Conditions for Obtaining an SPC in Switzerland – Quo Vadis?
Switzerland Moves Away from the Infringement Theory

Kilian Schärli
Dr., LL.M.,
Meyerlustenberger Lachenal Ltd., Zurich/Zug

Marco Borer
MLaw,
Meyerlustenberger Lachenal Ltd., Zurich/Zug

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I. Introduction
In deviation from its long-standing practice concerning the granting requirements for Supplementary Protection Certificates (SPCs), the Federal Supreme Court (FSC) harmonizes the interpretation of art. 140b para. 1 lit. a Patent Act (PatA) with the case law of the European Court of Justice (CJEU): in a landmark decision (BGE 144 I 11285), the FSC replaces the infringement theory with the disclosure theory. This article presents the relevant judgments of the Federal Patent Court (FPC), the FSC as well as the CJEU decisions and examines the change of practice, its effects on granted and pending SPCs and discusses a potential further harmonization with EU case law.
A. Importance of the SPC
As a rule, 8 to 12 years of the regular patent term have already elapsed for a patent holder before a medicinal product with a new active ingredient obtains its first marketing authorization (MA) and thus paving the way for an economic use in the form of the marketing of a product protected by the patent. The effective remaining and usable exploitation time of the patent is reduced by the time span between the patent application and the MA. Since the development of an active ingredient to a marketable product is an enormously costly and time-consuming process, the erosion of the patent term is accompanied by drastic economic deficits. Against this background, the SPC compensates the holders of pharmaceutical or plant protection patents against patent holders of products that do not require an MA. The aim of the SPC is to guarantee an effective term of protection of 15 years, whereby the SPC applies for a maximum of 5 years. Achieving this goal, however, requires that the duration of the MA procedure does not exceed 10 years. The SPC is a sui generis right and is located at the interface between patent law and authorization law. The two legal systems differ fundamentally. Patent law aims to protect innovative activity and reward creative inventions, while the function of the authorization law is to ensure that reliable, safe and scientifically-founded health care is provided to the population. The interests of the actors involved are just as contradictory: On the one hand, the interest of the generic companies to enter the market as quickly as possible is counteracted by the interest of the originators in the continuation of their protected market position. On the other hand, patients have an interest in not only cost-effective but also in new and innovative medicines.

In view of this conflict-ridden legal relationship, it is not surprising that Switzerland is now confronted by the SPC saga regarding the question of when a product is protected by the basic patent. Thus, the Swiss courts reconsidered their previous case law on the conditions for granting SPCs, which has finally led to a groundbreaking new practice.

B. Requirements for Obtaining an SPC – Switzerland Moves Away from the Infringement Theory
1. Requirements for Obtaining an SPC According to Art. 140b PatA
Art. 140b PatA contains the essential substantive granting requirements for obtaining an SPC. Para. 1 lit. a requires that the selected basic patent for the SPC protects the product defined in art. 140a PatA, i.e. an active ingredient or a combination of active ingredients (analogous provision according to the Regulation (EC) No. 469/2009 [hereinafter SPC Regulation] is art. 3 lit. a). Art. 140b para. 1 lit. a. A PatA expressly states that the protection can consist of a substance protection ("as such"), a manufacturing protection or a use protection. This para. 1 lit. b and 2 of art. 140b PatA lay down the relationship of the SPC to the MA of the product on which the SPC is based (analogous provisions in the SPC Regulation are art. 3 lit. b and 3 lit. d.). From this it can be deduced that each SPC is based on a patent (basic patent) on the one hand and on a MA for a medicinal product (or plant protection product) containing the product on the other. Thus, art. 140b PatA establishes the relationship between the SPC applied for a product, its basic patent and the MA on which the SPC is based.

2. Different Interpretations of "Protected by a Patent": Infringement vs. Disclosure Theory
With the introduction of the SPC, the question has arisen as to how exactly the concept that the product must be "protected" by a basic patent (art. 140b para. 1 lit. a PatA) should be interpreted. Two different approaches are available to answer this question: the infringement theory on the one hand and the disclosure theory on the other. According to the infringement theory, which stood solid as a rock and was applied in Switzerland for decades, it is sufficient if the product falls within the scope of protection of the patent claims of the basic patent. The CJEU took...
a different direction with the “Medeva et al.” decisions by following the disclosure theory, which states that it is not sufficient if the product infringes the claims of the basic patent, but requires that the product is “mentioned” or “specified” in the claims of the basic patent in order to obtain an SPC. The question according to which criteria a product can be regarded as protected by the basic patent in light of these two approaches becomes particularly relevant for combinations of active ingredients if only one component of the combination is specifically claimed in the basic patent.

3. Switzerland Moves Away from the Infringement Theory — New Legal Issues Arise

Recently, the FSC issued the landmark decision “Tenofovir” (BGE 144 III 265) concerning the granting requirements for SPCs on mono and combination products, with a focus on the application of the infringement or the disclosure theory. Pursuant to the FSC, the infringement theory shall still apply to existing SPCs, while new SPCs for combination products shall be examined in light of the disclosure theory, i.e., “Medeva et al.” rulings concerning combination products. The FSC’s decision leads to the fact that Swiss law is now closer in line with the EU’s legal understanding when it comes to the question whether a product is protected by the basic patent. However, the decision also raises some new legal issues, which also leads to legal uncertainty. Against this background, the present analysis is intended to deal with the following issues:

- What is the history behind this new far-reaching change of practice of the FSC?
- When is a product protected by the basic patent within the meaning of art. 140b para. 1 lit. a PatA and according to the new change of practice?
- What effects does the change of practice have on pending SPC applications?
- What does the new approach mean in terms of further harmonization with EU legislation and case law, in particular with regard to the implementation of the “Actavis et al.” case law?

II. History of Case Law: From Infringement to Disclosure Theory

A. Origin of the Infringement Theory in Swiss Case Law

Until recently, Switzerland stood solid as a rock and defended the infringement theory for SPCs for combination products, which had been confirmed by the FSC in the “Fosinopril” decision of 10 July 1998 (BGE 124 III 375). Pursuant to this decision the grant of an SPC requires that the product, its manufacture or use is protected by the basic patent. The FSC argued that if a third party uses a patented active ingredient in combination with another active ingredient, it is using the patent and consequently infringing it. The use of the patent-protected active ingredient is also an interference with the scope of protection of the patent if further elements are added. Therefore, the FSC concluded that the scope of protection of the basic patent covers not only the active ingredient fosinopril, but also a combination of active ingredients fosinopril with hydrochlorothiazide. Thus, an SPC for a combination of the active ingredients fosinopril and hydrochlorothiazide may also be granted on the basis of the basic patent protecting only the active ingredient fosinopril. Consequently, in determining whether the product for which an SPC was sought was protected by the basic patent, the FSC applied the infringement theory. The decisive factor was that the owner of the basic patent could prohibit the use of the combination of active ingredients according to patent law principles.

A few years later, the Federal Administrative Court (FAC) also applied the infringement theory in its decision of 18 August 2011 in accordance with the FSC case law “Fosinopril” and dismissed the application. The court stated that the product for which an SPC is claimed must be covered by the scope of the basic patent and must not necessarily exist in the patented subject-matter itself. The FAC was of the opinion that the invention consisted in the combination of two active ingredients according to patent law principles.

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13 Správ, ibid. fn. 10, 72; Broccker, ibid. fn. 4, art. 3 paras. 84 et seq.

14 FSC, judgment of 11 June 2018, BGE 144 III 285.


16 CJEU, judgment of 12 December 2013, C-443/12, “Actavis I”;
CJEU, judgment of 12 December 2013, C-484/12, “Georgetown II”;
CJEU, judgment of 12 March 2015, C-577/13, “Actavis II”.

17 FSC, judgment of 10 July 1998, BGE 124 III 375. In this decision the FSC had to decide whether an SPC could be granted for the combination of the active ingredients fosinopril and hydrochlorothiazide, based on a European patent which granted protection for the active ingredient fosinopril and based on a new MA obtained for the combination fosinopril and hydrochlorothiazide. It should be noted that for the active ingredient fosinopril alone, based on the same basic patent and the MA of a mono-product containing the active ingredient fosinopril, a first SPC had already been granted. See also FAC, judgment of 18 August 2011, B-3245/2010; FPC, judgment of 3 October 2017, O2017_001.


19 Schärl, ibid. fn. 10, 78.

20 FAC, judgment of 18 August 2011, B-3245/2010. The ruling was based on an SPC application for the product Panitumumab, based on a European patent which exclusively protected the combination of two active ingredients (including panitumumab) and a MA for a medicinal product containing the active ingredient panitumumab.
active ingredients and that the product could therefore only be considered for the combination of the active ingredients concerned within the meaning of art. 140b para. 1 lit. a PatA. Thus, the active ingredient claimed by the basic patent cannot be omitted without the monoclonal antibody falling outside the scope of protection of the basic patent.\(^{21}\) For the FAC, it was obviously self-evident that a product within the meaning of art. 140b para. 1 lit. a PatA is protected by the corresponding basic patent if the former falls within the scope of protection of the basic patent.

### B. Disclosure Theory According to EU Case Law – CJEU’s Decisions “Medeva et al.”

#### 1. Anchoring the Disclosure Theory

The question according to which criteria a product can be regarded as protected by the basic patent within the meaning of the SPC Regulation became also relevant in the EU, in particular for combinations of active ingredients if only one component of the combination was specifically claimed in the basic patent. First indications of how the analogous provision of art. 3 lit. a SPC Regulation was to be understood could be taken from the CJEU judgment “Farmitalia” (C-392/97). According to this decision the question whether a product within the meaning of art. 3 lit. a SPC Regulation is protected by the basic patent has to be decided under the provisions of national patent law.\(^{23}\) Following different rulings by various national courts, the CJEU provided new guidance in its “Medeva” judgment (C-322/10)\(^{23}\). Among other things, it ruled that the mere fact that under national law a product would infringe the claims of the basic patent is not in itself sufficient to fulfill the conditions of art. 3 lit. a SPC Regulation. Rather, in order to obtain an SPC for a product, the product must be “specified” or “identified” in the claims of the basic patent.\(^{24}\) While the CJEU applied the disclosure theory, it opposed the infringement theory. This new interpretation was confirmed by the CJEU in further rulings, e.g. in judgment C-6/11 of 25 November 2011 (“Dalichi Sankyo”), in judgment C-630/10 of 25 November 2011 (“University of Queensland”) and in judgment C-518/10 of 25 November 2011 (“Yeda Research”).

#### 2. Consequences

Accordingly, it is not possible to grant an SPC for the product A+B if, for example, the active ingredient A is only “specified” or “identified” in the claims of the basic patent\(^{25}\), even if the basic patent also contains patent claims which suggest the presence of further active ingredients without specifying them (e.g. a claim “medicinal product comprising the active ingredient A and further active ingredients as well as excipients”). In light of the disclosure theory it is also not possible to obtain an SPC for the product A if in the basic patent only combinations of active ingredients of A with further active ingredients are claimed, e.g. A+B and A+C.\(^{25}\)

### 3. Clarification for Functional Patent Claims – CJEU’s Decision “Eli Lilly”

After the decisions “Medeva et al.”, it remained unclear whether the term “specified” requires a product to be mentioned explicitly and individually within the wording of the claim, or whether it includes implicit coverage within a generally-defined class.\(^{26}\) For functional patent claims, the CJEU clarified in the decision “Eli Lilly” of 12 December 2013 (C-483/12) that it is not necessary for the fulfilment of art. 3 lit. a SPC Regulation that an active ingredient is structurally defined in the patent claims, e.g. by a chemical structural formula, but that functional definitions, such as a claim directed at antibodies with certain binding properties in the specific case, may also suffice. However, the CJEU requires that the patent claims – which in the case of a European patent are interpreted according to art. 69 and the Protocol on the interpretation of that provision – allow the conclusion for the skilled person that they must “relate implicitly, but necessarily and specifically, to the active ingredient in question”.\(^{27}\)

#### C. A Landmark Swiss Dispute: Gilead’s SPC for Truvada\(^\text{®}\)

##### 1. Background of the Dispute

The Swiss litigation that ultimately led to the groundbreaking change of practice is about the validity of Gilead Sciences Inc.’s Swiss SPC C00915894/01 for the combination of tenofovir disoproxil fumarate plus emtricitabine. The Swiss Institute of Intellectual Property (IPI) granted the SPC on 29 August 2008 based on the MA for Truvada\(^\text{®}\), which is a fixed-dose combination of the two antiretroviral medications tenofovir disoproxil fumarate and emtricitabine for treatment of HIV/AIDS.\(^{28}\)

On 3 January 2017 Mepha Pharma AG, a Swiss subsidiary of Teva, filed a revocation action against Gilead’s Swiss SPC with the FPC. Neither was the validity of the basic patent EP 0 915 894 attacked nor was it disputed that a generic of Truvada\(^\text{®}\) would infringe the (expired) basic patent and that Gilead’s SPC was therefore valid under the infringement

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21 FAC, judgment of 18 August 2011, B-3245/2010, cons. 5.
22 CJEU, judgment of 16 September 1999, C-392/97, “Farmitalia”, cons. 29.
23 CJEU, judgment of 24 November 2011, C-322/10, “Medeva”.
24 CJEU, judgment of 24 November 2011, C-322/10, “Medeva”, cons. 25 or 40.
25 CJEU, judgment of 25 November 2011, C-518/10, “Yeda Research”.
26 BRUCKNER, ibid. fn. 4, art. 3 para. 218.
27 CJEU, judgment of 12 December 2013, C-483/12, “Eli Lilly”, cons. 39.
28 The authors represented Gilead Sciences Inc. in the court proceedings.
theory. Rather, Mepha essentially argued that the \textit{ratio legis} of the Swiss law on SPCs requires that Switzerland should abandon the infringement theory traditionally employed (see above II A.), and that this change of practice should be applicable with immediate effect even for existing SPCs. Mepha took the view that Swiss courts should apply EU case law and therefore Gilead’s SPC would be invalid in light of the CJEU practice for combination products because the two active ingredients were not specified in the claims of the basic patent and did not correspond to the basic patent’s core inventive advance.\footnote{FPC, judgement of 3 October 2017, O2017_001, cons. 7; see also Holzer/Scharl/Borer, ibid. fn. 15.}

In contrast, Gilead put forward different arguments. First, it was of the opinion that Switzerland should stick to the infringement theory. Second, it argued that even if the EU practice for SPCs for combination products were to be introduced in Switzerland, this practice would only apply to new SPCs whose applications were filed after the change of practice. According to Gilead a change of practice could not have a retroactive effect. Third, Gilead took the position that even if the criteria established by the CJEU would apply to existing Swiss SPCs, those requirements – if correctly interpreted and applied – would be fulfilled by the SPC for Truvada.\footnote{FPC, judgement of 3 October 2017, O2017_001, cons. 8; see also Holzer/Scharl/Borer, ibid. fn. 15.}

\section*{2. Stick to the Practice – Federal Patent Court’s Decision of 3 October 2017}

Against this background, in October 2017 the Swiss FPC ruled in its decision O2017_001 that it was not appropriate to move away from the infringement theory that had been applied in Switzerland since the FSC decision “Fosinopril” in 1998. The FPC argued that legal certainty (at the time of the application of the Swiss SPC in 2006, the CJEU’s “Medeva” decision had not yet issued) demanded that the SPC must be judged under the infringement theory. Harmonization of Swiss law with European Union law did not compel adopting the CJEU’s case law after “Medeva”. While it is correct that the Swiss SPC was introduced to harmonize Swiss law with the then relevant European legislation regarding SPCs, harmonization was unnecessary because it would not lead to better market access (the free movement of goods). Switzerland was not part of the EU regulatory framework for the approval of pharmaceuticals. Medicinal products approved in Switzerland need separate approval in the EU, and vice-versa. Regulatory law therefore impeded the free movement of pharmaceuticals irrespective of whether SPC law was harmonized.\footnote{FPC, judgement of 3 October 2017, O2017_001, cons. 31 et seqq.}

The FPC could have left it at this, but it went on to assess whether applying the CJEU’s case law would benefit legal certainty.\footnote{The FPC examined several decisions of the CJEU dealing with SPCs for combination products (i.e. C-322/10 – “Medeva”, C-518/10 – “Yeda”, C-630/10 – “University of Queensland”, C-6/11 – “Dainchi Sankyo”, C-493/12 – “Eli Lilly” and C-443/12 – “Actavis/Sanoﬁ”) and came to the conclusion that the CJEU’s case law in this area of law was a “terminological mess” (“terminologisches Durcheinander”). According to the CJEU the requirements of art. 3 lit. a of the SPC Regulation, i.e. whether the product of an SPC is protected by the basic patent, are unclear and, therefore, there was no reason to move away from the infringement theory.\footnote{FPC, judgement of 3 October 2017, O2017_001, cons. 36 et seqq.} Furthermore, the court also noted that the CJEU’s case law was apparently so unclear that Arnold J, “a renowned expert in the area of SPC law” was forced again to submit a question to the CJEU (referred to [2017 EWHC 13 [Pat]]). Legal certainty would therefore suffer if Switzerland abandoned the (comparatively easy to apply) infringement theory. The FPC therefore dismissed the revocation action brought by Mepha against Gilead’s Swiss SPC.\footnote{FPC, judgement of 3 October 2017, O2017_001, cons. 50.}

\section*{3. Change of Practice – Federal Supreme Court’s Landmark Decision BGE 144 III 285}

The FPC’s judgment O2017_001 was appealed to the FSC by Mepha. While the FSC concluded in its decision “Tenofovir” of 11 June 2018 (BGE 144 III 285) that SPCs for combination products granted under the previous practice were still to be assessed in light of the requirements of the infringement theory, it advocated a change of its practice towards an interpretation of art. 140b para. 1 lit. a of a PatA in conformity with the CJEU’s case law for the granting of future SPCs (disclosure theory). In an obiter dictum, however, the FSC ruled that new SPCs for combination products must comply with the requirements of the “Medeva et al.” case law in the future.

Whether Gilead’s SPC for Truvada® meets these requirements was left open by the FSC, as this question was irrelevant since this SPC was examined according to the infringement theory. Thus, on 11 June 2018 the FSC dismissed Mepha’s appeal.

\subsection*{a) Change of Practice}

The FSC argues that a diverging practice between the CJEU and the Swiss courts in the field of SPCs is a serious reason for a change of practice of the Swiss law.\footnote{If correctly interpreted and applied the CJEU practice for combination products be-applicable with immediate effect even for existing SPCs. Mepha took the view that Swiss courts should apply EU case law and therefore Gilead’s SPC would be invalid in light of the CJEU practice for combination products because the two active ingredients were not specified in the claims of the basic patent and did not correspond to the basic patent’s core inventive advance. According to the FPC, the FSC dismissed Mepha’s appeal. While the FSC concluded in its decision “Tenofovir” of 11 June 2018 (BGE 144 III 285) that SPCs for combination products granted under the previous practice were still to be assessed in light of the requirements of the infringement theory, it advocated a change of its practice towards an interpretation of art. 140b para. 1 lit. a of a PatA in conformity with the CJEU’s case law for the granting of future SPCs (disclosure theory). In an obiter dictum, however, the FSC ruled that new SPCs for combination products must comply with the requirements of the “Medeva et al.” case law in the future. Whether Gilead’s SPC for Truvada® meets these requirements was left open by the FSC, as this question was irrelevant since this SPC was examined according to the infringement theory. Thus, on 11 June 2018 the FSC dismissed Mepha’s appeal. (comparatively easy to apply) infringement theory. The FPC therefore dismissed the revocation action brought by Mepha against Gilead’s Swiss SPC.}


\begin{thebibliography}{10}
\bibitem{FPC} FPC, judgement of 3 October 2017, O2017_001, cons. 36 et seqq.
\bibitem{FPC} FPC, judgement of 3 October 2017, O2017_001, cons. 44 et seqq.
\bibitem{FPC} FPC, judgement of 3 October 2017, O2017_001, cons. 50.
\bibitem{FSC} FSC, judgement of 11 June 2018, BGE 144 III 285, cons. 2.2. et seqq.
\end{thebibliography}
The FSC examined whether a change of practice could and should have an effect on SPCs that had already been granted, and, thus, whether Gilead’s SPC is valid even in the (not conclusively assessed and therefore hypothetical) case that the requirements for granting an SPC in light of the case law of the CJEU might not be fulfilled.30 The FSC emphasized that Gilead’s SPC was legally granted in light of the infringement theory in force at the time of the application and grant of Gilead’s SPC. The nullity grounds of the PatA refer to the question of whether the conditions for granting the SPC were fulfilled at the time of filing the SPC application. In the opinion of the FSC, this is clearly the case, since the infringement theory was undisputedly the relevant test at the time Gilead’s SPC application was submitted to the IPI.40 The FSC then examined whether, as an exception, a validly granted SPC can be revoked only because of a later change of practice, or more generally speaking, whether a legally binding administrative decision like the grant of an SPC could be reconsidered or revised as a result of a legal change of practice. As a general rule, the grant of an SPC cannot be revoked due to a later change of practice if the interest of the holder of the SPC in protecting his exclusive rights precedes the interest in the uniform implementation of the new law. Although this rule does not apply in absolute terms, the FSC could not see any particularly significant interest that would clearly demand a revocation of Gilead’s lawfully granted SPC simply because a change of practice has taken place many years after the grant. In the opinion of the FSC, Gilead’s interest in protecting its exclusive rights is clearly higher than the interest that in Switzerland all SPCs for combination products must be subject to exactly the same rules in the future.41

D. Clarification of Disclosure Theory at EU Level

1. CJEU’s Decision C-121/17 of 25 July 2018 – “Teva UK v Gilead”

In the judgment C-121/17 of 25 July 2018 (“Teva UK v Gilead”) the CJEU had the chance to clarify the question of when a product is protected by a basic patent within the meaning of art. 3 lit. a a SPC Regulation with regard to Gilead’s combination HIV treatment Truvada® (tenofovir disoproxil and emtricitabine). Gilead had obtained an SPC for the combination of tenofovir and emtricitabine based on Gilead’s patent EP 0915894, which claimed “[a]l pharmaceutical composition comprising a compound according to any one of claims 1 to 25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients” (claim 27). While the basic patent protected tenofovir, which was claimed in claim 25, emtricitabine was not disclosed in the patent and there was no evidence that it was known to be efficacious at the priority date of the patent. Gilead had relied upon the fact that “optionally other therapeutic Ingredients” would encompass emtricitabine to obtain the SPC.

The CJEU confirmed and specified its previous case law on the question of when a product is protected by a basic patent within the meaning of art. 3 lit. a a SPC Regulation.42 Neither has the CJEU gone with Justice Arnold’s proposal in the referring decision nor with the interpretation provided by the Advocate General. The CJEU introduced a “two-pronged test” for whether a product consisting of a combination of ac-

37 FSC, judgment of 11 June 2018, BGE 144 III 285, cons. 3.2. et seq.; see also Holzer/Scharli/Borer, ibid. fn. 15.
38 For detailed information see Romandni, Art. 3(a) SPC Legislation, An Analysis of the CJEU’s Ruling in Teva (C-121/2017) and a Proposal for its Implementation, Max Plank Institute for Innovation and Competition Research Paper No. 18-22, 2018, 1, 15.
39 In the referring decision Justice Arnold of the UK High Court of Justice decided to stay the proceedings and offered his own view stating at cons. 97: “In my view, the answer is that the product must infringe because it contains an active ingredient, or a combination of active ingredients, which embodies the inventive advance (or technical contribution) of the basic patent. Where the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent.” UK High Court, judgment of 13 January 2017, [2017] EWHC 13 (Pat), cons. 97.
40 In the above discussed case C-121/17 Advocate General proposed that the criterion should be whether “on the priority date of the patent, it would have been obvious to a skilled person that the active ingredient in question was specifically and precisely identifiable in the wording of the claims of the basic patent. In the case of a combination of active ingredients, each active ingredient in that combination must be specifically, precisely and individually identifiable in the wording of the claims of the basic patent.” (Opinion of Advocate General Wathelet delivered on 25 April 2018, Case C-121/17 “Teva UK Gilead,” cons. 88).
tive ingredients is “protected by a basic patent in force”. Accordingly, a product can only be regarded as protected by a basic patent if: (1) the product which is a subject-matter of the SPC is necessarily covered by the invention protected by the patent as it results from the disclosure as a whole; this involves examining whether the skilled person, with the help of his general expertise and on the basis of disclosure in the patent, can clearly see that the product is a characteristic necessary for the solution of the technical problem as described by the patent; and (2) one of the patent claims necessarily and specifically refers to the product, even if it is not expressly mentioned in the claims.\(^{45\text{a}}\)

The skilled person must therefore be able to specifically identify the product in the light of all information disclosed by the patent according to the state of the art at the priority/application date of the patent. If the skilled person needs knowledge or further research results which become apparent only after the filing/priority of the patent application in order to be able to identify the product, the requirements of art. 3 lit. a SPC Regulation are not fulfilled. When examining what is considered necessary and specifically identifiable for the skilled person, the description and drawings as provided for in art. 69 EPC and its Protocol on the interpretation of that provision shall be used.

The CJEU left it to the national court to determine, on the facts of the case, whether Gilead’s combination SPC meets these two criteria.\(^{46\text{a}}\)

2. **UK High Court’s Decision of 18 September 2018 – Truvada Does Not Comply with Art. 3 Lit. a SPC Regulation**

On 18 September 2018\(^{47\text{a}}\), Justice Arnold of the UK High Court of Justice, which made the referral to the CJEU in the case “Teva UK vs Gilead”, handed down his final judgment and came to the conclusion that the criteria established by the CJEU were not fulfilled in the specific case because, according to the disclosure theory, for the skilled person the patent is directed solely at the active ingredient tenofovir and possible combinations with other anti-retroviral active ingredients not specifically subject of the invention. Moreover, there is no indication for the skilled person to combine tenofovir with emtricitabine and therefore the product “tenofovir+emtricitabine” cannot be considered as “protected” within the meaning of art. 3 lit. a SPC Regulation and can thus not be the subject matter of an SPC based on this basic patent.\(^{48\text{a}}\)

3. **New CJEU cases**

At EU level, further CJEU cases concerning art. 3 lit. a SPC Regulation are currently pending.\(^{49\text{a}}\) Among others, it is disputed whether there are special criteria for the chemical compound claimed as Markush formulas or to what extent individualization of a product claimed as a functional new class of ingredients is necessary.

### III. Implications of Federal Supreme Court’s Change of Practice

#### A. New Interpretation of “Protected by a Patent”

1. **New Criteria and a Case-by-Case Decision**

Whether a product is protected by the basic patent within the meaning of art. 140b para. 1 lit. a PatA must always be examined on the basis of case-by-case decision in accordance with the CJEU case law.\(^{50\text{a}}\) It is clear from the FSC’s ruling that future SPCs for combination products can only be granted if all active ingredients are encompassed by the wording of the claims, either explicitly or, if construed in the light of the description, implicitly, but necessarily and specifically. Therewith, the FSC adopts the criteria developed in “Medeva et al.”.

In response to the FSC’s decision “Tenofovir”, the IPI has implemented its “Medeva et al.” approach within the amended chapter 13.2.1 of the “Guidelines for the Substantive Examination of National Patent Applications”.\(^{51\text{a}}\) The IPI concludes that its “Medeva et al.” approach (including the concrete case studies), which was consolidated with the interested parties, is consistent both with the decision of the FSC and the CJEU decisions. The “Medeva et al.” approach and the associated case studies\(^{52\text{a}}\) provide a detailed interpretation of how the terms “mentioned” or “relate, implicitly but necessarily and specifically, to the active ingredient in question”, must be understood. Even though EU case law still leaves some ambiguities regarding the interpretation of art. 3 lit. a SPC Regulation, the following principles can be laid down for Switzerland:

\(^{45\text{a}}\) CJEU, Judgment of 25 July 2018, “Teva UK vs Gilead”, C-121/17, cons. 52 et seqq., in particular cons. 57.

\(^{46\text{a}}\) CJEU, Judgment of 25 July 2018, “Teva UK vs Gilead”, C-121/17, cons. 56.

\(^{47\text{a}}\) UK High Court, judgment of 18 September 2018, [2018] EWHC 2416 (Pat).

\(^{48\text{a}}\) UK High Court, judgment of 18 September 2018, [2018] EWHC 2416 (Pat), cons. 37 et seqq.

\(^{49\text{a}}\) See CJEU reference for a preliminary ruling C-114/18, “Sandoz and Hexal” and CJEU reference for a preliminary ruling C-650/17, “Royalty Pharma Collection Trust”.

\(^{50\text{a}}\) FSC, judgement of 11 June 2018, BGE 144 III 285, cons. 2.2.6; IPI, Guidelines for the Substantive Examination of National Patent Applications, no. 13.2, 108.

\(^{51\text{a}}\) The application of these criteria had already been subject of consultation process initiated by the IPI some years ago within the framework of the IPI’s initiative to change its SPC granting practice in order to be in line with the EU case law (see IPI, Change of practice for granting supplementary protection certificates (SPCs), available under: https://www.ipe.ch/de/recht-und-politik/immaterialgueterrecht-national/praxisaenderungen.html, last visited 4 December 2018).

\(^{52\text{a}}\) IPI, Case studies of guideline 13.2.1.
- To fulfill the requirement of art. 140b para. 1 lit. a PatA it is not necessary for the product to be explicitly mentioned in the claim or the description of the basic patent. However, it must clearly fall within the scope of protection of a patent claim, e.g. by being contained in a Markush formula or defined by its properties ("bronchodilator with the following properties... "). The mere mention in the description (e.g. as additional information) is not sufficient. If the product is only mentioned in the purpose statement of a patent claim, this is also not sufficient ("disposable syringe for the administration of active substance B "). Since the active ingredient itself is not protected, 53

- In addition, for the application of art. 140b para. 1 lit. a PatA it has to be determined whether the product covered by the MA for medicinal products, as applied for in the SPC application is reproduced in the patent claims in a manner recognizable to the skilled person. This is generally the case if the product (the active ingredient/combination of active ingredients) can either be derived from the wording of the patent claims by functional (e.g. binding properties, specific effects) or structural (e.g. designation of a common, essential structural element) features or is covered by a structural formula. 54 The product (or its individual active ingredients) may either be mentioned explicitly (by name) in one of the claims, or implicitly covered by a claim. According to BGE 144 III 285 "implicit" means that the claim relates implicitly, but necessarily and specifically, to the product of the SPC. 55

2. **IPI Points the Way to Clarity for Swiss SPCs**

In addition to the implementation of the FSC’s change of practice regarding the application of art. 140b para. 1 lit. a PatA, the IPI developed fictional "case studies" as an aid for interpretation. 56 The IPI distinguishes between three different cases:

a) **Cases in Which SPCs May Not Be Granted**

According to the IPI, in principle, no SPC can be granted in the following cases:

- **Single active ingredient**: The SPC application concerns a single active ingredient. The patent claims of the basic patent contain a process that can be applied very broadly, so that no specific reference can be made to the class of active ingredients concerned (e.g. manufacturing process for proteins in general). The requirement "specifically" is not met.

- **Combination of active ingredients**: The SPC application concerns A+B, but the basic patent does not mention B in any way. Product A+B is neither explicitly nor implicitly mentioned in the claims of the basic patent.

- **Combination of active ingredients**: The SPC application concerns A+B, but the basic patent contains only claims of type "A another "active ingredient"... " (without any further indication of structure etc.). "Active ingredient" does not relate "specifically" to B.

**Use, indication, dosage**: It may happen that the patent-protected type of use differs from the pharmaceutical type of use (e.g. MA for A: 50 mg, invention as claimed by the patent: use of A: 100 mg; or MA for A for the treatment of breast cancer, invention as claimed by the patent: A for use in a medication for treating headache). The product of the MA is neither explicitly nor implicitly mentioned in the patent claims.

b) **Cases in Which an SPC May Principally Be Granted**

According to the IPI, in principle, an SPC may be granted in the following cases:

- **Single active ingredient**: The SPC application concerns an antibody that binds to a specific epitope. This antibody is claimed accordingly and is sufficiently disclosed in the patent, but without specifying a specific sequence. The product can therefore also be defined by functional features, provided that it is disclosed in a manner which is recognizable to the skilled person.

- **Combination of active ingredients**: The SPC application concerns a combination of A+B, if B is part of a group of active ingredients claimed in the combination which has a common structure or a common essential structural element or functional element (e.g. "antibiotics from the group of beta-lactams"). The skilled person recognizes that B is implicitly included in the claims of the basic patent.

c) **Borderline Cases**

According to the IPI, the following scenarios represent borderline cases:

- **Combination of active ingredients**: The SPC application concerns a combination of A+B, whereby B is part of a long list or several lists of individual active ingredients or groups of substances ("washlist"). Instead of a general solution, the assessment of the SPC application is based on the case law and practice concerning the disclosure of specific embodiments in cases with a large number of

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56 IPI, Case studies of guideline 13.2.1.
57 IPI, Case studies of guideline 13.2.1.
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alternatives. The grant of an SPC becomes more questionable, the more unspecified and the longer the lists are and the greater the number of lists is.

- **Combination of active ingredients**: The SPC application concerns A+B, whereby the claimed B in the basic patent belongs to a group of active ingredients with the same function, which has no common structure/similarity. The effect to be achieved should be credible for all members of the group of active ingredients. In addition, B must be disclosed in the group of active ingredients in a manner recognizable to the skilled person.

- **Manufacturing process and product-by-process claims**: The products obtained from the process in the patent claims must have common structural or functional features. It is clear to the skilled person that these features also apply to the product of the SPC application.

B. **What Happens with Pending SPC Applications?**

According to the language of the decision of the FSC, the infringement theory seems to apply to already granted SPCs prior to the judgment of 11 June 2018. Pursuant to the FSC's judgment, SPCs granted in a formally final administrative decision cannot be reconsidered or reversed due to a change of case law. Moreover, the obtained legal positions continue to enjoy protection. 60

However, it is unclear how pending SPC applications are to be assessed under this new case law. The IPI comes to the conclusion that the change of practice must be applied immediately and to all pending SPC applications. 61 The IPI bases its interpretation, on the one hand, on the general principle of the immediate applicability of FSC rulings, which applies irrespective of the area of law. 62 On the other hand, an SPC application, unlike an SPC that has already been granted, does not give priority to the applicant's interest in the protection of legitimate expectations over the objective pursued with the change of practice as an important public interest. In addition, the IPI emphasizes that the FSC only discusses the question of the protection of legitimate expectations in connection with an SPC already granted. Finally, the IPI considers its opinion confirmed by the fact that the FSC did not make use of its competence to issue transitional provisions for cases not closed yet (such as SPC applications).

The authors DORIGO and WILMING also support the IPI's opinion and thus, plead for the application of the disclosure theory on pending SPC applications. 63 DORIGO points out that neither a formally final administrative decision has been issued, which must be respected, nor a legal position has been acquired so far, which could be weighed up against the public interests in health care and in a harmonization of SPCs in the neighboring countries. 64 WILMING does not see any overriding interests of the applicants to still get SPCs granted contrary to the change of practice either. To strike the balance, he suggests giving the applicants a chance to amend their pending applications in view of the changed practice. 65

The pending SPC applications have been prepared and filed in light of the infringement theory. The PatA explicitly provides that an SPC shall be granted if the requirements for the grant of the SPC are met at the filing date of the application. The applications for SPCs for combination products that are still pending before the IPI were filed in consideration of the then valid infringement theory. As shown above, whether an SPC can be granted for a combination product depends on a decisive extent on whether the infringement or the disclosure theory is applied. 66 Under the infringement theory, research-based companies could better predict whether they would receive an SPC or not. The disclosure theory, on the contrary, is still a controversial approach, the significance of which needs to be further clarified by case law. Especially with regard to companies' trust in obtaining sufficient protection to amortize their investments, the infringement theory should also be applied on pending SPC applications. It is therefore questionable whether the IPI's opinion sufficiently takes into account the interests of research-based companies.

C. **Further Harmonization Required?**

Now that it has been established that the IPI follows the CJEU case law applying the disclosure theory for future SPCs, the question arises whether the European case law on "Actavis et al." 67 will also be adopted for the application of art. 140c para. 2 PatA (the analo-
1. “Actavis et al.” Case Law

The “Actavis et al.” case law concerns the interpretation of art. 3 lit. c SPC Regulation and thus the question of whether several SPCs can be granted for different products on the basis of the same basic patent. This case law has a decisive influence on the granting of SPCs for combination products of already known active ingredients.

It is clear from the decisions “Actavis”69, “George-town II”70 and “Actavis II”71 that the interpretation of art. 3 lit. c SPC Regulation is based on the definition of “product” and that the grant of a second SPC depends on whether the product (for example the combination of active ingredients) can be qualified as inventive or whether on the contrary it is already qualified as “known” by the basic patent, in which case the patentholder cannot be rewarded with the grant of a second SPC. More than one SPC may be granted per basic patent72 as long as any further SPC based on the same basic patent according to art. 3 lit. a SPC Regulation, is apparent from the basic patent and has an inventive step.73 The purpose of the CJEU is to ensure that patent holders are not rewarded for belated marketing for an invention “in any possible form”. Thereby, an artificial extension of exclusive market access, or “evergreening”, can be avoided.

Pursuant to this approach, a second SPC may be granted for another subject-matter of the basic patent, e.g. for a combination of active ingredients, if it is patentable in itself. This may appear appropriate in cases where the combination of active ingredients) can be qualified as inventive and has an inventive step.73 The purpose of the CJEU is to ensure that patent holders are not rewarded for belated marketing for an invention “in any possible form”. Thereby, an artificial extension of exclusive market access, or “evergreening”, can be avoided.

At this point, it should be clarified how far the fictional disclosure content of the previously SPC-protected subject-matter reaches from the basic patent.

2. Open Questions for Combination Products

The examination as to whether the combination A+B is a (substantial) invention corresponds to an examination as to whether the product is new and inventive (e.g. in a nullity action). Under the assumption that A is new and inventive, this is automatically also the case for A+B under patent law principles. In order to be applicable to combination products, the test requires the fiction that A is known, so that only the combination A+B could possibly be a patentable invention. Therefore the following is necessary for the assessment of the second SPC or the second invention:

- determination of a fictitious state of the art; this includes, in addition to the “genuine” state of the art, the active ingredient A;
- assessment of whether the second invention is still new and inventive under these circumstances.

With regard to the question of the fictitious state of the art, i.e. the sum of the disclosures before the filing or priority date and the subject-matter already protected by an earlier SPC, it seems unclear, whether only the subject-matter or also its technical effects and advantages are considered fictitiously known in order to assess inventive step. For example, if the active ingredient A is considered to be fictitiously known, there may be no incentive to combine it with another active ingredient B. The inventive step may not be considered to be fictitiously known. However, if, in addition to active ingredient A, its effects are also considered to be fictitiously known, this knowledge could provide an incentive for the skilled person to combine A with certain other substances, such as active ingredient B.

At this point, it should be clarified how far the fictional disclosure content of the previously SPC-protected subject-matter reaches from the basic patent.

3. Sufficient Incentive for Innovation?

Further harmonization should take place with careful consideration of the interests involved and the objectives pursued by the SPC legislation. While the adoption of the disclosure theory with regard to harmonization with EU legislation is to be advocated, one should keep in mind that the “Medeva et al.” approach places higher requirements on the grant of an SPC than the infringement theory.

In connection with the application of the disclosure theory and a possible implementation of the “Actavis et al.” approach, we see a potential danger that the incentive of innovative companies to develop combination products could be reduced. We believe that this effect could occur in particular if new findings arising during the development of a medicinal product (and after the filing of the basic patent) could not be rewarded with an SPC under the disclosure theory or the “Actavis et al.” approach because the new active ingredient may not be protected by the basic patent or has already been claimed by an SPC.

How research and development is structured depends mainly on how strong the originator's exclusivity rights are. In order to amortize investments, it is essential for research-based companies that sufficient protection is available not only for new active ingredients, but also for so called “line extensions”, such as combination products, the development of which is partly based on already known active ingredients. The possibility of obtaining an SPC thus

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69 CJEU, judgment of 12 December 2013, C-443/12, “Actavis”.
70 CJEU, judgment of 12 December 2013, C-443/12, “Actavis II”.
71 CJEU, judgment of 12 March 2015, C-577/12, “Actavis II”.
73 CJEU, judgment of 12 December 2013, C-443/12, “Actavis”.

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largely controls the research and development behaviour of the originators and their willingness to further develop uses of already known active ingredients.

Against this background and the fact that the grant of SPCs for combination products is subject to increasingly stringent requirements, pharmaceutical companies may have an incentive to market mono-products instead of combination products. This would increase the number of mono-products on the market, which could ultimately lead to patients being deprived of certain combination products. Furthermore, this could lead to a considerable disadvantage for patients, as the combination of mono-products is increasingly shifted to the medical practice. Combination products, which have been sufficiently tested and scientifically proven to be effective and safe would be driven out of the market as a consequence. 

IV. Conclusion

The FSC’s change of practice leads to the implementation of the EU case law “Medeva et al.” in the interpretation of art. 140b para. 1 lit. a PatA. In light of the harmonization sought, this new case law should be welcomed. However, this entails legal uncertainties as to how this approach must be understood. Even though the CJEU has specified the approach in its latest decision “Teva UK v Gilead”, many questions still remain unanswered. Ultimately, a case-by-case assessment will always be necessary as to whether the criteria for art. 140b para. 1 lit. a PatA laid down in the FSC decision “Tenofovir” (or CJEU’s decisions “Medeva et al.”) are fulfilled. Fortunately, the IPI has issued some helpful interpretation aids, which facilitate the answer to the question of when a product is protected by the basic patent under art. 140b para. 1 lit. a PatA.

Through the adoption of the IPI’s “Medeva et al.” approach, European case law will inevitably have a considerable influence on the application of art. 140b para. 1 lit. a PatA. It remains to be seen whether the restrictive approach will be further tightened in the future. A stricter application of this approach could have an impact on innovative activities of research-based industries and finally, on public health. As the FSC applies the change of practice only on the granting of future SPCs, the judgment rightly protects the interests of patent and MA holders of pharmaceutical products (originators) who have made considerable time-consuming and costly efforts for the authorization and marketing of their products. Anything else would be tantamount to the expropria-

tion of legally protected property positions. On the other hand, the decision leaves open whether the change of practice should also apply to pending SPC applications and as a consequence further contributes to legal uncertainty. Contrary to the IPI’s position, in our view, the infringement theory should also apply to pending SPC applications.

The adoption of the “Actavis et al.” approach is questionable with regard to ensuring legal certainty, as the approach is not yet fully developed and leaves some questions unanswered. The decision in favor of harmonization should also be based on a careful consideration of all interests involved. While the change of practice of the FSC is to be supported in the view of the harmonization with EU case law and legislation, it must not be overlooked that the change of practice places higher requirements on the granting requirements for SPCs. This could have a detrimental impact on research-based industries and under certain circumstances also on public health. The implementation of the “Actavis et al.” approach would mean further restrictions for the access of research-based industries to SPCs, especially with regard to the development of already known substances (line extensions), as it is the case with many combination products. Whether the goal of the SPC to provide research-based industries with an additional incentive and to promote their innovative activities can still be achieved under restrictive conditions needs to be carefully reviewed. Especially in view of the steady number of approved new active substances (NAS) in relation to increasing research and development costs (up to USD 2.6 billion compared to USD 179 million in 1970) and the great importance of line exten-

76 Willi/Kaufmann/Stauffacher are criticizing the FSC judgment regarding the fact, that the change of case law does not apply to granted SPCs. According to the authors it is questionable how the FSC’s decision can be brought in line with basic principles of intellectual property law. With reference to the FSC’s decision in the trademark case BGE 4A 38/2014 (“Kotytrader”) the authors emphasize that the grant of an intellectual property right is deemed without prejudice for a later revocation and wonder why this should be different for SPCs (Willi/Kaufmann/Stauffacher, Pharma Circular I Update on SPC in Switzerland – Supreme Court adopts Medeva with Swiss finish: Granted SPC cannot be revoked, available under: https://www.streichenberg.ch/en/pharma-healthcare-en/pharmacircular-en/update-on-spc-in-switzerland/, last visited 4 December 2018).


sions for public health, the implementation of the "Actavis et al." approach could cause the desired balance of interests to waver at the expense of the research-based industry. For these reasons, further harmonization should also take into account a possible change in the long-term research behavior of large pharmaceutical companies, as this change in research behavior could also affect patent litigation, life cycle management for medical products and pediatric research. The future will have to show what impact this will have on research and development activities and thus on Switzerland as a pharmaceutical location. It remains to be hoped that the new direction will not harm innovative activities and finally, public health.

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