Bundesgericht
Tribunal fédéral
Tribunale federale
Tribunal federal
Federal Supreme Court

4 A_576/2017

Decision of 11 June 2018
1st Civil Law Division

Members of the Court

Federal Judge Kiss, President,
Federal Judges Klett, Hoh, Niquille, May Canellas.
Court clerk Leemann.

Parties to the proceedings

A._____AG,
represented by attorney Andrea Mondini,
Appellant,

against

B._____Inc.,
represented by attorneys Dr. Simon Holzer, Dr. Kilian Schärli and Dr. Michael Ritscher
Respondent,

Subject matter

Supplementary Protection Certificate,
Appeal against the decision of the Federal Patent Court of 3 October 2017 (02017_001).

Facts:

A.

A.a A._____AG, (Plaintiff, Appellant), among other things, has the purpose of distributing and manufacturing drugs and chemical products.

A.b B._____Inc. (Patent Holder, Defendant, Respondent) with registered offices in the United States is the holder of the European patent xxx. On 21 March 2006, Swissmedic granted the authorization for a medicinal product. On that basis, the patent holder was granted the Supplementary Protection Certificate (SPC) no. yyy for "tenofovir disoproxil fumarate + emtricitabine" on 29 August 2008.

A.c By submission of 3 January 2017 to the Federal Patent Court, the Plaintiff requested Respondent's Swiss SPC to be declared invalid. The Plaintiff claimed that the Swiss practice on the interpretation of Art.140a et seqq. of the Swiss Federal Patent Act (*PatA*) should be disregarded and adapted to the case law of the Court of Justice of the EU (CJEU). Following the so-called Medeva practice, the Respondent's SPC was to be declared valid, according to the Applicant.

A.d With its decision of 3 October 2017, the Federal Patent Court dismissed the revocation action. The court came to the conclusion that the Respondent's SPC yyy was valid under the so-called infringement test (BGE 124 III 375). There was no reason for a change in case law according to this decision, since the CJEU's practice was not clear, but the Medeva ruling of the CJEU had led to further referrals of national courts, which themselves had not clarified the criteria by which within the meaning of Art. (3)(a) of the relevant EU regulation it should be assessed whether "the product is protected by a basic patent in force".

B.

B.a By its appeal in civil matters, the Appellant seeks (1) the annulment of the Federal Patent Court decision of 3 October 2017 and the acknowledgment of the invalidity of the SPC yyy for "tenofovir disoproxil fumarate + emtricitabine", (2) in the alternative, the annulment of the decision under appeal and the referral of the case back to the lower court with the instruction that a new decision must be made in the sense of the considerations of the Federal Supreme Court. The Appellant

asserts that the lower court interpreted Art. 140b (1) PatA in breach of federal law.

B.b In its response to the appeal in civil matters submitted by the Appellant, the Respondent requests the dismissal of the appeal, to the extent possible; in the alternative, that the case be referred back to the lower court. The Respondent argues that a change of practice was not indicated in the present case, but that this would have not changed the outcome of the proceedings anyway, since the contested certificate was validly granted in any event and, as such, there was no ground for invalidity; in addition, even if the CJEU practice were applied, the SPC would be valid for tenofovir disoproxil fumarate and emtricitabine since that combination was specified by the basic patent to the person skilled in the art as set forth by Art. 69 EPC.

B.c The parties submitted an unsolicited reply and rejoinder.

B.d Together with its submission of nova on 26 April 2018, the Appellant submitted the Opinion of the Advocate General in CJEU proceedings C-121/17.

By submission of 11 May 2018, the Respondent commented on the foregoing.

B.e By submission of 30 May 2018, the Appellant filed the minutes of the hearing of the German Federal Patent Court held on 15 May 2018 and a decision issued by the Paris Tribunal de Grande Instance on 25 May 2018. Since this submission of nova was not decisive for the decision at hand, it was not sent to the Respondent.

Considerations:

1.
This appeal in civil matters (Art. 72 of the Swiss Federal Supreme Court Act, *SCA*) is directed against a final decision (Art. 90 SCA) of the Federal Patent Court (Art. 75(1) SCA); the Appellant lost the first instance dispute (Art. 76 SCA) and a specific value in dispute is not required (Art. 74(2)(e) SCA). The appeal, which was submitted in time (Art. 100 SCA), is therefore admissible subject to the requirement of a sufficient reasoning (Art. 42(2) and 106(2) SCA).

2.
According to Art. 140a(1) of the Federal Law of 25 June 1954 on patents for inventions (Swiss Federal Patent Act; SR 232.14), the Swiss Federal Intellectual Property Institute (IPI) grants a supplementary protection certificate for active ingredients and combinations of active ingredients of medicinal products upon request (certificate, hereinafter also "SPC" [Supplementary Protection Certificate]). Active ingredients or combinations of active ingredients are referred to as products (paragraph 2). The certificate is issued under Art. 140b PatA for Inventions if, at the filing date of the application, "the product as such, a process for its manufacture or its use is protected by a patent" (lit. a), and official authorisation has been granted for placing the product on the market in Switzerland as a medicinal product (lit. b).

2.1 The supplementary protection certificate is intended to compensate for the fact that the time-consuming regulatory approval procedure for pharmaceuticals delays the market launch and thus shortens the remaining patent protection term (BGE 124 III 375 consid. 1 p. 376 with further references, see also KILIAN SCHÄRLI, Das ergänzende Schutzzertifikat für Arzneimittel, Luzerner Beiträge zur Rechtswissenschaft, Vol. 73, 2013, para. 11 p. 5; CHRISTOPH GASSER, Das ergänzende Schutzzertifikat, in: Patentrecht und Know-how, unter Einschluss von Gentechnik, Software und Sortenschutz,, SIWR Vol. IV, 2006, p. 683). The certificate is issued following the first authorization as a medicinal product for a period not exceeding five years; this is calculated so that the effective protection period for an approved medicinal product can be a maximum of 15 years, with the "SPC" protection beginning with the expiry of the basic patent (see also CHRISTOPH BERTSCHINGER, Quasi-Verlängerung des Patentschutzes: Ergänzende Schutzzertifikate, in: Schweizerisches und europäisches Patentrecht, , Vol. VI, 2002, para. 10.9 p. 342, para. 10.21 p. 348; SCHÄRLI, ibid., para. 47 et seqq. p. 18).

2.1.1 In contrast to US or Japanese regulations (see STEFAN KOHLER/LUKAS FRIEDLI, Ergänzende Schutzzertifikate für Arzneimittel, sic! 2011 p. 92; BERTSCHINGER, ibid., para. 10.3 p. 340; GASSER, ibid., p. 685 et seqq.), such compensation for the time-consuming authorization procedure for medicinal products is not achieved by a temporal extension of the patent protection, but by an independent intellectual property right. Unlike the patent, this independent exclusive right does not protect a technical teaching, but a preparation (see KOHLER/FRIEDLI, ibid., p. 93; SCHÄRLI, ibid., para. 73 et seqq.). At least, it concerns a

dependent property right that is only valid within the framework of a valid patent (Art. 140b(1)(a) PatA). In addition, its grant depends on an official authorization to place the product on the Swiss market as a medicinal product (Art. 140b(1)(b) and (2) PatA, see in particular Art. 9(1) of the Federal Law of 15 December 2000 on medicinal products and medical devices [*TPA*; SR 812.21] and BGE 141 II 91 consid. 2 p. 96; 132 II 200 consid. 1; SCHÄRLI, ibid., para. 246).

2.1.2 According to the original CJEU practice on Art. 3 of the European SPC Regulation, it was left to national case law to decide which requirements had to be met for a product to be "protected by a basic patent in force" (see KILIAN SCHÄRLI/SIMON HOLZER, Ergänzende Schutzzertifikate für Wirkstoffkombinationen?, sic! 2012 p. 289). After that, different national case laws have developed. While in some countries – as in Switzerland – a product was considered protected by a basic patent as long as it falls within its scope of protection ("infringement theory"), case law in other EU Member States required (in line with the "disclosure theory") that the product be disclosed or specified in the claims of the basic patent (see SCHÄRLI, ibid. paras. 203, 205).

2.1.3 With the "Medeva" judgement (C-322/10 of 24 November 2011 *Medeva BV*, Slg. 2011 1-12051), the CJEU in conclusion supported the interpretation of Art. 3 of European Regulation 469/2009 of 6 May 2009 on the supplementary protection certificate for medicinal products which required that the product must be specified in the claims of the basic patent in order for an SPC to be granted (SCHÄRLI/HOLZER, ibid., p. 287, also see KLAUS GRABINSKI, in: Benkard, Europäisches Patentübereinkommen, 2nd Ed., Munich 2012, N 41 on Art. 63 EPC). Consequently, the questions submitted to the court in that case were answered in such a way that, in relation to combination products (medicinal products with multiple active ingredients), the active ingredients claimed as a product (i.e. as an active ingredient or combination of active ingredients) must be specified in the claims of the basic patent, but however, that there was no harm if the authorized medicinal product contained further active ingredients. As clarified in decision C-518/10 of 25 November 2011 (Yeda Research and Development Company Ltd ["Yeda"], ECR 2011, I-12209), a product cannot be claimed for just one single active ingredient if this [active ingredient] is claimed only within a combination of active ingredients in the basic patent. Finally, in decision C-493/12 of 12 December 2013 (Eli Lilly and Company Ltd ["Eli Lilly"]) it was clarified that active

ingredients are also specified in the claims of the basic patent even if these claims, pursuant to Art. 69 of the European Patent Convention of 5 October 1973, revised in Munich on 29 November 2000 (EPC 2000; SR 0.232.142.2), interpreted in the light of the description, implicitly but necessarily and specifically cover the relevant active ingredient.

2.2 A change in case law of the Federal Supreme Court can generally only be justified if the new solution corresponds to a better understanding of the ratio legis, to changes of external circumstances or to a change of the legal perspective; otherwise the current practice is to be maintained. Therefore, a change of practice must be based on serious substantial grounds, which – in particular in the interest of legal certainty – must be all the more relevant, the longer the law considered incorrect or no more up to date has been applied (BGE 143 IV 9 consid. 2.4; 138 III 359 consid. 6.1; 136 III 6 consid. 3; 135 I 79 consid. 3 p. 82; decision 4A_7/2018 of 18 April 2018 consid. 2.3.1, intended for publication).

2.2.1 The instrument of the Supplementary Protection Certificate seeks to compensate for the loss of time caused by the medicine registration procedure, in order for the research industry to recoup its investment (above, para. 2.1). This purpose can be achieved in different ways. As a consequence, the extension of protection for medicinal products is not only regulated in a variety of different manners but it is also generally subject to further requirements; the design of the regulation is namely based on the balance of the interests of all stakeholders belonging to the health and pharmaceutical sector. By the different interpretations of the protection requirement under which the claimed product must be "patent protected" (or "protected by a basic patent in force"), the objective of the protection extension is achieved regardless of whether the infringement or the disclosure theory is applied. As to the actual design, however, the Swiss SPC regulation deviates from that of the European Union or those of neighbouring states if the previous practice is maintained. Given the foregoing it may be assumed that CJEU case law based on the theory known as disclosure theory, may now be considered as established.

2.2.2 The instrument of the Supplementary Protection Certificate has been adopted from EU law. In the Federal Council's message of 18 August 1993 on the amendments of the Swiss Federal Act on Patents for Inventions (BBI 1993 III 708), Art. 3 of the Regulation is expressly referred to. According to such article

the product, at the time of the application for obtaining the relevant certificate, must be protected by a patent in force and a valid authorization for marketing it as a medicinal product must be available (BBI 1993 III 711). The Federal Council proposed that the EU (formerly EC) regulation should be adopted by taking a substantive approach and initially justified this with a general endeavour to model Swiss law as compatibly as possible with European law, but also added in particular that the European solution was well-thought-out, so that it could be expected to prove effective; and that furthermore the EU Regulation will be applicable to Liechtenstein as part of the EEA (BBI 1993 III 712 et seqq.). The endeavour to align Swiss regulations to the law of neighbouring EU states to the extent possible is considered in the interpretation of the corresponding legal provisions according to consistent practice of the Federal Supreme Court, particularly in the context of teleological and historical interpretation (see BGE 137 II 199 consid. 4.3.1 p. 209; 130 III 182 consid. 5.5.1 p. 190; 129 III 335 consid .5.1 p. 341 and consid. 6 p. 350, with further references). It must be examined whether the current established case law of the CJEU, which differs in particular with regard to SPCs for combination products, justifies a change of the Swiss practice.

2.2.3 In view of the alignment of Swiss law to European legal developments pursued by the legislator, the interpretation and application of the corresponding European provisions cannot be disregarded when interpreting Swiss law. Given the concretisation and specification of harmonized provisions carried out by legal practice and their further development over time, alignment can only be achieved to a limited extent with a (single, selective) change in the law. If the revision of the law is also aimed at achieving a co-directional development, this requires a harmonized interpretation and application of the corresponding provisions. With respect to the interpretation of parallel EU provision the CJEU practice must be considered in particular, since it is binding for EU member states. A CJEU practice divergent from Swiss case law regarding the application of an autonomously adopted regulation can thus constitute a serious reason for a change of practice, if the aim of the legislator, to harmonize Swiss law with EU law, should be maintained. Of course, it is always necessary to examine whether the solution supported by the CJEU is in line with what the Swiss legislator intended to achieve by the autonomously adopted regulation or, on the contrary, whether there are better reasons for maintaining the deviating Swiss legal practice.

2.2.4 In Switzerland, it has been noted that the case law on the interpretation of parallel provisions by the CJEU on one side and by the Federal Supreme Court on the other side has developed differently. Efforts have therefore been made by the IPI in particular to initiate a change in the granting practice in line with the "Medeva" decision. As a result of a consultation process, a letter from the IPI of 13 January 2017 which contained principles for the planned amendment of the relevant Granting Directive (13.2.1); the interested parties have essentially agreed to this proposal, believing that the proposed new Directive will enable the criteria of the CJEU's "Medeva" decision to be implemented in a manner that provides sufficient legal certainty and consistency. The fact that the interested parties favour the adaptation of Swiss practice to the CJEU case law may be considered a strong indication of the belief that the CJEU practice mentioned above should also be adopted in Swiss legal practice, to ensure the conformability of the regulation regarding supplementary protection certificates pursued by the legislator.

2.2.5 The interpretation of the protection requirement of Art. 140b (1)(a) PatA for inventions "protected by a patent" in BGE 124 III 375 differs conceptually from the interpretation of Art. 3 of the applicable EU Regulation "protected by a basic patent in force" by the CJEU. Based on the infringement theory in contrast to the disclosure theory not only individual disputes are handled differently. This would be the inevitable consequence of the fact that the Swiss courts are not obliged to submit legal questions to the CJEU and to follow CJEU case law. Rather, it is a fundamentally different understanding of the granting requirement "protected by a (basic) patent in force", which is why a parallel development of legal practice on supplementary protection certificates appears to be no longer possible. The aim pursued by the Swiss legislator of harmonizing the protection level for the institute of Supplementary Protection Certificates with that of neighbouring countries is therefore not achieved. Since the CJEU practice now appears to be established, there are genuine reasons for changing Swiss case-law in order to adapt it to the concept pursued by the CJEU. The assessment of the protection, in particular with regard to combination products, which differs from previous Swiss practice, was considered to be legally correct and coherent by the interested parties. The fact that CJEU case law is not clear in every detail, as the lower court points out, does not change the fact that a practice change in the sense of an adaption to the European concept of the so-called disclosure theory seems appropriate.

2.2.6 BGE 124 III 375 cannot be upheld anymore. If the basic patent specifies only one of two active substances, a product cannot be claimed as a supplementary protection certificate after the drug's authorization if it contains two active substances. Rather, Art. 140b PatA must be interpreted in accordance with the European practice (Art. 3 of Regulation (EC) No 469/2009) in such a way that the active substances of the product must be specified in the basic patent by designating them in the patent claims or in which the patent claims – in the light of the description (Art. 51(3) PatA, Art. 69 EPC 2000) – at least implicitly but necessarily relate to these active substances in a sufficiently specific manner.

3.

Since the lower court based its decision on the infringement theory, which, due to the change of practice is no longer applicable, and the subject of certificate no. yyy undoubtedly falls within the scope of protection of the basic patent xxx, it has not been conclusively examined whether the disputed supplementary protection certificate could have been granted if, at the time of grant, it had been examined whether the active ingredients claimed by the product were specified at least implicitly but necessarily in the claims of the basic patent (disclosure theory). It also left open as to whether the supplementary protection certificate, which was undeniably legitimately granted based on the prevailing practice at that time, should be revoked in the event of a later change in case-law of the granting requirements.

Both questions are dealt with controversially by the parties in the present proceedings. While the first question raises issues concerning patent law, the second one provides for a general legal problem. Since both parties have commented in detail on those questions, it is justified, for reasons of procedural economy, to assess how the change in case law will affect the already validly granted protection certificates, namely whether the supplementary protection certificate yyy ("tenofovir disoproxil fumarate + emtricitabine") remains valid for the case – which has not been conclusively assessed – that the granting requirements under the disclosure theory were not met. The SPC yyy was granted to the Respondent following its application of 13 September 2006 based on xxx and on the basis of the Swissmedic authorization (of 21 March 2006) on 29 August 2008 with the term of protection starting from 25 July 2017.

3.1 Art. 140k(1) PatA concerns the invalidity. According to this, the certificate is invalid if

(a) it was granted contrary to Art. 140b, 140c(2), Art. 146(1) or Art. 147(1), (b) the patent lapses before its maximum term expires (Art. 15 PatA), (c) the patent is declared null and void, (d) the patent is limited to the extent that the product for which the certificate was granted is no longer covered by the claims, (e) after the lapse of the patent, grounds exist which would have justified the declaration of nullity of the patent under letter c or a limitation under letter d.

The Appellant is of the opinion that the SPC is invalid because the requirements for the relevant granting were never met (Art. 140k(1)(a) PatA). It was argued, in particular, that the requirement set forth in Art. 140b(1)(a) PatA was never satisfied, according to which a certificate is issued "if, at the time of application (a) the product as such, a process for its manufacture or its use is protected by a patent".

3.2 This view according to which the requirements for granting the protection certificate were never satisfied if pursuant to amended case-law on the interpretation of Art. 140b PatA they should no longer be met, cannot be followed. The Appellant rightly does not deny that the contested requirement, according to which the product must be "protected by a patent", was met in accordance with the legal practice at the time of the grant. According to the legal situation at the time of granting the SPC, the supplementary protection certificate was not issued contrary to Art. 140b in the sense of Art. 140k PatA. Rather, it must be assumed that the requirements were met at the time of granting, according to the interpretation of Art. 140b(1)(a) PatA and the corresponding practice for granting supplementary protection certificates, relevant at that time. The supplementary protection certificate for the contested product was granted to the Respondent with a formal and legally binding decision. It was not granted contrary to Art. 140b PatA and therefore there is no ground for invalidity according to Art. 140k PatA. Rather, it must be examined, in accordance with general principles, whether the change of case-law justifies the revocation of the order granting the certificate in dispute and thereby favouring the Respondent.

3.3 According to the general principle on intertemporal law under Art. 1 of the Final Title of the Swiss Civil Code (*Schlusstitel zum Schweizerischen Zivilgesetzbuch - SchlT ZGB*), the legal effects

of circumstances which occurred previously remain subject to those provisions of federal or cantonal law which were applicable when the circumstances occurred (paragraph 1). Accordingly, the legally binding nature and consequences of acts which took place before the commencement hereof remain subject to the law which was applicable at the time (paragraph 2). An exception applies to legal norms drawn up for the sake of public policy and good morals (Art. 2 SchlT ZGB). Furthermore, the legal effects of circumstances which occurred while the previous law was still in force and which enjoy no protection under the new law are subject to the latter once it has come into force (Art. 4 SchlT ZGB, cf. Art. 1 et seqq. of the Final Title of the Swiss Civil Code BGE 140 III 404 consid. 4.2 p. 406 with references).

If a change of law had occurred after the grant of the supplementary protection certificate, in principle the certificate could not be taken away from the entitled party (subject to Art. 2 of the Final Title of the Swiss Civil Code) even if under the new law the grant would no longer be possible. Since, with the grant of the certificate, the patent holder is essentially granted the right to prevent others from commercially using the product with respect to all l uses as medicinal products authorized before the expiry of the certificate (Art. 140d in connection with Art. 8 PatA). In principle, this legally protected right cannot be revoked due to a change in the law concerning the granting requirements (see also, for the constitutional prohibition of retroactivity, BGE 138 I 189 consid. 3.4 p. 193 et seqq., with references, decision 2C_1105/2016 of 20 February 2018 consid. 4.1, intended for publication).

3.4 In principle, legally binding administrative orders cannot be reconsidered or revised due to a change in case law. The Federal Supreme Court particularly stated this with respect to administrative decisions regarding pension payments and continuous payments of the social insurance (BGE 141 V 585 consid. 5.2; 135 V 201 consid. 6.1.1 p. 205, 215 consid. 5.1.1; 129 V 200 consid. 1.2 p. 202; 121 V 157 consid. 4a p. 162; 120 V 128 consid. 3c p. 132; 119 V 410 consid. 3b p. 413; 115 V 308 E. 4a/dd p. 314). Accordingly, a change of practice may, by way of exception, only lead to the amendment of a final order (with effect for the future) if the new practice becomes generally applied to such an extent that failure to comply with it would appear to be a breach of the principle of equality, especially if the former practice would only be maintained with regard to a single

insured person or a small number of insured persons, so that non-compliance in a single case would appear as inequitable privileged treatment and as violation of the principle of equal treatment (BGE 135 V 201 consid. 6.1.1 p. 205 et seqq., 215 consid. 5.1.1 p. 219 et seqq., each with references).

3.5 In principle, a final and binding order cannot be revoked if the interest in the protection of legitimate expectations prevails over the interest in the correct implementation of the objective law: this is generally the case if the administrative decision has established a subjective right or if the administrative decision was issued in a proceeding in which the opposing interests were to be mutually examined and weighed against each other, or if the private individual had already made use of a right granted to him by the order. However, this rule is not absolute: even in those three cases, revocation can be considered if required by a particularly important public interest (BGE 137 I 69 consid. 2.3 p. 71 et seqq.; 127 II 307 consid. 7a p. 313 et seqq.; 121 II 273 consid. 1a/aa p. 276; each with references).

3.6 With the Supplementary Protection Certificate the Respondent was granted an exclusive right, according to which it can prevent others from commercially using the product with respect to all the uses as medicinal products authorized before the expiry of the certificate (Art. 140d in connection with Art. 8 PatA). This right was granted within a proceeding in which the requirements for granting were thoroughly examined. Even if the legal effects of the protection certificate granted by decision of 29 August 2008 only commence with the expiry of the patent protection of the basic patent on 25 July 2017, the Respondent's interest in protecting its legitimate expectation is substantial. On the opposite, no particularly important public interest regarding the retrospective application of a change in case law to an already issued SPC is recognizable. The public interest in equal treatment of all those subject to the law, which appears significant in the field of social insurance, hardly exists in the case at hand. Besides the fact that the number of registered and granted certificates is rather low, despite their economic importance, (see SCHÄRLI, ibid., paras. 18 et seqq. p. 7 for the years 1995 to 2011), the purpose of granting an SPC is precisely to provide the holder with the privilege of an exclusive right to market the product. If a change in case law limits the granting prerequisites for certain situations, as in this case, the interests of the other market participants are considered of higher

significance and the balancing of interests in general – including public interests in health care – is carried out in a different manner. However, this changed assessment and balancing of the interests involved does not justify the revoking of legally acquired rights.

3.7 On 29 August 2008 the Respondent was formally and lawfully granted the supplementary protection certificate no. yyy. Such certificate could not be revoked even in case the requirement provided for in respect of the granting at hand, namely "protected by a patent" within the meaning of Art. 140b PatA according to the now changed practice, was no longer met. As a result, the appeal shall be dismissed.

4.

The appeal is dismissed. Considering the outcome of the proceedings, the costs are to be borne by the Appellant (Art. 66(1) SCA). In addition to that, the Appellant must pay a reimbursement to the Respondent for the party costs of the proceedings before the Federal Supreme Court (Art. 68(2) SCA).

Accordingly, the Federal Supreme Court decides that:

1.

The appeal is dismissed.

2.

The court costs of CHF 15,000.- will be charged to the Appellant.

3.

The Appellant must pay the Respondent a reimbursement of CHF 17,000.- for the party costs in respect of the proceedings at hand.

4.

This decision will be communicated in writing to the parties and the Federal Patent Court.

Lausanne, 11 June 2018

On behalf of the 1st Civil Law Division

of the Swiss Federal Supreme Court

The President:	The court clerk:
[SIGNATURE]	[SIGNATURE]
Kiss	Leeman

[STAMP]