in itself considered to be inventive, the proposed combination of active ingredients is, whether because, for instance, it claims in advance to have unexpected synergistic therapeutic effects, or whether the combination of active ingredients, despite producing no increased benefit, should nonetheless be surprisingly useful because unexpected additive treatment effects and at the same time reduced side effects are obtained than those to be expected from an application of the inventive single preparation, or whether surprisingly lower side effects are reported (because, for example they cancel each other out) than those that were expected from the two combined active ingredients.

In the context of the above considerations, there is no substantive examination of patentability, which would indeed be inappropriate under Article 3 of the SPC Regulation, as the question of inventive step only arises in principle in the context of a challenge to the validity of the basic patent, while the case of the nullity of an SPC is solely a matter of whether the filed active ingredient represents a protected subject matter of the basic patent (Article 3(a) of the SPC Regulation) and if a certificate has already been granted for it (Article 3(c) of the SPC Regulation). To the extent that it is clarified for the latter purpose – as explained above – whether the basic patent (as worded and as its claims are explained for the person skilled in the art in the descriptive text) has *one* or more invention(s) as its content, only the content of the basic patent is determined by way of interpretation of the property right, but it is not verified whether the contents of the patent specification that are indicative of one or more subject matters of the invention are consistent with the true technical conditions.

If the basic patent merely presents the active ingredient combination placed under secondary protection as one possible embodiment of the invention of the single active ingredient, it is therefore inconsequential that its provision actually constituted an independent invention. No pertinent examination takes place, and the grant of a single SPC for the solely inventive single active ingredient of the basic patent is all that occurs. This is also appropriate, because the patent proprietor would have been at liberty to word the basic patent in a technically accurate manner (scil. in the sense of the existence of two inventions), or else, if he was still uncertain of the independent grantability of the active ingredient combination at the time of the filing of the basic patent, to refrain from mentioning it in the basic patent within the period of time allowed for a separate subsequent application. The basic patent therefore relating only to the single active ingredient

would nevertheless confer patent protection to him against any combination of active ingredients containing the patented active ingredient; at the same time, he would retain the option of a later separate subsequent application for the combination of active ingredients, as soon as their particular (inventive) usefulness had become verifiable. Any patent proprietor who acts strategically inexpediently in this respect by overhastily extending the basic patent to a combination of active ingredients whose surprising usefulness and advantageous effects have not yet been reliably recognised must bear the legal consequences of his actions, given aspects of fairness.

Of course, the reverse constellation is also thinkable where the basic patent wrongly claims two independent inventions, even though no such thing exists at all with regard to the active ingredient combination. According to the foregoing, two certificates would have to have been granted in this case, with this being the case even after an attack on the legal validity of the basic patent; this would be unsuccessful due to the fact that the granted ancillary claim for the combination of active ingredients would have to be valid independent of its own inventive step, as it is supported by the inventive achievement that required the provision of the single active ingredient. If a nullity attack on the basic patent were to be unsuccessful – as described – no interpretation-relevant correction of the descriptive text could take place that addresses the true facts, either (scil. existence of only *one* invention with respect to the single active ingredient). Ultimately, though, there can be no serious doubts that the patent proprietor may not be allowed to illegitimately obtain an additional second certificate, to which he is not entitled according to the objective facts, by means of an objectively incorrect, possibly even deliberately incorrect representation of the technical circumstances. Therefore, for the factual circumstances under consideration, an exception must be allowed to the principle that only the actual content of the basic patent is of interest for the granting of the certificate. As regards the accusation that the basic patent unjustifiably lays claims to two independent inventions, the question (which is per se meaningless at this point) as to whether two independent inventions are truly given is to be investigated in the context of the granting of a second certificate for the combination of active ingredients (as no consideration is given to this in the legal validity proceedings on the basic patent).

(4)

In the case in dispute, the content of the basic patent does not provide sufficient evidence that the combined use of ezetimibe and simvastatin, compared to the single preparation ezetimibe, is capable of supplying advantages that were unforeseeable on the priority date which could suggest that the combination of active ingredients placed under secondary protection is more than a mere modification of the invention of the ezetimibe active ingredient; on the contrary, the circumstances in the case in dispute is quite similar to the one in the main proceedings for which the CJEU already rejected a second certificate in its preliminary ruling in *Actavis v. Sanofi*.

(a)

As in that case, the Regional Court too held that the person skilled in the art can attribute a merely additive therapeutic effect to the disputed active ingredient combination ezetimibe + simvastatin, expressed in the fact that the active ingredient simvastatin that was established on the priority date for cholesterol treatment – as in the previously known prior art – reduces the synthesis of cholesterol in the liver, while ezetimibe also pursues the inventively novel approach of additionally inhibiting the intestinal absorption of dietary cholesterol. Since the basic patent does not suggest at any point that in combination with the active ingredient ezetimibe of the invention, the common active ingredient simvastatin has an unexpected efficacy beyond what is expected in a respective monotherapy, the person skilled in the art can conclude from reading the basic patent that each of the combined active ingredients makes its expected contribution to the cholesterol reduction, namely ezetimibe in the intestine in the manner described in the basic patent for the novel active ingredient, and simvastatin in the liver as was foreseeable by the skilled person having the knowledge of the priority date. It may well be that the usefulness of hydroxy-substituted azetidinones (especially ezetimibe) had not yet been conclusively clarified at the time, because there was no already *approved* active ingredient in this class whose utility and harmlessness had been certified. The Division also cannot rule out, for lack of its own technical expertise, that the person skilled in the art by no means considered the active ingredient combination placed under secondary protection to be self-evident, because it was clear to him that the interactions of the combined active ingredients ezetimibe and simvastatin had not yet been explored and were therefore uncertain. Leaving aside whether and, if so, what legal consequences are to be drawn from the fact that given such a starting position, Injunction Plaintiff would have only made speculative considerations in the basic patent on the efficacy and safety of the active ingredient combination claimed by it, the only decisive factor in the present injunction proceedings is that no such certainty from the view of the skilled person is attainable for the Division without expert advice (which is inadmissible in the proceedings for interim relief on grounds of procedural law) that could cause the issuance of an order for injunctive relief to be justified.

Even though this is no longer decisive in view of the foregoing, the merely additive effect of the combined active ingredients, which take action at different points in the organism, is also consistent with the actual conditions according to the current state of knowledge. With reference to concrete trial results that were the basis for the authorisation of the medicinal product, the Regional Court namely determined that the purely cumulative effects in the reduction of LDL cholesterol result that are shown in the table below:

Active ingredient administration	**Reduction in cholesterol**	**Total reduction in cholesterol**
Monopreparation 10 mg simvastatin	27 %	

Monopreparation 10 mg ezetimibe	19 %	
	Total:	**46 %**
Combination of 10 mg ezetimibe + 10 mg simvastatin		**46 %**

In its appeal, Injunction Plaintiff has nothing to counter the foregoing findings of the Regional Court. In its application (page 9), it itself stated – on the contrary:

> *"The combined use of both hydroxy-substituted azetidinones, such as ezetimibe, and cholesterol biosynthesis inhibitors, such as simvastatin, exploits the combined effect of both active ingredients. On the one hand, the active ingredient ezetimibe reduces the absorption of dietary cholesterol in the digestive tract. On the other, the use of simvastatin ensures that the body's own production of cholesterol* (note: in the liver) *is inhibited. This helps to lower the total amount of cholesterol in the body and thereby prevent atherosclerosis, or to reduce and reverse its harmful effects."*

Consequently, it merely referred elsewhere in the application (page 11) to an increased therapeutic benefit of the combination of active ingredients compared to monotherapy with statins, which obviously does not contravene a purely additive effect of the combined active ingredients in the cholesterol reduction.

(b)
Given that claim 17 equally names various other statins as the active ingredient to be combined with ezetimibe in addition to simvastatin (including lovastatin, pravastatin, fluvastatin), all of which are identified as suitable for cholesterol biosynthesis inhibition, there is no reason to presume that the selection of the specific inhibitor simvastatin could for instance constitute a contribution going beyond what was directly obvious (namely the use of a common statin to influence cholesterol synthesis in the liver). Injunction Plaintiff has nothing of substance to counter these accurate considerations of the Regional Court, either.

Again, nothing else results in the present context, if – solely as a precautionary measure – the current state of knowledge is additionally taken into consideration. In this regard, the Regional Court held – unchallenged by the appeal – that according to the explanations of Injunction Plaintiff's own private expert (Prof. Dr. Assmann), not only simvastatin proved to be effective in combination with ezetimibe, but equally lovastatin, pravastatin and atorvastatin.

c)
Instead, Injunction Plaintiff primarily argues that reduced side effects are associated with the combination therapy, which had made the combination of active ingredients usable for a broad patient population. This aspect too – as the Regional Court

rightly observed – is not mentioned at all in the basic patent and must therefore be disregarded in the legal assessment. In the appellate proceedings as well, Injunction Plaintiff cannot name even a single passage of the specification that deals with the problem of side effects and any related advantages of the combination of active ingredients, but confines itself to inadequate blanket assertions.

There is also no indication that the skilled person could have been aware on the priority date of the basic patent, without an explicit reference in the text of the description, of the relations which Injunction Plaintiff believes give rise to the particular value of its active ingredient combination of ezetimibe + simvastatin, where it states in its application (page 11):

> *"This novel and innovative combination of two different groups of active ingredients made it possible to lower cholesterol levels beyond what was possible with statin therapy alone. In addition, the problem was solved that the use of statins can cause side effects and intolerances. The combination with novel active ingredients such as ezetimibe namely allowed the amount of statin administered to the patient to be reduced, while achieving the same or even better results in terms of lowering cholesterol levels. In other words, the active ingredient combination enables a broader therapeutic window."*

Hence, that the availability of an enteric, low side effect alternative active ingredient (ezetimibe) offers the option of avoiding high statin doses that are associated with significant side effects, by using ezetimibe in lieu of a portion of the harmful statin dose for cholesterol reduction, necessitates the knowledge that hydroxy-substituted azetidinones, and especially ezetimibe, have a significantly lower side-effect potential than statins, notably simvastatin. Nothing has been put forward, nor is anything apparent, indicating a pertinent knowledge in the art independently of a corresponding disclosure by the injunction patent specification. On the other hand, once said knowledge has been attained or is to be assumed in the context of the understanding in the art when reading the basic patent specification, it is a technical triviality that the adverse event record of a therapeutic treatment is necessarily more favourable if the dose of a side effect-intensive active ingredient (simvastatin) is reduced and replaced by the administration of another, side effect-free or low side effect active ingredient (ezetimibe).

(5)

The fact that parallel certificates were deemed grantable for the certificate of injunction in different European jurisdictions does not give rise to a decision that is more favourable to Injunction Plaintiff. Admittedly, the Division must take note of the findings in question and include them in its deliberations; however, it is of course not bound to them. They can therefore only be relevant in the sense and to the extent that they give rise to considerations that are germane to the decision, which are inconsistent with our view of the matter and therefore have to be considered

argumentatively. Considerations that are inconsistent with the decision reached by the Division (i.e. with supporting justifications) are not apparent (to the extent the texts of parallel decisions were even produced in translations into German). As a general rule, the foreign findings are already not based on a correct legal starting point, because the strict binding to the preliminary rulings already handed down by the CJEU in the *Actavis v. Sanofi* and *Actavis v. Boehringer* cases is disregarded.

That aside, the Division is of the opinion that in a case such as this one in any event, it is necessary to obtain a preliminary ruling from the CJEU that specifies the previous case law prior to any decision on the validity of the second SPC. This applies a fortiori in that the certificate of injunction will expire in the near future, which is why the nullity decision can easily be postponed in order to refer to the CJEU. Hence, even if the legal situation were not to be clearly assessed to the detriment of Injunction Plaintiff in light of foreign findings affirming a second certificate, but were instead to be regarded as open, an injunction order would not come into consideration. After all, where the legal validity of the property right of injunction is uncertain, which must be presumed without a preliminary ruling by the CJEU, there can be no interim relief that anticipates the main proceedings.

III.

The decision concerning the costs is based on Section 91 para. 1 ZPO. The order regarding provisional enforceability is based on Sections 708 no. 10, 711, 713 ZPO.

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