Bundespatentgericht
Tribunal fédéral des brevets
Tribunals federale del brevetti
Tribunal federal da patentas
Federal Patent Court

O2017_001

Judgement of 3 October 2017

Judiciary Body of the Court	President Dr. iur. Dieter Brandle, Judge Dr. sc. nat. ETH Tobias Bremi (Reporter), Judge Dr. iur. Christoph Gasser, Judge Prof. Dr. iur. Daniel Kraus, Judge Dipl. Chem.-Ing. ETH Marco Zardi, First court clerk lic. iur. Susanne Anderhalden
Parties to the proceedings	**Mepha Pharma AG,** Kirschgartenstr. 14, 4051 Basel, represented by lic. iur. Andrea Mondini, Schellenberg Wittmer Rechtsanwälte, Löwenstrasse 19, PO Box 2201, 8021 Zurich, technically advised by patent attorney Dr. Andreas Welch, Hepp Wenger Ryffel AG, Friedtalweg 5, 9500 Wil, Plaintiff against **Gilead Sciences Inc.,** 333 Lakeside Drive, US-94404 Foster City, CA, represented by Dr. iur. Simon Holzer, Dr. iur. Kilian Schärli and Dr. iur. Michael Ritscher, Meyerlustenberger Lachenal (Zurich), Forchstrasse 452, PO Box 1432, 8032 Zurich, technically advised by patent attorney Dr. Andreas Schöllhorn, Latscha Schöllhorn Partner AG, Austrasse 24, 4051 Basel, Defendant
Subject	Nullification of an ESZ; Combination Preparation

The Federal Patent Court considers:

Procedural history:

1.

With submission of 3 January 2017 (act. 1) Plaintiff submitted the following prayers of relief:

"(1) The Swiss SPC C00915894/01 "tenofovir disoproxil fumarate + emtricitabine" shall be declared invalid.

(2) Court and attorneys' fees, including costs of the patent attorney necessarily engaged plus value added tax, shall be borne by Defendant."

The statement of claim was, after the parties had agreed on English as the language of the proceedings (act. 1_3), written in the English language.

The supplementary protection certificate C00915894/01 (hereinafter "SPC in dispute") is based on EP 0 915 894 B1 (act. 1_33, following "Basic Patent"), which was granted on 14 May 2003 in the name of the Defendant, as well as on the Swissmedic marketing authorization No. 57316 of 21 March 2006 (act. 1_2 and act. 1_9).

2.

With its statement of defense of 22 March 2017 (act. 8) Defendant requested that Plaintiff's motion shall be entirely dismissed, as well as all costs and fees, including the expenses for the patent attorney's advice, shall be borne by Plaintiff.

3.

The main hearing with reply and rejoinder took place on 21 August 2017 (act. 37). The parties received the minutes of the hearing by letter dated 6 September 2017 (act. 38). On 14 September 2017, Defendant requested a correction and an amendment of the protocol (act. 39). This request was partly approved and the protocol has been amended accordingly (act. 43, act. 44).

Procedural:

4.

The Plaintiff is a corporation based in Switzerland. The Defendant is an American company based in the USA.

According to art. 1 para. 2 IPRG in combination with art. 22 para. 4 LugÜ as well as art. 26 para. 1 lit. a PatGG, the Federal Patent Court has jurisdiction over this matter.

According to art. 110 para. 1 IPRG Swiss Law is applicable.

Facts and statements:

5.

Plaintiff does explicitly not challenge the validity of the Basic Patent, on which the SPC in dispute is based (act. 1 N 51).

6.

Nor does Plaintiff challenge that the SPC in dispute was issued in accordance with the current granting practice of the Federal Institute of Intellectual Property ("IGE") as well as in accordance with the Federal Supreme Court's case law in the Fosinopril decision from 1998 (BGE 124 III 375), since the subject matter of the SPC in dispute is within the scope of protection of the Basic Patent EP 0 915 894 B1.

7.

The Plaintiff only asserts that the application of the Swiss patent law, as far as it refers to supplementary protection certificates, shall be adapted to the case law of the CJEU (cf. act. 1 N 53-81), thus, that it should turn away from the Federal Supreme Court's case practice (especially BGE 124 III 375, Fosinopril) and the granting practice of the IGE. Amongst other things, because the legal provisions for supplementary protection certificates in Switzerland are structured in accordance with those in the European Union and, therefore, the interpretation of the EU legal provisions by the CJEU should be considered by the Swiss courts and granting authorities (act. 1 N 82-86). Further, Plaintiff points out that just recently an initiative was launched by the IGE to adapt the granting practice for supplementary protection certificates in light of the case law of the CJEU (cf. act. 1 N 87-91). All involved parties, including the associations of the originators, have welcomed an adjustment of the granting practice for supplementary protection certificates closer to the case law of the CJEU and asked for a prompt implementation (cf. letter from the associations to the IGE of 7 February 2017 according to act. 34_53). According to Plaintiff, it is obvious that the infringement test laid down in the Federal Supreme Court's case law leads to unjustified results (act. 1 N 92-95, act. 34 S. 15 below and S. 16 above), and the parallel case law in several European countries show that the path taken by the CJEU is the right one (cf. act. 1 N 96-105, act. 34 S. 35 -37).

8.

The Defendant, on the other hand, denies that the SPC in dispute is to be revoked.

This is mainly based on the assertion that the validity of the SPC in dispute is to be assessed according to the law at the time when the SPC in dispute was granted (cf. art. 140b PatG, "at the time of the request", cf. also act. 8 RZ 80 and act. 36). At the time of the application date, only the infringement test was established, and even within the EU the infringement test was applied, since the Medeva decision was only issued in 2011.

Also, Defendant claims that the requirements for a change in practice are not met (act. 36). The Fosinopril decision is almost 20 years old and this is also true for the practice of the IGE. The reasons for a change of practice must be assessed much more strictly the longer the application of law or the concerned practice has been undisputed and unchallenged (act. 8 N 81-84). Furthermore, the legal basis for supplementary protection certificates in Switzerland and the EU are not exactly the same and a change of Swiss case law in light of the case law of the CJEU is therefore not mandatory (act. 9 N 85-89). Furthermore, Defendant points out that the case law of the CJEU regarding supplementary protection certificates has caused more uncertainty than clarity and has led to a series of decisions that still appear to be incomplete and difficult to understand.

Also, the SPC in dispute is not to be revoked even in the event of a change of practice (act. 8 RZ 110-119, act. 36, as well as act. 37 S. 4), because then, due to the constitutional right of property and the Defendant's legitimate expectations (protection of vested rights), a change of practice may only be announced in an obiter dictum, but the new point of view may not be applied to the present case, and no retroactive effect is therefore allowed.

Finally, the SPC in dispute is not to be revoked even in the event of a change of practice with retroactive effect (act. 36, as well as act. 37 p. 21 ff.) because the application of the Medeva case law to the present case does not make the SPC in dispute invalid (act. 8 RZ 120-147).

9.

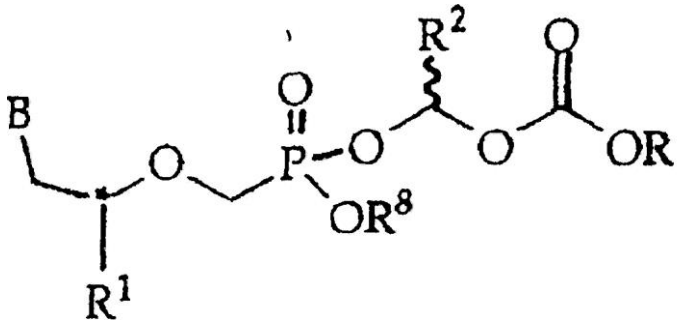
This raises the questions as to whether the established Fosinopril case law of the Federal Supreme Court shall still be relevant or whether it shall be abandoned in light of the CJEU case law and, if the latter is the case, whether the SPC in dispute shall be revoked.

Basic Patent, marketing authorization and supplementary protection certificate:

10.

The Basic Patent (act. 1_33) claims in claim 2 the following active ingredient:

2. The compound of claim 1 having formula (1)



(1)

wherein

B is guanin-9-yl, adenin-9-yl, 2,6-diaminopurin-9-yl, 2-aminopurin-9-yl or their 1-deaza, 3-deaza, or 8-aza analogs, or B is cytosin-1-yl;

R is independently -H, C1-C12 alkyl, C5-C12 aryl, C2-C12 alkenyl, C2-C12 alkynyl, C7-C12 alkenylaryl, C7-C12 alkynylaryl, or C6-C12 alkaryl, any one of which is un-substituted or is substituted with 1 or 2 halo, cyano, azido, nitro or -ORs in which R^3 is C1-C12 alkyl, C2-C12 alkenyl, C2-C12 alkynyl or C5-C12 aryl;

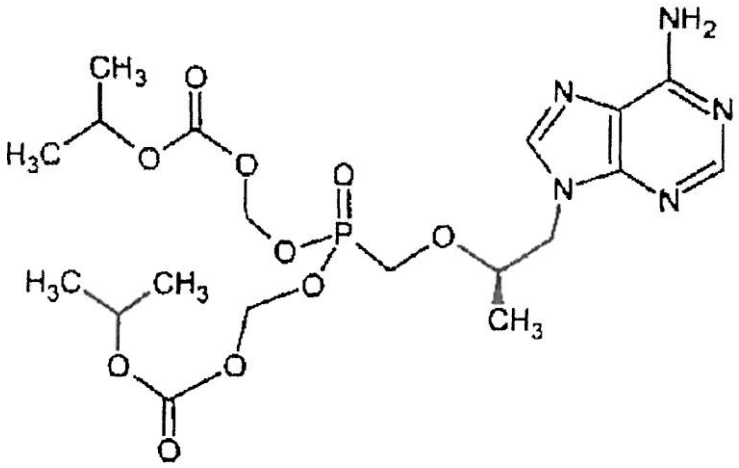
R^1 is hydrogen, -CHs, -CH2OH, -CH2F, -CH=CH_2, or -CH2N3, or R^1 and R^8 are joined to form -CH2-;

R^2 independently is hydrogen or Ci-Ce alkyl; and

R^8 is hydrogen or -CHR^2-0-C(0)-0R, or R^8 is joined with R^1 to form -CH2-;

and the salts, hydrates, tautomers and solvates thereof.

Tenofovir disoproxil, a nucleoside reverse transcriptase inhibitor (NRTIs) as an active ingredient with antiviral effects (cf. Basic Patent claim 26 and [0044], retroviruses and HIV explicitly mentioned), is undisputedly covered by it, because it has the following structure



and therefore literally fulfils claim 2 for the selection R = Isopropyl (claim 15), R^1 = -CHs (claim 4), R^2 = -H (claim 5), R^8 = -CHR^2-0- C(0)-0R (claim 2) and B = Adenin-9-yl (claim 2).

The fumarate salt of tenofovir disoproxil is also covered by the basic patent as the salts of the active ingredient are explicitly mentioned in claims 1 and 2.

11.

In addition, the Basic Patent also includes a generic claim 27, which is inter alia directed at combination products:

27. A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients.

The other active ingredients are only mentioned in paragraph 47 of the Basic Patent and are not specified in more detail:

[0047] While it is possible for the active ingredients to be administered as pure compounds it is preferable to present them as pharmaceutical formulations. The formulations of the present invention comprise at least one active ingredient, as above defined, together with one or more acceptable carriers and optionally other therapeutic ingredients. The carrier(s) must be "acceptable" in the sense of being compatible with the other ingredients of the formulation and not deleterious to the patient.

In addition, the following can be found in connection with aerosol formulations in paragraph 59:

[0059] Formulations suitable for nasal or inhalational administration wherein the carrier is a solid include a powder having a particle size for example in the range 1 to 500 microns (including particle sizes in a range between 20 and 500 microns in increments of 5 microns such as 30 microns, 35 microns, etc.). Suitable formulations wherein the carrier is a liquid, for administration as for example a nasal spray or as nasal drops, include aqueous or oily solutions of the active ingredient. Formulations suitable for aerosol administration may be prepared according to conventional methods and may be delivered with other therapeutic agents. Inhalational therapy is readily administered by metered dose inhalers.

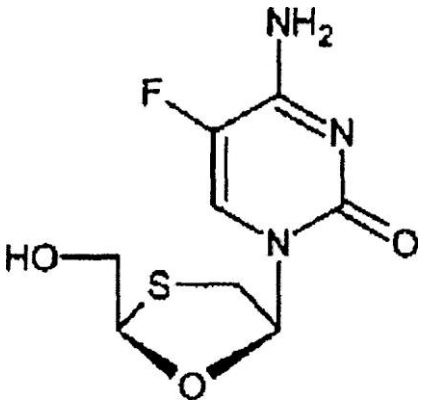
Further information on co-formulations can be found in paragraphs [0061]-[0064], but without specific reference to other therapeutic ingredients.

12.

The Defendant received a first marketing authorization for the active ingredient tenofovir disoproxil fumarate for the product Viread® under No. 56251 on 6 December 2002 (cf. act. 1_20).

13.

Emtricitabine is another NRTI as active ingredient with antiviral effect with the following structure:



14.

The Defendant received a first marketing authorization for the combination of the active ingredients tenofovir disoproxil fumarate together with emtricitabine for the product Truvada® under No. 57316 on 21 March 2006 (act. 1_2 as well as act. 1_9).

15.

Since the Basic Patent undisputedly protects the active ingredient tenofovir disoproxil fumarate, and it is undisputedly not excluded by the claim language of the product claims 1 and 2 of the Basic Patent that this active ingredient is formulated in combination with another active ingredient, and combination products are further expressly protected by claim 27 of the Basic Patent, the combination of the active ingredients tenofovir disoproxil + emtricitabine, which are the subject matter of the relevant marketing authorization, are also undisputedly protected by the Basic Patent.

16.

The SPC in dispute is based on the marketing authorization No. 57316 issued by Swissmedic on 21 March 2006 and was granted for the following combination of active ingredients: tenofovir disoproxil fumarate + emtricitabine (act. 1_2). To this extent, everything is undisputed among the parties.

Assessment according to previous case law:

17.

The combination of active ingredients tenofovir disoproxil fumarate + emtricitabine is a product within the meaning of art. 140a para. 2 PatG, for which a supplementary protection certificate ("Certificate") is granted upon request (art. 140a para. 1 PatG).

At the application date, i.e. on 13 September 2006 (act. 1_2), the following requirements of art. 140b PatG were undisputedly fulfilled:

– The product was protected by the Basic Patent (cf. above, undisputed);

– For the distribution of the product as a drug there was a first marketing authorization for the relevant combination of active ingredients in the form of the marketing authorization No. 57316, which was granted on 21 March 2006 (undisputed).

The other requirements of the 1st section of the 7th title of the Swiss Patent Act were also fulfilled in 2006, therefore Defendant had a valid claim for the granting of the SPC in dispute.

18.

In its Fosinopril[1] decision, the Federal Supreme Court clearly stated that, in addition to the requirements set out in art. 140b PatG, no further requirements may be requested.

[1] BGE 124 III 375 on 10 July 1998.

In particular, regarding the requirements of art. 140b para. 1 lit. a PatG, the Federal Supreme Court confirms that it is only required that the product, in the form in which it is authorized as a drug, is protected by the patent, but not that the product for which a certificate is requested must be specified in the wording of the claims of the underlying patent (so called infringement test).[2]

19.

Whether the validity of the SPC in dispute is to be assessed solely on the basis of the case law and practice in force at the time of the grant of the SPC (main position of Defendant) or whether the assessment is to be made from today's point of view (main position of Plaintiff) can remain open because, as will be explained below, there is no reason to change the practice anyway.

Reasons for a change of practice?

20.

After the Fosinopril decision, it seems that there have been no further decisions of the Federal Supreme Court that had to deal with the issue of combination products and abandoned the infringement test according to the Fosinopril decision.

Following the Fosinopril case law the IGE has also granted supplementary protection certificates for active ingredient combinations, as the one that is protected by the SPC in dispute, for almost 20 years.

21.

In particular, the following aspects discussed below speak against a change of practice and an adaption of the case law of the European Union, i.e. a departure from the infringement test, in connection with the application of art. 140b para. 1 lit. a PatG.

22.

The legal basis for the grant of an SPC in accordance with the PatG is clear and unambiguous. Art. 140b para. 1 lit. a PatG requires that the product is protected by the basic patent, no more and no less. Whether this requirement is fulfilled (infringement test) can be determined by applying general patent rules (in particular art. 51 und art. 66 PatG as well as art. 69 EPC) and the relevant case law. This means that there is no room for another interpretation in specific situations, let alone room for the application of additional requirements for supplementary protection certificates by the Swiss case law.

The introduction of additional requirements that would go beyond the requested protection by the basic patent as required by Art. 140b para. 1 lit. a PatG for the

[2] Cf. paragraph 2.

granting of supplementary protection certificates would probably require an amendment of the law by the legislator.

23.

The case law of the Federal Supreme Court (Fosinopril) on the infringement test is clear and unambiguous and has existed unchallenged for decades.

24.

It is correct that, as the Plaintiff points out, that the supplementary protection certificates were introduced in 1995 into the Swiss Patent Act in order to harmonize with the regulation in force since 2 January 1993[3] in the EU at that time and that those provisions were closely aligned with the European regulation in force at the time.[4] With regard to the procedure for granting the certificates, their registration on the patent register and the publications of the IGE, thus for the regulation of the details at the second level of Swiss law, the Federal Council was instructed in art. 140l para. 2 PatG to take the regulation in the European Community into account.

This instruction is addressed to the Federal Council with regard to the enactment of the ordinance and only stipulates that the regulations in the European Community shall be taken into account.

Therefore, art. 140l para. 2 PatG does not address the civil courts with regard to the interpretation of the law. The civil courts therefore have no obligation to follow EU case law.[5] However, it is taken into account, as outlined below.

[3] Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, published in the Official Journal of the European Communities on 2 July 1992, No L 182/1, now replaced by Regulation No 469/2009 of 6 May 2009.

[4] Cf. message of 18 August 1993, especially p. 712 and 713 as well as 729-734, AS 1995 2879; BBl 1993 III 706.

[5] This in contrast to international agreements such as the Lugano Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, Protocol 2 on the uniform interpretation of the Convention and on the Standing Committee, SR 0.275.12.

The CJEU decision Medeva:

25.

With regards to the need for harmonization, Plaintiff especially invokes the CJEU decision Medeva[6] of 24 November 2011 (cf. act. 1_63-64).

In that case, the basic patent EP 1 666 057 protected a process for the manufacture of a vaccine, wherein two antigens of bordetella pertussis, one as 69 kDa antigen and one as filamentous haemagglutinin antigen, were produced individually and then combined in the vaccine in a certain ratio. The patentee Medeva had applied for a large number of supplementary protection certificates in which, in addition to these two antigens, additional active ingredients were claimed. The UK Intellectual Property Office rejected these applications on the grounds that the supplementary protection certificates mentioned additional active ingredients which were not specified in the claims of the basic patent.

Medeva filed an appeal against this decision with the High Court of Justice of England and Wales, and after the High Court dismissed the appeal, Medeva filed a second appeal with the Court of Appeal (England and Wales). The Court of Appeal referred six questions to the CJEU on the interpretation of Regulation 469/2009 on supplementary protection certificates.

Relevant for the present case are the questions 1-5, which read as follows:

1. Regulation No 469/2009 ... recognises, amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to holders of national or European patents to be under the same conditions, as indicated in recitals 7 and 8 [in the preamble to that regulation], In the absence of Community harmonization of patent law, what is meant in Article 3(a) of ... Regulation [No 469/2009] by "the product is protected by a basic patent in force" and what are the criteria for deciding this?

2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of ... Regulation [No 469/2009] and, if so, what are those further or different criteria?

[6] C-322/10, act. 1_37.

3. In a case like the present one involving a multi-disease vaccine, are there further or different criteria for determining whether or not “the product is protected by a basic patent” according to Article 3(a) of... Regulation [No 469/2009] and, if so, what are those further or different criteria?

4. For the purposes of Article 3(a) [of Regulation No 469/2009], is a multi-disease vaccine comprising multiple antigens “protected by a basic patent” if one antigen of the vaccine is “protected by the basic patent in force”?

5. For the purposes of Article 3(a) [of Regulation No 469/2009], is a multi-disease vaccine comprising multiple antigens “protected by a basic patent” if all antigens directed against one disease are “protected by the basic patent in force”?

The CJEU answered these five questions as follows:

1. Article 3(a) 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 the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.

Thus, the Medeva decision rules on the understanding of art. 3 para. 1 lit. a of the Regulation[7] and on the interpretation of the formulation “protected by the basic patent”, and, states for the granting of a supplementary protection certificate the following negative requirement: The supplementary protection certificate must not refer to active ingredients which are not specified in the wording of the claims of the basic patent *(precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients* ***which are not specified in the wording of the claims of the basic patent).***

According to Medeva, the subject matter of the supplementary protection certificate must therefore be covered by the scope of protection of the basic patent. If this is the case, however, before granting a supplementary protection certificate, it must also be checked whether the supplementary protection certificate refers to active ingredients which are specified in the claims of the basic patent. The supplementary protection certificate can only be granted if this is the case.

[7] Art. 3 of the Regulation No 469/2009: A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application: (a) the product is protected by a basic patent in force; (b)...

Thus, Medeva seems to establish an additional – though negatively formulated – requirement for the infringement test.

26.

The elements of the reasoning of Medeva can be summarized as follows:

In the CJEU decision Farmitalia[8] it was stated that the infringement test had to be assessed in accordance with the (national) patent law regulations due to the lack of harmonization of patent law regulations within the EU.[9]

Paragraphs no. 24-27 of the decision read as follows (emphasis added):

24. It should be noted that Regulation No 469/2009 establishes a uniform solution at European Union level by creating a SRC which may be obtained by the holder of a national or European patent **under the same conditions in each Member State.** It thus aims to **prevent the heterogeneous development** of national laws leading to further disparities which would be likely to create **obstacles to the free movement of medicinal products within the European Union** and thus directly affect the establishment and functioning of the **internal market** (see Case C-350/92 Spain v Council [1995] ECR M985, paragraphs 34 and 35; Case C-127/00 Hassle [2003] ECR 1-14781, paragraph 37; and Case C-482/07 AHP Manufacturing [2009] ECR I-7295, paragraph 35).

25. Moreover, it should be recalled that Article 5 of Regulation No 469/2009 provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) of the Regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent.

26. Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, a SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation.

27. That approach is also borne out by the second subparagraph of paragraph 20 of the explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) ('the explanatory memorandum'), which, in so far as concerns what is 'protected by the basic patent', refers expressly and **solely to the wording of the claims of the basic patent.**

[8] C-392/97 [1999] ECR 1-5553.
[9] Medeva, reasons for decision 21-23.

> That interpretation also accords with that given in recital 14 in the preamble to Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30), which refers to the need for 'products' to be 'the subject of patents specifically covering them'.

27.

With the additional requirement of the Medeva decision the CJEU wanted to harmonize the granting practice of supplementary protection certificates within the EU.

28.

This raises the issue of whether it is appropriate to adopt this Medeva harmonization within the EU in a kind of autonomous implementation for Switzerland. For this purpose it needs to be checked whether the reasons for harmonization given in the Medeva decision also apply to Switzerland.

29.

The application of inconsistent national patent laws for the infringement question is considered to be problematic with regards to supplementary protection certificates (Medeva, para. no. 24), as this could result in contradicting national supplementary protection certificates being granted. This could limit the free movement of medicinal products within the EU, thus directly affect the EU's internal market. Accordingly, the CJEU has to apply an autonomous interpretation.

30.

The other paragraphs (no. 25-27) of the Medeva decision do not provide additional information on other reasons or objectives pursued by the judgement.

Paragraph no. 25 is obviously incomprehensible, which has been confirmed several times in foreign judgments.[10]

Paragraph no. 26 has nothing to do with the facts in the Medeva decision or with the present facts. In the case at hand the question is not how it should be decided if a basic patent only protects a combination of two active ingredients, but the supplementary protection certificate is directed at only one of the active ingredients.

[10] Cf. for example High Court of Justice of England and Wales, Teva, [2017] EWHC 13 (Pat).

The reference in paragraph 27 to the fact that the travaux préparatoires refer to the wording of the claims with respect to the question what has to be understood by "protected by the patent" is also not helpful. This does not go beyond what is required for European patents in Art. 69 EPC and for Switzerland in Art. 51 PatG.

No Application of Medeva in Switzerland:

31.

Switzerland is not part of the EU internal market. The bilateral agreements open only specific sectors. In particular concerning medical products, Switzerland is not linked to the internal market, as for example parallel imports in this area are under certain conditions expressly excluded by law (cf. art. 9a para. 5 PatG).

Therefore, the arguments raised in Medeva with regard to the internal market cannot be transferred to Switzerland, especially not for pharmaceutical products such as the ones here, with state-regulated prices.

32.

In connection with the harmonization of the granting practice for supplementary protection certificates it must also be taken into account that the granting is essentially determined by the harmonization of the marketing authorization system, which has been harmonized at European level.[11]

Switzerland does not participate in this European marketing authorization system nor is this European marketing authorization system automatically recognized in Switzerland. Switzerland has an autonomous marketing authorization procedure.[12] The difference that results from the different marketing authorization systems (time of marketing authorization and scope of marketing authorization) in Switzerland and in the EU lead to different supplementary protection certificates, irrespective of how the authorized product is to be handled regarding the protection by the basic patent.

33.

Even if one were to follow the Medeva case law, this would not lead to a harmonization with the EU in regard to the protection on the basis of supplementary protection certificates, because even then the different marketing authorizations would still lead to different supplementary protection certificates in the EU and in Switzerland.

[11] European Medicines Agencies (EMA), Regulation (EG) No. 726/2004
[12] Swissmedic, Federal Act on Medicinal Products and Medical Devices, SR 812.21

34.

Thus, if one were to follow the Medeva decision, this would not result in essentially identical supplementary protection certificates for the EU and Switzerland, nor would it lead to a significant improvement of the free circulation of medical products. In light of art. 9a para. 5 PatG, the legislature does not want this free circulation of medicinal products anyway.

35.

Accordingly, the reasons given for the harmonization in the Medeva decision cannot, to the extent that they are comprehensible, be applied to Switzerland.

Would it be possible to increase legal certainty and consistency by adopting the Medeva case law in Switzerland?

36.

Ultimately, the Medeva decision attempts to achieve a determination of the criteria that must be met when comparing the basic patent and the requested supplementary protection certificate, which is autonomous and independent from national patent legislation and related case law.

If a harmonization by alignment with the Medeva decision is envisaged, it is necessary to consider in advance whether the objective of harmonization and improved legal certainty has been effectively achieved by the Medeva practice. As it is explained below, this objective has clearly not been achieved, at least at this point in time. To the contrary, the autonomous implementation of a solution that raises more questions than it solves, does not appear to be appropriate.

Additional proceedings before the CJEU:

37.

The Medeva decision was followed by a whole series of further decisions, which, with regards to combination products, had to deal with the interpretation of Art. 3 lit. a of the Regulation.

38.

In the Yeda case (act. 1_42[13]), the basic patent protected the combination of the active ingredients cexitumab und irinotecan. Yeda had requested two supplementary protection certificates, one for cexitumab and one for cexitumab and irinotecan. The question arose as to whether a supplementary protection certificate for cexitumab, although this active ingredient was for itself not covered by the patent claim, only in combination with irinotecan, could also be granted on the grounds that the provider of cexitumab would commit an indirect patent infringement.

[13] C-518/10

With regard to the supplementary protection certificate for cexitumab only, the CJEU ruled that in the case of a combination product, if the combination is protected in the basic patent and the supplementary protection certificate is for one active ingredient only, the supplementary protection certificate may not be granted. It ruled concretely: ... *precluding the competent industrial property office of a Member State from granting a supplementary protection certificate where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient,* **is not the subject of any claim relating to that active ingredient alone.**

39.

In the University of Queensland case (act. 1_40[14]), the CJEU was asked to determine what the ***criteria*** should be, according to which it is determined whether a product is ***protected by the basic patent***. This case was about several supplementary protection certificates for vaccines, and in the decision the CJEU argued similar as in Medeva, but expressed the answers to the questions differently, namely as follows: *as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients* ***which are not identified in the wording of the claims of the basic patent.***

40.

In the Daiichi Sankyo case (act. 1_41[15]), the CJEU also used the same wording in its reply to essentially the same question ***(identified in the wording of the claims).***

41.

In the Eli Lilly case (act. 1_39[16]), in which the CJEU was again asked what ***criteria*** should apply for determining whether a product is ***protected by the basic patent***, it was not a question of whether a supplementary protection certificate for a combined product could be granted. The question was whether a supplementary protection certificate for a specific active ingredient could be granted if the basic patent only mentioned an extremely generic class of ingredients in the claims covering the specific active ingredient. The CJEU explained that in such a situation it was not possible to say that the active ingredient was specified in the wording of the claims.

The CJEU stated (cf. paragraph no. 44) that it was not necessary for the active ingredient to be identified in the claims through a structural formula. If the claims mention the active ingredient in a functional formula, this does not preclude the granting of a supplementary protection certificate, provided that the active ingredient is covered by the scope of protection of the basic patent and the claims implicitly but

[14] C-630/10
[15] C-6/11
[16] C-493/12

necessarily and specifically related to the active ingredient in question (*preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the Interpretation of that provision, that* ***the claims relate, implicitly but necessarily and specifically, to the active ingredient in question).***

42.

In the Actavis/Sanofi case (act. 1_44[17]) the basic patent protected the active ingredient irbesartan. Sanofi had received a first supplementary protection certificate for this active ingredient alone and applied for a further certificate with longer duration for irbesartan combined with hydrochlorothiazide.

In this procedure, the CJEU was again asked what the *criteria* should be, according to which it is determined whether a product is *protected by the basic patent*.

The CJEU held that the second supplementary protection certificate for the combination could not be granted because there had already been a corresponding certificate (the one for the individual active ingredient), thus the requirement of art. 3 lit. c of the Regulation was not met (corresponds to Art. 140c para. 2 PatG).

However, the judgement stated that the aim of the supplementary protection certificate was to take into account ***the core inventive advance that is the subject of the basic patent***.

[17] C-443/12

43.

The Actavis/Boehringer Ingelheim case (act. 1_34[18]) was about the active ingredient telmisartan in combination with hydrochlorothiazid. The basic patent protected telmisartan alone and Boehringer had already received a supplementary protection certificate for this active ingredient on the basis of a marketing authorization for the single active ingredient. On the basis of a marketing authorization for the combination product, Boehringer subsequently applied for a further supplementary protection certificate with the same basic patent, whereby only in the course of the application process the basic patent was amended in such a way that it contained a claim for the combination of the two specific active ingredients telmisartan and hydrochlorothiazide.

In the ruling, the CJEU stated that the active ingredient must constitute the subject-matter of the invention covered by the basic patent *(must constitute **the subject-matter of the invention covered** by that patent, cf. paragraph no. 38),* and in the answer it said that the first authorization is the one which constitutes the sole subject-matter of the invention *(where a basic patent includes a claim to a product comprising an active ingredient **which constitutes the sole subject- matter of the invention**, for which the holder of that patent has already obtained a supplementary protection certificate, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second supplementary protection certificate for that combination).*

Conclusion with respect to the Medeva follow-up cases:

44.

Considering this series of decisions by the CJEU, it can be observed that the CJEU repeatedly had to decide on the fundamental question of which criteria are applicable to determine whether the product is protected by the basic patent in the sense of art. 3 lit. a of the Regulation.

Apparently, the Medeva decision could not clarify the legal situation; it has rather caused uncertainties. The answers given by the subsequent decisions of the CJEU were not suitable either to support a consistent case law or to provide the authorities with better guidelines for the issuance of supplementary protection certificates than the infringement test, on the contrary.

[18] C-577/13.

This can be demonstrated by comparing the different terminology used in each decision:

Decision	*Core statement*
Medeva	***which are not specified in the wording of the claims of the basic patent***
Yeda	***is not the subject of any claim relating to that active ingredient alone.***
Actavis/Sanofi	***core inventive advance that is the subject of the basic patent***
University of Queensland und Daiichi Sankyo	***which are not identified in the wording of the claims of the basic patent***
Eli Lilly	***the claims relate, implicitly but necessarily and specifically, to the active ingredient in question***
Actavis/Boehringer Ingelheim	***the subject-matter of the invention covered which constitutes the sole subject-matter of the invention,***

45.

Plaintiff's argument may fall short that "specified", "subject of", "identified", "relate, implicitly but necessarily and specifically" would always mean the same thing and ultimately define what would be the "inventive advance" or synonymously "the sole subject matter" and would equal "core inventive advance" (act. 34 p. 9-13). It may also fall short if the Defendant describes the CJEU's language as „salad" (act. 37 p. 35), but a certain "terminological confusion" (act. 37 p. 5), as it is also described by the Defendant, or at least a significant uncertainty seems to exist.

It can be assumed that the CJEU would have used the same terminology had it always wanted to express the same thing. Moreover, if the CJEU really intended to express the same thing with the different words, it would have referred to Medeva and refrained from making further decisions with additional guiding principles.

46.

Therefore, it is no surprise that recently in the proceedings [2017] EWHC 13 (Pat) Judge Arnold of the High Court of Justice again submitted the same question to the CJEU with an extensive reasoning:

"What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of the SRC Regulation?"

Despite being a renowned expert in this field of supplementary protection certificates, Arnold was not capable of drawing criteria from the above-mentioned case law which would allow him to determine whether or not a product is protected by the basic patent in the sense of art. 3 lit. a of the Regulation and in light of the Medeva decision and its subsequent decisions.

47.

An attempt of harmonization by alignment with the Medeva case law would therefore not lead to a higher level of legal certainty or consistency, because apparently, it is still unclear within the EU what would be required in addition to the infringement test. Consequently, the granting practice within the EU is still heterogeneous.

Thus, there is no reason to deviate from the infringement test and the proven case law established by the Swiss Federal Supreme Court in its Fosinopril decision.

Attempt to apply the Medeva principles to the present case:

48.

If one would attempt to apply the Medeva case law to the present case, the answer would not be clear for the reasons given below. Also because of that, an adoption of the Medeva case law is not indicated and the Fosinopril case law can be confirmed – at least at this point in time and as long as the CJEU does not define clear criteria.

49.

As described above and not disputed by the parties, the basic patent protects the active ingredient tenofovir disoproxil as fumarate salt. Therefore, the subject matter of the SPC in dispute falls within the scope of protection of the basic patent.

Claim 27 of the Basic Patent protects a pharmaceutical composition that contains a active ingredient like tenofovir disoproxil as fumarate salt together with a pharmaceutically-accepted carrier and optionally, with other active ingredients. This is also described in [0047] of the Basic Patent.

Therefore, a combination of tenofovir disoproxil as fumarate salt in combination with another active ingredient is explicitly specified in the claims of the basic patent, even though only as an option. The individual and specific other active ingredient of the

SPC in dispute, emtricitabine, is not explicitly mentioned in the basic patent - neither in a claim in combination with tenofovir disoproxil as fumarate salt nor elsewhere in the description.

Is it sufficient in the sense of the Medeva case if the generic term (other active ingredient) is mentioned in a claim, and is therefore "s*pecified in the wording of the claims"* in the sense of Medeva?

In support of this point of view, it could be argued that the CJEU considered a supplementary protection certificate admissible in its Eli Lilly decision, where only an extremely generic substance class was explicitly specified in the claims and only a member from an very large number of possible elements from a generic substance class was mentioned instead of a specific substance. Despite the fact that the additional substance emtricitabine is not mentioned, the claims would *relate, implicitly but necessarily and specifically, to the active ingredient in question.*

However, this point of view is not in line with the CJEU decision Actavis/Sanofi according to which tenofovir disoproxil may be considered the core inventive advance of the basic patent, but not the other active ingredient and certainly not the specific selection of the other active ingredient emtricitabine (not the *core inventive advance that is the subject of the basic patent).*

The requirements that have been set by Medeva and the subsequent decisions are unclear und consequently do not allow a clear statement for the present case. The "art. 69 EPC and protocol test" to which the parties have repeatedly referred as the current EU-standard also seems to be self-contradictory, because on the one hand, the disclosure of the description should not be taken into account (cf. act. 37 p. 18), while on the other hand art. 69 EPC and the protocol explicitly stipulate that the description has to be taken into consideration.

Even by trying to apply the Medeva case law by the CJEU to the present case, there would be no answer to the question whether the "SPC in dispute" is legally valid, since the Medeva criteria are unclear.

50.

A similar conclusion is reached by the English Judge Richard Arnold regarding the facts which are under discussion here.[19] The above-mentioned most recent case concerns the exact same basic patent as in the present case, the supplementary protection certificate is based on the same combination, in a only a slightly and insignificantly different wording *(Composition containing both Tenofovir disoproxil, optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with Emtricitabine).* The English judge also felt unable to assess

[19] [2017] EWHC 13 (Pat)

whether, in the light of CJEU case law, the corresponding supplementary protection certificate is legally valid or not.

In addition, the English ruling also states that, despite the case law of the CJEU, contradicting supplementary protection certificates have been granted in different EU member states for the combination of tenofovir disoproxil with emtricitabine (cf. paragraphs 92 and 93).[20]

51.

If harmonization with the CJEU's case law should be considered at all, it appears to be premature to adjust the Swiss case law at any rate, as long as there is no comprehensible and clearly enforceable case law on the part of the CJEU. An attempt to adopt the CJEU's case law at the present time would only lead to an increase in legal uncertainty.

There is currently no clear convergence of the CJEU's case law in sight, i.e. it is not to be expected that this situation will improve in the short or medium term.

Summary:

52.

The infringement test, as confirmed by the Federal Supreme Court in its Fosinopril decision, is simple and comprehensible and leads to a high level of legal certainty. By contrast, the case law of the CJEU is not suitable for determining in a simple and comprehensible manner whether a supplementary protection certificate can be granted for a product in the light of the basic patent. This can be shown by a never-ending series of submissions, which - after the CJEU decision Medeva (C-322/10) - led to a series of attempts by the CJEU to make the case more specific, and resulted once again in a submission question regarding the same facts as in the present case.

Therefore, as long as there is no established case law of the CJEU which would lead to a higher degree of legal certainty for applicants and third parties, a change in Swiss case law is not indicated. The strict requirements for a change of practice are clearly not fulfilled.[21]

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[20] In his decision, Judge Arnold makes a suggestion as to how, in the sense of the Medeva decision, it could be assessed whether a combined preparation could possibly be protected by a protection certificate (see reason for decision 97). He believes that the combination can only be protected by a protection certificate if the combination achieves the inventive advance (or technical contribution) of the basic patent. Such an approach, which is ultimately based on statements from the CJEU's Actavis/Sanofi ruling, does not seem to lead to better results. The claim principle (cf. art. 51 PatG), which has just been introduced to create legal certainty for third parties, would thus be supplemented without a legal basis by further vague concepts in the sense of the "core idea of the invention" or "technical progress", which would hardly allow to increase legal certainty, on the contrary.

[21] Cf. BGE138 III 270 para. 2.2.2. with further references.

53.

The action for invalidity is therefore dismissed accordingly.

Court costs

[para. 54 deals with the court costs]

The Federal Patent Court rules that:

1. The action is dismissed.

2. The court fee shall be set at CHF 60'000-;
   Further costs amount to: CHF 1'908.35; translation costs.

3. The court costs of CHF 60,000 will be charged to the Plaintiff and offset against the advance payment. The further costs of CHF 1,908.35 (translation costs) are charged to the Defendant.

4. The Plaintiff is obliged to indemnify the Defendant for party costs of CHF 50’000.

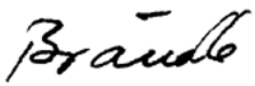
5. Written communication to the parties, to the Defendant accompanied by invoice No. 1185000910 and after the decision as become final, to the Swiss Federal Institute of Intellectual Property, each against confirmation of receipt.

Instruction on rights of appeal:

This decision may be appealed within 30 days of its receipt by filing appeal in civil matters to the Federal Supreme Court, 1000 Lausanne 14 (art. 72 et seq., 90 et seq and 100 of the Swiss Federal Supreme Court Act of 17. June 2005 [BGG, SR 173.110]). The submission shall be written in an official language and shall contain the requests and the reasons together with a statement of evidence and signature. The contested decision and the evidence, as far as it is in the possession of the appellant, shall be attached. (cf. art. 42 BGG).

St. Gallen, 3 October 2017

In the name of the Federal Patent Court

President	First court clerk
	
Dr. iur. Dieter Brändle	lic. iur. Susanne Anderhalden

Sent by mail: 4 October 2017