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

S2017_006

Judgement of 12 October 2017

Judiciary Body of the Court	President Dr. iur. Dieter Brandle, Judge Dr. sc. nat. ETH Tobias Bremi (Referent), Judge Dipl. Chem.-Ing. ETH Marco Zardi, First court clerk lic. iur. Susanne Anderhalden
Parties to the proceedings	**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, Plaintiff against **Mepha Pharma AG,** Kirschgartenstr. 14, 4051 Basel, represented by lic. iur. Andrea Mondini, TIMES Attorneys, Falkenstrasse 27, 8024Zurich technically advised by patent attorney Dr. Andreas Welch, Hepp Wenger Ryffel AG, Friedtalweg 5, 9500 Wil, Defendant
concerning	Infringement of an SPC / preliminary injunction

The Federal Patent Court considers:

Procedural history:

1.

With submission of 28 August 2017, Plaintiff submitted the present request for an ex parte preliminary injunction respectively a preliminary injunction concerning SPC infringement with the following prayers for relief (act. 1):

1. "Defendant to be preliminary prohibited under the threat of a disciplinary fine of CHF 1,000 per day according to art. 343 para. 1 lit. c Code of Civil Procedure (ZPO), but at least CHF 5,000 according to art. 343 para. 1 lit. b ZPO, as well as under a threat of penalty for its executives according to art. 292 Swiss Criminal Code (StGB) in case of future violation, from importing, storing, manufacturing, offering, selling or in any other way marketing itself or through third parties pharmaceutical products containing tenofovirdisoproxil in the form of its phosphate salt and emtricitabine for the term of protection of the SPC in dispute No. C00915894/01.

2. The preliminary injunction in accordance with prayer for relief no. 1 shall be ordered ex parte, thus it shall be ordered without hearing the Defendant for the moment.

3. Costs to be borne by Defendant and legal fees to be reimbursed by Defendant."

2.

With the decision of 30 August 2017, in approval of the request for ex parte preliminary injunction, Defendant was preliminarily prohibited under the threat of a disciplinary fine of CHF 1‘000 per day and under the threat of penalty for its executives according to art. 292 StGB in case of future violation, from importing, exporting, storing, manufacturing, offering, selling or in any other way marketing itself through third parties pharmaceutical products containing tenofovirdisoproxil in the form of its phosphate salt and emtricitabine (According to the Swissmedic marketing authorizations nos. 66181 and 66217) for the term of protection of the SPC in dispute C00915894/01 (act. 2).

3.

With submission of the response to the ex parte preliminary injunction of 21 September 2017, Defendant submitted the following requests (act. 9):

1. "The request for preliminary injunctions shall be entirely dismissed;

2. The ex parte preliminary injunction according to the decision of 30 August 2016 shall be lifted entirely.

3. Court and attorney's fees, including costs of the patent attorney necessarily incurred, shall be borne by Plaintiff."

4.

Subsequently, the parties were summoned to the hearing on 9 October 2017 (act. 10).

5.

On 27 September 2017, Defendant requested the following ex parte amendment of the preliminary injunctions (act. 12):

"Verdict no. 1 of the preliminary injunction decision should be amended to provide that the warehouse stock held by Defendant as identified in No. 1 of the judgment dated 30 August 2017, be inventoried and sealed; possibly these products are to be kept with an independent third party (e.g. at Kühne+Nagel AG, Im Wannenboden 8, 4133 Pratteln) at the expense of Defendant."

6.

With decision of 28 September 2017, Defendant's request was approved and Defendant was allowed, through amendment of verdict no. 1 of the decision of 30 August 2017, to store Emtricitabine-Tenofovir Mepha as far as it was already in stock when Defendant received the decision of 30 August 2017 (act. 13).

7.

The settlement hearing took place on 9 October 2017 (act. 20).

Procedural:

8.

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

According to art. 1 para. 2 IPRG in combination with art. 2 para. 1 and art 60 para. 1 Lugano Convention (LugÜ) as well as art. 10 AND art 109 para. 1 lit. a PatGG, the Federal Patent Court has jurisdiction over this matter.

In application of art. 23 para. 3, 1st sentence, PatGG, the court takes its decision in a panel of three judges.

Assessment:

9.

According to art. 77 PatG in connection with art. 261 para. 1 ZPO, the court shall order preliminary measures provided that Plaintiff makes plausible that a right to which he or she is entitled has been violated or a violation is anticipated (lit. a) and the violation threatens to cause a disadvantage, which can not be easily remedied (lit. b). An assertion is made plausible if the judge considers it to be predominantly true, meaning that it is not required that all doubts are eliminated. The opposing party also has to make its objections only plausible.[1] In addition, there must be certain urgency and the measure to be implemented must also be appropriate.[2]

10.

In support of its request, Plaintiff asserts that the Swiss SPC of Plaintiff C00915894/01 (SPC in dispute; act. 1_1), the concerning basic patent EP 0 915 894 B1 (Basic Patent; act. 1_2-3) and the original products TRUVADA® and ATRIPLA® of Plaintiff, which are protected by the SPC in dispute, are all very familiar to the court from the nullity proceedings O2017_001 (act. 1_4-6).

According to Plaintiff, Defendant has created the impression by initiating the aforementioned nullity proceedings and by corresponding with Plaintiff, that Defendant wants to have examined by the court whether the SPC in dispute is legally valid in view of the case law of the CJEU and the necessity postulated by Defendant of the Swiss SPC case law with the EU case law, prior to launching Defendant's generic drug Emtricitabine-Tenofovir-Mepha 200mg/245mg lactab (marketing authorization no. 66181).

1 BGE 132 III 83 consideration 3.2; BGE 103 II 287 consideration 2; Leuenberger/Uffer-Tobler, Schweizerisches Zivilprozessrecht, Bern 2010, para. 11.193 f.

2 BSK ZPO-Sprecher, N 10 to art. 261 ZPO.

Now, Defendant, as an answer to a warning letter from Plaintiff, has announced – just two days after the hearing held on 21 August 2017 (02017_001) – that Defendant will not wait for the judgement in the nullity proceedings, but rather launch the generic version of TRUVADA® immediately ("imminent") on the Swiss market (cf. act. 1_12).

Plaintiff states that a further generic drug of Defendant to the original product ATRIPLA® of Plaintiff with the combination of active ingredients Efavirenz-Emtricitabin-Tenofovir-Mepha received a marketing authorization on 18 July 2017 (no. 66217). This particular generic drug was probably not expressly mentioned in Defendant's letter of 23 August 2017 because Defendant had not yet received a warning letter from Plaintiff concerning this generic drug. The difference between the generic drug to TRUVADA® and the generic drug to ATRIPLA® is that the latter contains the active ingredient efavirenz in addition to tenofovirdisoproxil and emtricitabine. However, according to Plaintiff this combination of tenofovirdisoproxil, emtricitabine and efavirenz also infringes the SPC in dispute which protects tenofovirdisoproxil and emtricitabine as the relevant product. Plaintiff asserts that the scope of protection of a SPC, according to art. 140d PatG, which contains two active ingredients, also protects any drug containing these two ingredients together with a third active ingredient.

Plaintiff assumes that Defendant has already started marketing activities and will likely be included in the list of specialties on 1 September 2017. The validity of the Basic Patent was expressly acknowledged by Defendant in the nullity proceeding 02017_001, which is why the validity of the Basic Patent also has to be assumed in the proceeding at hand. The validity of the SPC in dispute was challenged by Defendant in the nullity proceedings solely on the basis of case law of the CJEU that was only issued long after the SPC in dispute was granted. According to Plaintiff, the question whether the Swiss courts have to follow the case law of the CJEU can and must be left open in this proceeding as it will be decided in the nullity proceedings on the merits. For the requested preliminary injunction it must suffice that Defendant has acknowledged in its reply in the nullity proceedings that according to the established practice, that was applied by the Federal Supreme Court and the Federal Administrative Court, as well as by the Federal Institute of Intellectual Property, and that is not criticized by the Swiss doctrine, that the SPC in dispute is valid. Likewise, Defendant has acknowledged in the nullity proceedings that Plaintiff's drug TRUVADA® (respectively the active ingredients contained in TRUVADA®) is the product that forms the basis of the SPC in dispute. Defendant's attacked generic drug inarguably corresponds to Plaintiff's drug TRUVADA®, thus it also falls into the scope of protection of the SPC in dispute.

Plaintiff asserts that the same applies to Defendant's generic drug to the original drug ATRIPLA®. For this reason, only the infringement of the SPC in dispute by Mepha's Emtricitabin-Tenofovir Mepha has been demonstrated by Plaintiff.

Due to the already initiated or admittedly imminent launch of Emtricitabin-Tenofovir Mepha, and the likely listing in the Swiss pricing and reimbursement list, Plaintiff believes it is necessary to approve the requested injunction promptly. Plaintiff is, as known to the court, suffering irreparable harm, which becomes exponentially bigger and less assessable each day (act. 1).

11.

Defendant challenged the violation of the SPC in dispute on the one hand by invoking its invalidity, while essentially presenting the same arguments as in the above-mentioned nullity proceedings on the merits 02017_001 between the same parties. On the other hand Defendant argued even on the assumption that the SPC in dispute is valid, there was no interference with its scope of protection because the SPC in dispute mentions the fumarate salt of tenofovirdisoproxil and the product of the Defendant is the phosphate salt of tenofovirdisoproxil. Plaintiff's description of the product in the SPC in dispute was narrowly chosen, focusing on a specific salt and thus does not extend protection to other salts of tenofovirdisoproxil according to Defendant. Accordingly, insofar as this is relevant for a SPC at all, there is no literal infringement.

In addition, Defendant points out that there was also no infringement under the doctrine of equivalents, namely that the Drospirenone questions (decision S2013_001) had to be taken into account for the assessment of such a violation, but Plaintiff did not make any kind of reference to those. The same technical function is denied by Defendant, accessibility and equivalence are neither claimed nor apparent (act. 9).

Although Plaintiff's request for an ex parte preliminary injunction had explicitly challenged not only the combination of active ingredients tenofovirdisoproxil phosphate and emtricitabine (Defendant's marketing authorization no. 66181), but also the combination of active ingredients tenofovirphosphate, emtricitabine and efavirenz (Defendant's marketing authorization no. 66217), Defendant did not comment on the subject of the latter in its first response, but only said it was not under discussion (cf. act. 9 N 6). At the hearing, Defendant clarified that the marketing of this product is not immediately planned (cf. act. 20 p. 5).

12.

With regard to the first argument on the non-infringement of Defendant, namely that the SPC in dispute should not be valid because the infringement test according to the case law of the Fosinopril decision by the Federal Supreme Court should not be applied, but rather the new case law of the CJEU, it may be fully referred to the judgment of 3 October 2017 given to the same parties in the proceedings on the merits 02017_001. In this decision, it was held that the SPC in dispute is valid, which is therefore also to be assumed in this case.

13.

Defendant has undisputedly obtained two new marketing authorizations for the combination of tenofovirdisoproxil phosphate and emtricitabine, namely marketing authorization nos. 66181 as well as 66217. These marketing authorizations are based on the marketing authorization for Plaintiff's original products TRUVADA® and ATRIPLA®.

Furthermore, it is undisputed that the active ingredient tenofovirdisoproxil is subject to the Basic Patent of the SPC in dispute and is covered by its scope.

It is also undisputed that the SPC in dispute, regarding the active ingredient tenofovirdisoproxil, does not refer to the phosphate but specifically to the fumarate salt form. The specific active ingredients of the SPC in dispute as well as the first marketing authorization of Plaintiff on one hand and the second marketing authorizations of Defendant on the other hand, are therefore not identical.

14.

An SPC is infringed, if during the preliminary proceedings with regard to the attacked product– in this case Emtricitabin-Tenofovir Mepha (marketing authorization no. 66181) or the product with additionally efavirenz (marketing authorization no. 66217) – the following requirements are made plausible:

1. The use of the challenged products constitutes a use of the protected product in the SPC. It is therefore to be assessed if the challenged product falls under the scope of the **product of the SPC** (art. 140d para. 1 PatG: "The protection of a certificate extends, ..., to any use of the product, ...").

2. The challenged product must be a medicinal product that has been authorized before the expiry of the certificate (art. 140d para. 1 PatG: "The protection of a certificate extends to any use of the product as a medicinal product that has been authorized before the expiry of the certificate").

3. The challenged product must fall into **the scope of protection of the basic patent** (art. 140d para. 1 PatG: "The protection of a certificate extends, within the limits of the scope of protection conferred by the patent ...", art. 140d para. 2 PatG: "The certificate grants the same rights as the patent and is subject to the same restrictions.").

15.

The law defines **products** (cf. art. 140a para. 1 PatG) as "active ingredients or combination of active ingredients". The term "product" is equally used in connection with supplementary protection certificates for the grant requirements (art. 140b and 140c PatG) and in determining the scope of protection and effects (art. 140d PatG). The law does not provide more precise definitions of the relevant product.

The dispatch of the Federal Council of 1993 to amend the PatG[3] notes the following concerning art. 140a PatG:

"This paragraph shall specify the range of products eligible for the grant of a supplementary protection certificate. In accordance with the EC Regulation on supplementary protection certificates (EC Regulation), this is not the (human or animal) medicinal product such as authorized as a pharmaceutical specialty, but rather the active ingredient or combination of active ingredients that is used in such a medicinal product."

With regards to the grant requirements, the guidelines of the Federal Institute of Intellectual Property (FIIP) for the substantive examination of patents and SPCs (version of 1 April 2017, cf. p. 106) state about the product:

"The product is defined as an active ingredient or a combination of active ingredients (art. 140a para. 2 PatG). Therefore, the term “product” in art. 140b PatG is not to be interpreted as the pharmaceutical speciality such as authorized, but rather as the active ingredient (or the combination of active ingredients) that is used in such a medicinal product (see dispatch of the Federal Council of 18 August 1993, p. 24).

[3] BBl 1993 III 706, p. 729.

In order to prevent uncertainties with regard to the products, the designation in the application must be unambiguous. It must comprise only the chemical substance (or the substances) in accordance with the official registration certificate. The following designations are possible: The systematic chemical name (e.g. from CAS or IUPAC), the INN (International Nonproprietary Name; also abbreviated as DCI), the designation on the registration certificate, the entry in the Index Nominum or on the list of pharmaceutical substances. Ambiguous designations and trademark names are not accepted because the latter designate a pharmaceutical speciality and not the active ingredient or the combination of active ingredients. By analogy, designations of the medicinal product such as “nasal administration of the active ingredient A” are not permitted either."

With regards to salt forms and esters, the FIIP guidelines for the substantive examination state the following[4]:

"When there are multiple authorizations for various salt forms or ester of one active ingredient, they are usually considered to be one chemical combination, or rather the same product. These salts, respectively esters, serve the handling of the active ingredient in production, processing or administration (such as improving solubility) or the stabilization of the active ingredient. For example, if there are three authorizations for carboxylic acid, the first one as free acid, the second one as sodium salt and the third one as potassium salt, the relevant authorization is the one that was granted first.

But if the salt form (respectively the counterion) or the ester group has an influence upon the pharmacological effect in the body, this will be considered a new invention. The modified effect based on the specific salt or ester form must result from the patent.”

A different interpretation of the definition of “product” for the grant requirements and the scope of protection, as pleaded by Defendant (cf. act. 20 p. 7, 10), does not seem to be coherent with the law.

The abovementioned sources and the legal doctrine quoted by the Plaintiff (see also the compilation in act. 16 p. 3 below - p. 5 above) credibly show that the relevant product in connection with an SPC is not limited to the specific specialty according to the authorization, but also covers derivatives and in particular various salt forms thereof, insofar as these, and this is an important addition, show the same pharmacological effect.

[4] Guidelines for the substantive examination of national patent applications, version of 1 April 2017, p. 107.

In this sense, Plaintiff's interpretation is credible when it proposes the following definition of “product” relevant to the present procedure (cf. act. 16, p. 5):

"Emtricitabine plus tenofovirdisoproxil fumarate and all derivatives thereof (i.e. in particular all salt forms), to the extent that they have the same pharmacological effects and are covered by the Basic Patent EP 0 915 894 B1."

16.

According to art. 12 HMG, a second marketing authorization may be granted for a medicinal product which is essentially the same as an already authorized medicinal product (original product) and is intended for the same use. The application can then rely on the results of the pharmacological, toxicological and clinical tests of the original product.

According to the Swissmedic guidelines for the authorization of medicinal products for human use with a known active ingredient, different salts, esters, ethers, isomers, mixtures of isomers, compilations or derivatives of an active ingredient are considered to be the same active ingredient, provided that the applicant can prove that the findings on quality, safety and efficacy are transferable to the newly registered product with sufficient probability.[5]

In order to obtain the second marketing authorization for nos. 66181and 66217 based on the marketing authorizations of Plaintiff's original products, Defendant submitted corresponding technical documentation to Swissmedic, proving that if tenofovirdisoproxil *phosphate* is used instead of tenofovirdisoproxil *fumarate* like in the original product, the quality, safety and efficacy are almost identical. The corresponding documentation seems to have been sufficient for the authority to grant the second marketing authorization. Accordingly, it is undisputed that when tenofovirdisoproxil is supplied to the human body it will transform into tenofovir, the actual therapeutically effective molecule (cf. act. 1_8 p. 7, act. 1_14 p. 15).

[5] Swissmedic’s HD-Guidelines for the authorization of medicinal products for human use with a known active ingredient, para. 1.1.1.

17.

It already results from the fact alone that Defendant's second marketing authorizations have been granted that the two forms of the attacked embodiment with the phosphate salt of the active ingredient tenofovirdisoproxil have the same pharmacological effects as those of the fumarate salts of the active ingredient tenofovirdisoproxil according to the first marketing authorizations and the SPC. The Defendant did not assert anything else.

18.

In principle, the legal basis for the legal authorization of medicinal products and the legal basis for a violation of the SPC are different. However, in order to assess the legal question as to whether an identical product within the meaning of art. 140d PatG is given, it is first necessary to assess the technical question of the same pharmacological effect.

In this present case, it is precisely this technical preliminary question for the assessment as to whether a similar product within the meaning of art. 140d PatG is given that matches with the assessment of the marketing authorization authority. The assessment of the marketing authority answers the question as to whether, in accordance with art. 12 HMG, the active ingredient is essentially the same as the one used in the first marketing authorization and as to whether quality, safety and efficacy are transferable in accordance with the guidelines of the marketing authorization authority.

If Defendant's documentation for the second marketing authorization has been considered as sufficient evidence of the same pharmacological effect by the marketing authorization authority, it must be assumed with respect to the SPC that there is the same product.

The situation could only be assessed differently if the modified salt form had an unexpected additional or different effect. However, this has not been alleged in the present case. Moreover, it is also questionable whether a second marketing authorization could have been obtained in such a situation, since the efficacy would not necessarily be transferable according to the guidelines of the marketing authorization authority.

19.

In proceedings before the marketing authorization authority, Defendant has based its request for obtaining a second marketing authorization exactly on the same pharmacological effect. For this purpose, Defendant has submitted evidence according to which the modified form, tenofovirdisoproxil phosphate, has the same pharmacological effect as the tenofovirdisoproxil fumarate in the original product. In the marketing authorization procedure, Defendant was therefore explicitly concerned with demonstrating that the modified form of this active ingredient does not, applying the strict medicinal products standards, deviate in any way from the original product in any relevant respect in terms of its effect. The core of the marketing authorization procedure was therefore precisely to show that it was about a pharmacologically identical alternative to the original product, which Defendant in said

procedure apparently also managed to show.

For this reason, in the present infringement proceedings, Defendant could not claim that the modified form was not identical in effect, because this would not be credible since it would be contradictory.[6]

The first requirement for the infringement of the SPC in dispute described above in para. 14 (the attacked embodiment falls within the product definition of the supplementary protection certificate) is thus credibly fulfilled.

20.

The Defendant does not challenge that the attacked embodiments, which are the subject of marketing authorizations nos. 66181 and 66217, constitute authorized medicinal products.

The second requirement for the violation of the SPC in dispute mentioned above in para. 14 is thus also fulfilled.

21.

In addition, the Defendant does not deny that the attacked embodiments lie within the scope of protection of the Basic Patent.

The Defendant only denies that the attacked embodiment lie within the scope of protection of a hypothetical claim based on the Basic Patent, in which the active ingredient, which is broadly defined by a Markush formula, would be hypothetically replaced in claim 1 or 2 of the Basic Patent by tenofovirdisoproxil fumarate and the other therapeutic components according to claim 27 by emtricitabine. However, this is not the aspect to be assessed in the violation of a supplementary protection certificate. Proceeding in this way would also raise follow-up questions, which were raised by the Defendant itself (act. 20 p. 9 et seq.), namely, for example, which description would be assigned to such a hypothetical claim as an aid to interpretation.

[6] cf. BGE 4A_590/2016.

The aspect that the active ingredient is usually named more specified in the supplementary protection certificate than in the basic patent has already been examined under the first requirement and in connection with the definition of the relevant product. With respect to the third requirement the classic patent law method is used to check whether the attacked product lies within the scope of protection of the basic patent.

Therefore, also the third requirement for the violation of the SPC in dispute mentioned above in para. 14 is thus credibly fulfilled.

22.

In connection with the argument that the attacked embodiment does not lie within the scope of protection, the Defendant asserts, among other things, that the Plaintiff itself, when applying for the SPC in dispute, has formulated a narrow version which was expressly directed at the specific salt, the fumarate, and did not mention the tenofovirdisoproxil alone. Thus, Defendant argues that this narrow wording must also be binding for the Plaintiff and the use of other salts cannot be held against third parties pursuant to the principle of protection of a legitimate expectation and the prohibition of contradictory behavior. Furthermore, Plaintiff's other SPC, which has since been dropped, covers the product with three active ingredients, in addition with efavirenz (C00915894/02, withdrawn on 22 September 2015), showing that it would also have been possible to make tenofovirdisoproxil alone and not the more specific fumarate salt the subject of the SPC in dispute (act. 20 p. 8).

23.

It should be noted that the Plaintiff’s marketing authorizations for the two products are different. For the product of the combination of active ingredients under the name Truvada (marketing authorization no. 57316), the marketing authorization has been granted on 24 September 2010 for the following composition (cf. act. 1_13): "tenofovirum disoproxilum fumaras 300 mg, emtricitabinum 200 mg". In contrast, for the triple combination under the name Atripla (marketing authorization no. 60011), authorization has been granted on 20 November 2009 for the following composition (cf. act. 1_16): "efavirenzum 600 mg, emtricitabinum 200 mg, tenofovirum disoproxilum 245 mg ut tenofovirum disoproxilum fumaras, excipiens pro compresso obducto.".

Thus, tenofovirdisoproxil was explicitly mentioned in the marketing authorization for the triple combination of active ingredients and was then further specified as fumarate. In such cases, the FIIP accepts that the wording of the SPC is directed at the active ingredient without a specific salt form. On the contrary, only tenofovirdisoproxil fumarate was mentioned in the marketing authorization for the double combination of active ingredients, which means that only the fumarate is accepted for the protection certificate in accordance with the FIIP guidelines. ("In order to avoid any ambiguity concerning the product, the name on the certificate application must be unequivocal. It may only include the chemical substance (s) in

accordance with the official registration document."[7]).

Therefore, the specific wording of the SPC in dispute cannot be considered as delimitation from the prior art by the right holder, it is rather determined by the wording of the medicinal marketing authorization. Thus, it is plausible that based on marketing authorization no. 57316, the Plaintiff would not have been able not obtain an SPC that mentions tenofovirdisoproxil but not tenofovirdisoproxil fumarate. A limitation of the scope of protection under patent law therefore cannot be deduced from this, provided that - as it is undisputedly the case here - the same pharmacological effect is given with the salt other than fumarate.

24.

According to the Defendant's letter dated 23 August 2017, the launch of the product Emtricitabin-Tenofovir-Mepha 200mg/ 245mg is imminent (act. 1_12). Concerning the product with the additional active ingredient efavirenz, the Defendant stated that no marketing activities are planned. (act. 20 p. 5). However, the grant of Defendant's second marketing authorization and the behavior of the Defendant regarding the product Emtricitabin-Tenofovir-Mepha is enough to make plausible the risk of first infringement also regarding the second product.

25.

Thus, a potential violation of the Plaintiff's claims has been made plausible.

26.

Irreparable harm is obvious simply because of the Plaintiff's difficulties to prove damages in ordinary proceedings on the merits. On the one hand, there is a problem of causality between the sales of the Defendant and the decline in sales of the Plaintiff, especially if - which would be the case if the requested preliminary measure were not ordered - other generic drug manufacturers were to enter the market. In addition, the price reduction resulting from the availability of generic medicines would also have to be included in the Plaintiff's disadvantage, which makes the difficulties to prove damages obvious. In this way, a disadvantage, which cannot be easily remedied, is plausible.

[7] Guidelines for the substantive examination of national patent applications, version of 1 April 2017, p. 106.

Since the Defendant explicitly states in its letter (act. 1_12) that the launch of its product is “imminent” also the urgency requirement is met. The imminent launch of the product can only be prevented by issuing a preliminary injunction.

27.

Consequently, Plaintiff’s application for interim measures has to be granted – with the restrictions according to the decision dated 28 September 2017 (act. 13), which have been acknowledged by the Plaintiff. The Defendant is prohibited (alone or through third parties) from importing, exporting, storing (to the extent that the products were not already stored prior to the decision of 30 August 2017), manufacturing, offering, selling or placing otherwise on the market pharmaceutical products containing tenofovirdisoproxil in the form of a phosphate salt and emtricitabine according to Swissmedic MA nos. 66181 and 66217 during the term of the Swiss SPC C00915894/01.

Enforcement measures:

28.

With this judgement the court may order enforcement measures, at the request of the successful party (art. 236 para. 3 ZPO). The decision lies within the discretion of the court.[8] The prohibition to be ordered is issued under the threat of a penalty of CHF 1,000 per day and under the threat of penalty for its executives according to art. 292 StGB in case of future violations (art. 236 para. 3 in connection with art. 343 para. 1 lit. a and c ZPO).

Security deposit:

29.

The security deposit of CHF 250’000, ordered by the decision of 30 August 2017 in accordance with art. 264 para. 1 ZPO, is undisputed and accepted by both parties (cf. act. 16 p. 1 no. 1) and will therefore be maintained.

[8] Sutter-Somm/Hasenbohler/Leuenberger, ZPO Komm., N 25 et seq. to Art. 236 ZPO.

Deadline for filing action in the ordinary proceedings:

30.

The court shall set a deadline within which the Plaintiff must file his or her action in ordinary infringement proceedings on the merits; otherwise, the ordered preliminary injunction would become automatically ineffective in the event of default (art. 263 ZPO).

Costs and compensation claims:

31.

The court fee shall be set at CHF 13,000 based on the amount in dispute of CHF 250’000 (act. 1 para. 17 et seq., act. 9 para 11 and art. 1 in connection with art. 2 KR-PatGer). The court costs will be charged to the Plaintiff and offset against the advance payment. The final decision on the procedural costs for the interim measures shall be taken in the final decision in infringement proceedings on the merits (art. 104 para. 3 ZPO).

The Defendant has requested the involvement of a translator for the hearing (act. 11). Accordingly, the translator was summoned by the court. Shortly before the hearing, the Defendant decided not to use the translator. The resulting translator's compensation of CHF 1,350 is therefore the result of unnecessary costs caused by Defendant. These costs will therefore be imposed on the Defendant in any event (art. 108 ZPO). In the event that the Plaintiff fails to file the action in the proceedings on the merits within the given time limit, this ruling on costs should still apply and the Plaintiff shall pay Defendant’s attorney’s fees. These are fixed at CHF 11,000 for legal representation. For the patent attorney's advice, the Defendant claimed an amount of CHF 28,382.40 (incl. VAT), which was specified (act. 19) and remained undisputed. The total attorney’s fees must therefore be set at CHF 39,382.40 (art. 3, 4, 5, 6 and 9 para. 2 KR-PatGer).

The Federal Patent Court therefore rules:

1. The application for a PI is granted and the Defendant is prohibited (itself or through third parties) under the threat of penalty of CHF 1,000 per day and a fine for Defendant's executives in case of any noncompliance according to art. 292 StGB from importing, exporting, storing (to the extent that the products were not already stored prior to the decision of 30 August 2017), manufacturing, offering, selling or placing otherwise on the market pharmaceutical products containing tenofovirdisoproxil in the form of a phosphate salt and emtricitabine according to Swissmedic MA nos. 66181 and 66217 during the term of the Swiss SPC C00915894/01.

2. The security deposit of CHF 250'000 according to the decision of 30 August 2017 is still necessary.

3. Plaintiff is set a deadline until **13 November 2017** to commence infringement proceedings on the merits to have the present PI confirmed. If this deadline is not met, the PI will be lifted.

4. The court fee shall be set at CHF 13,000. Further costs amount to 1,350 (translation costs).

5. The court costs of CHF 13'000 will be charged to the Plaintiff and offset against the advance payment. The final decision on the procedural costs for interim measures shall be taken in the final decision on the merits. The translation costs of CHF 1,350 must be borne by the Defendant in any event.

6. If Plaintiff does not commence proceedings on the merits within the deadline according to verdict no. 3 above, it has to compensate Defendant for the preliminary injunction proceedings with CHF 39,382.40.

7. Written communication to the parties together with the minutes of the oral hearing (act. 20) and accompanied by invoice No. 1185000915 to the Defendant and after the decision has become final, to the Swiss Federal institute of Intellectual Property, each with acknowledgement of receipt.

Instruction on rights of appeal:

This decision may be appealed within **30 days** of its receipt by filing an 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, 12. October 2017

In the name of the Federal Patent Court

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

Sent to the parties: 12.10.2017