Unofficial Translation of the

Judgment of the Swiss Federal Patent Court of 21 March 2013

Case No. S2013_001

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Preface

The Institute for Economic Law at the University of Bern, under the leadership of Prof. Dr. Cyrill P. Rigamonti, is pleased to provide the following unofficial translation of the Swiss Federal Patent Court's important judgment of March 21, 2013, in case no. S2013_001 involving the doctrine of equivalents. This judgment was upheld on appeal by the Swiss Federal Supreme Court in its decision of August 21, 2013, in proceedings no. 4A_160/2013. Translator's notes have been added as footnotes where appropriate. The German original can be accessed on the website of the Swiss Federal Patent Court in PDF format.

This unofficial translation serves our goal of increasing access to the jurisprudence of the Swiss Federal Patent Court by creating materials in English for a broader audience. This translation has not been commissioned by the Swiss Federal Patent Court, and there is no affiliation between the Swiss Federal Patent Court and the Institute for Economic Law at the University of Bern.

The following judgment was primarily translated by Emmanuel Igbokwe, MLaw, former academic assistant to Prof. Dr. Cyrill P. Rigamonti, Director of the Institute for Economic Law, University of Bern, Switzerland.

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Summary[1]

Article 109 PatA[2]; Article 69 EPC; Protocol on the Interpretation of Article 69 EPC of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000; Article 66 para. 1 let. a PatA; *imitation (equivalence).*

All three of the following questions must be cumulatively answered in the affirmative in order to establish that a process or device in dispute uses a teaching of a patent despite the fact that one or more features of the claim are not literally reproduced but instead have been replaced by other features:

1. Do the replaced features have the same objective function? (same effect)

2. Are the replaced features and their same objective functions obvious to a person having ordinary skill in the art on the basis of the teaching of the patent? (accessibility)

3. After reading the wording of the claim in light of the description, would a person having ordinary skill in the art consider the replaced features as a solution of equal value? (equal value) (consid. 17.2)

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1 Translator's note: This summary section was published by the Swiss Federal Patent Court in English, and is, therefore, essentially reproduced as is. The rest of the case has been translated from German.

2 Translator's note: "PatA" refers to the Swiss Patent Act of 25 June 1954, as amended (SR 232.14).

Bundespatentgericht
Tribunal fédéral des brevets
Tribunale federale dei brevetti
Tribunal federal da patentas
Federal Patent Court

S2013_001

Judgment of 21 March 2013

Composition of the Court

President Dr. iur. Dieter Brändle

Judge Dr. sc. nat. Tobias Bremi (Judge-Rapporteur),

Judge Dr. phil. II, dipl. chem. Erich Wäckerlin,

First Clerk of the Court lic. iur. Jakob Zellweger.

Parties to the Proceedings

A. AG,[3]

represented by attorneys Dr. Michael Ritscher and Dr. Simon Holzer, Meyerlustenberger Lachenal, Forchstrasse 452, Postfach 1432, 8032 Zürich, and advised by patent attorney Gregor D. König, König Szyka Tilmann von Renesse, Mönchenwerther Strasse 11, D-40545 Düsseldorf, Germany,

Plaintiff

v.

B. AG,

represented by attorneys Dr. Christoph Willi and James Merz, Streichenberg and Partner, Stockerstrasse 38, 8002 Zurich, and advised by patent attorneys Dr. Rainer Friedrich and Dr. Holger Schimmel, df-mp, Theatiner-strasse 16, D-80333 München, Germany,

Defendant

Subject Matter

Patent Infringement / Preliminary Measures

[3] Translator's note: It is standard practice for the Swiss Federal Patent Court to anonymize judgments in preliminary proceedings.

Considerations of the Federal Patent Court:

Facts:

1.

The plaintiff submitted an application for preliminary measures dated 7 January 2013, received on 9 January 2013, and requested the following:

> Preliminary measures shall be issued at the latest by 21 January 2013
>
> 1. The opposing party shall, subject to a disciplinary fine of CHF 1,000 per day pursuant to Article 343 para. 1 let. c CPC[4], but at minimum CHF 5,000 pursuant to Article 343 para 1 let. b CPC, and subject to criminal punishment by a fine against the members of its management pursuant to Article 292 SCC[5] in the event of a repeat occurrence, be preliminarily enjoined from importing into Switzerland, either on its own or through a third party, and from storing, offering for sale, selling or placing on the market by any other means contraceptives containing the active substance drospirenone "D 1" (Swissmedic license number a), "D 2" (Swissmedic license number b), "D 3" (Swissmedic license number c) and "D 4" (Swissmedic license number d), especially the products that were seized by the Customs Inspectorate Pratteln during importation into Switzerland on 19 December 2012 and on 21 December 2012.
>
> 2. The opposing party shall, subject to a disciplinary fine of CHF 1,000 per day pursuant to Article 343 para. 1 let. c CPC, but at a minimum of CHF 5,000 pursuant to Article 343 para 1 let. b CPC, and subject to criminal punishment by a fine against the members of its management pursuant to Article 292 SCC in the event of repeat occurrence, be preliminarily ordered to recall the products according to Request No. 1 that it brought into circulation, i.e. by informing all known customers of said products, within a maximum of 5 calendar days after this judgment has become final, that the opposing party will take back the products in question and reimburse the purchase price as well as all other costs and expenses.
>
> 3. The injunction according to Request No. 1 and the order according to Request No. 2 are to be issued ex parte, i.e. preliminarily without a prior hearing of the opposing party, and are to be issued or communicated to the Parties and the Swiss Customs Administration, Directorate General of Customs, Monbijoustrasse 40, 3011 Bern, at the latest by 21 January 2013.
>
> 4. Subsidiarily to Request No. 3, the preliminary injunction according to Request No. 1 and the order according to Request No. 2 shall be issued after hearing the opposing party, whereas, however, the Swiss Customs Administration, Directorate General of Customs, Monbijoustrasse 40, 3011 Bern, shall be preliminarily instructed no later than 21 January 2013 to retain all goods concerning drospirenone and ethinylestradiol, which were seized by the Customs Inspectorate Pratteln within

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4 Translator's note: "CPC" refers to the Swiss Code of Civil Procedure of 19 December 2008, as amended (SR 272).

5 Translator's note: "SCC" refers to the Swiss Criminal Code of 21 December 1937, as amended (SR 311.0).

the scope of the assistance of the Customs Administration on 19 December 2012 and 21 December 2012, at least until a decision on Requests No. 1 and No. 2 above is issued.

5. All costs and fees shall be borne by the opposing party.

The plaintiff relies on two patents in suit in support of its requests, namely European Patent EP 0 918 791 B3, which was limited in limitation proceedings (hereinafter '791), and European Patent EP 1 149 840 B1, which was finally upheld in opposition proceedings as well as in subsequent appeals proceedings before the European Patent Office (EPO) (hereinafter '840; note that the version of the claims maintained by the EPO Board of Appeal is to be considered hereinafter). Patent '840 derives from a divisional application relating to the parent application of Patent '791.

In the plaintiff's presentation of the facts, it was said that the defendant obtains the active substances for the products from Company K, that these substances are subsequently formulated and packaged by Company L and are then imported into Switzerland. It was further said that Company K manufactures the active substance either by using a conventional method (hereinafter the "first method") or by using a changed method (hereinafter the "second method"), in which, particularly for the elimination of water, pyridine/water is used instead of p-toluenesulfonic acid. It was also said that these manufacturing methods are known on the one hand (first method) from a judgment by the Landgericht [District Court] of Düsseldorf of 26 June 2012 – in that case also in connection with the question of infringement of the '840 Patent – and on the other hand (second method) from the correspondence between another generic manufacturer and the defendant's supplier.

2.

After examining the plaintiff's application for preliminary measures and the defendant's protective letter dated 28 December 2012, the President of the Court issued an order dated 9 January 2013 setting a short and non-extendable deadline for the defendant to respond to the application for preliminary measures by 21 January 2013 (Article 253 CPC).

The President also instructed the Customs Inspectorate Pratteln to continue to retain the units of pharmaceutical D, which it had confiscated according to its letters of 19 and 21 December 2012, pending further instructions from the Federal Patent Court.

The court order was issued with a notification that the Parties would immediately be contacted with respect to scheduling a hearing date, provided a hearing was deemed necessary after receipt of the defendant's response to the application for preliminary measures.

Finally, the plaintiff was given until 21 January 2013 to make an advance payment on account of the estimated court costs in the amount of CHF 30,000.

3.

In its timely response to the application for preliminary measures dated 21 January 2013, the defendant made the following requests:

> 1. The application for preliminary measures dated 7 January 2013 shall be dismissed.
>
> 2. The shipments containing pharmaceutical D, which were seized according to the reports of the Customs Inspectorate Pratteln of 19 and 21 December 2012, shall be released with immediate effect.
>
> 3. All costs and fees plus VAT shall be borne by the plaintiff, including the costs of the necessary engagement of patent attorneys and the fees accrued in connection with the protective letter.

The defendant asserted in its response that the patents in suit are not infringed and, subsidiarily, if the Federal Patent Court were to come to the conclusion that there is infringement by equivalents of the patents in suit, that the patents in suit are not valid. The defendant also denied that the first method was applied, but it did not deny that the second method was used. Furthermore, it asserted that the active substance, which was manufactured by applying the [second] method, was just one of many active components of the product imported into Switzerland and thus that there is no product that is directly derived from the method in question. Moreover, the defendant asserted that, since the method in question is not carried out within Switzerland, the protection of the process claims of the patents in suit cannot be extended to the products it imported.

4.

On 18 January 2013, the Parties were summoned to an oral hearing (reply and rejoinder) set for 31 January 2013.

5.

By letter dated 25 January 2013, the President of the Court pointed out to the plaintiff that its request must show concretely how every single feature of the claim is technically implemented in the accused embodiment; and that this also applies to process patents. The plaintiff submitted a statement on 30 January 2013.

6.

During the hearing of 31 January 2013, the President referred to the aforementioned statement of the plaintiff and explained that it was apparently intended as advance information, but that it does not fit into the course of the proceedings. He pointed out to the plaintiff that it must incorporate the assertions made in this statement into its oral reply if it wanted the Court to take them into account.

In its reply, the plaintiff stated that it stood by Requests No. 1 and No. 2 made as part of its application for preliminary measures and supplemented them with the following new subsidiary request:

> Subsidiarily to Requests No. 1 and No. 2, the injunctions demanded in Request No. 1 and the order to remedy the unlawful situation demanded in Request No. 2 are to be pronounced with respect to the contraceptives containing the active substance drospirenone "D 1" (Swissmedic license number a), "D 2" (Swissmedic license number b), "D 3" (Swissmedic license number c) and "D 4" (Swissmedic license number d), especially the products that were seized by the Customs Inspectorate Pratteln during importation into Switzerland on 19 December 2012 and on 21 December 2012, whereby the active substance drospirenone (6β, 7β; 15β, 16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone) contained in these products was manufactured through elimination of water from 6β, 7β; 15β, 16β-dimethylene-5β-hydroxy-3-oxo-17α-androstane-21,17-carbolactone by adding p-toluenesulfonic acid or pyridine with water.
>
> Subsidiarily to Requests No. 1 and No. 2, the injunctions demanded in Request No. 1 and the order to remedy the unlawful situation demanded in Request No. 2 are to be pronounced with respect to the contraceptives containing the active substance drospirenone "D 1" (Swissmedic license number a), "D 2" (Swissmedic license number b), "D 3" (Swissmedic license number c) and "D 4" (Swissmedic license number d), especially the products that were seized by the Customs Inspectorate Pratteln during importation into Switzerland on 19 December 2012 and on 21 December 2012, whereby the active substance drospirenone (6β, 7β; 15β, 16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone) contained in the products in question was manufactured by catalytic hydrogenation of 17α-(3-hydroxy-1-propynyl)-6β, 7β; 15β, 16β-dimethylene-5β-androstane-3β, 5, 17β-triol into 17α-(3-hydroxy-1-propyl)-6β, 7β; 15β, 16β-dimethylene-5β-androstane-3β, 5, 17β-triol by subsequent oxidation into 6β, 7β; 15β, 16β-dimethylene-5β-hydroxy-3-oxo-17α-androstane-21,17-carbolactone in the presence of the catalyst TEMPO (2,2,6,6-Tetramethylpiperidin-1-yl)-oxyl).

In its rejoinder, the defendant stated that it stood by the requests it made in its response to the application for preliminary measures and, as a procedural matter, requested that the judgment not be published.

Following oral reply and rejoinder, Judge Dr. sc. nat. Tobias Bremi stated his view of the case [as a technical judge] to the Parties (Minutes, pp. 37-46). The Parties thereafter submitted their positions with respect to this statement (Minutes, pp. 46-49).

By letter dated 4 February 2013, the plaintiff submitted a judgment of the Court of Appeals of Torino of 24 December 2012 as well as an English translation of said judgment.

The minutes of the hearing were delivered to the Parties on 11 February 2013.

7.

By submission dated 7 February 2013, the plaintiff requested that the Court, within the framework of the already pending preliminary proceedings, issue an ex parte injunction regarding the sale, etc., of the contraceptives D that are the subject of these proceedings. The plaintiff asserted – as a new fact –, that it had become aware, on the

same day, that the defendant was now distributing within Switzerland those infringing goods that had obviously not been detained by the customs authorities.

On 13 February 2013, the Federal Patent Court, without hearing the defendant, ordered the following:

> 1. The defendant is hereby, subject to a disciplinary fine of CHF 1,000 per day pursuant to Article 343 para. 1 let. c CPC, but at minimum CHF 5,000 pursuant to Article 343 para 1 let. b CPC, and subject to criminal punishment by a fine against the members of its management pursuant to Article 292 SCC in the event of a repeat occurrence, preliminarily enjoined with immediate effect from importing by itself or through a third party, from storing, offering for sale, selling or placing on the market by any other means, in Switzerland, the contraceptives containing the active substance drospirenone "D 1" (Swissmedic license number a), "D 2" (Swissmedic license number b), "D 3" (Swissmedic license number c) and "D 4" (Swissmedic license number d), whereby the active substance drospirenone (6β, 7β; 15β, 16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone) contained in the products in question was manufactured through eliminating water from 6β, 7β; 15β, 16β-dimethylene-5β-hydroxy-3-oxo-17α-androstane-21,17-carbolactone by adding p-toluenesulfonic acid or pyridine with water.
>
> 2. The defendant is hereby, subject to the same penalty noted above, preliminarily ordered to recall the products according to Order No. 1 above, which it brought into circulation, i.e. to inform all known customers about these products, within 24 hours of receipt of this Order, that the defendant will take these products back and will refund the purchase price as well as other expenses.

The Court set a deadline for the defendant to submit its views (Order No. 3) and ordered the plaintiff to provide security in the amount of CHF 250,000 (Order No. 4).

8.

By submission dated 14 February 2013, the plaintiff informed the Court of the points in the minutes of the hearing which were, in its view, incorrect and requested that said points be rectified accordingly.

In its statement dated 14 February 2013, the defendant requested that the entire decision of 13 February 2013 be set aside (No. 1) and, subsidiarily, that Order No. 2 of said decision be set aside (No. 2), and that all costs and fees, plus value added tax, be borne by the plaintiff (No. 3). Further, the defendant requested as a procedural matter that the deadline set in Order No. 2 of the decision of 13 February 2013, according to which the defendant was given 24 hours to inform all known customers about the ordered recall, be lifted and, if necessary, that the deadline be set anew. The defendant supported its request by asserting that the plaintiff had unjustly created the impression that the defendant had started distributing the contested products after the hearing of 31 January 2013. The defendant also asserted that it had already made said products available on the market in Switzerland before the plaintiff launched any judicial initiatives. The defendant, moreover, stated that it had, by letter dated 12 February 2013, that is, prior to the injunction of 13 February 2013, already informed all known

customers and wholesalers that it had ceased the distribution of the contested products, and that it offered to take back the contested products from its customers and wholesalers. Therefore, Order No. 2 of the ex parte decision has become moot. The defendant also asserted that said order is disproportional.

In its submission of 18 February 2013, the defendant informed the Court that it had not yet been able to examine the minutes due to the vacation of one of its lawyers and requested that a formal deadline for any corrections to the minutes be set for 6 March 2013. Thereafter, the Court informed the defendant, in a letter dated 20 February 2013, that a formal deadline for the submission of possible objections to the minutes of the hearing would not be set.

In its submission of 20 February 2013, the defendant requested that the decision of 13 February 2013 be set aside. Subsidiarily, the defendant requested that Order No. 2 of the decision of 13 February 2013 be set aside and that all costs and fees, including VAT, should be borne by the plaintiff.

In its submission of 27 February 2013, the plaintiff submitted its position on the defendant's motion to set aside and other assertions made by the defendant in its submission of 20 February 2013.

In its submission of 28 February 2013, the defendant requested that the minutes of the hearing of 31 January 2013 should, with regard to the passages referred to in its arguments, be verified against the recorded audio of the hearing and, where necessary, be rectified.

In its submission of 4 March 2013, the defendant returned to the request it brought forward during the hearing, i.e. that the judgment should not be published, and submitted the following requests:

> 1. The Court shall refrain from publishing the decision concluding the present proceedings S2013_001.
>
> 2. Subsidiarily, all information concerning the method of manufacture applied by the defendant and its suppliers should be blacked out or be redacted by other means.

In the same submission of 4 March 2013, the defendant also stated its position on the observations forwarded by the plaintiff in its submission of 27 February 2013.

Assessment:

9.

The Parties' requests for rectification of the minutes shall first be dealt with before entering into the merits of the case.

According to Article 235 para. 2 CPC, statements relating to the facts of the case are to be placed in the minutes in their essence to the extent they are not already included in

the written submissions of the parties. The court decides on applications for rectification of the record (para. 3).

Statutory law does not contain any deadline regarding applications for the rectification of the minutes. It must therefore be assumed that requests for the rectification of the minutes must be submitted **immediately after obtaining knowledge** of an alleged mistake, otherwise they will not be considered (see Eric Pahud, DIKE-Komm-ZPO, Art. 235 N 24; KUKO ZPO-Naegeli, Art. 235 N 14; Leuenberger in Sutter/Somm/ Hasenböhler/Leuenberger, ZPO Komm., 2d ed., Art. 235 N 18; Laurent Killias in Berner Kommentar, Art. 235 ZPO N 19).

In its submission dated 14 February 2013, the plaintiff timely responded to the delivery of the minutes of the hearing on 11 February 2013. The plaintiff complained of five specific places in the minutes, which it considered incorrect and then suggested how said places should be rectified. The plaintiff's requests for the correction of the minutes are justified; in granting the plaintiff's requests, the minutes shall be rectified accordingly.

In its submission dated 28 February 2013, the defendant requested that the minutes of the hearing of 31 January 2013 should, with respect to the places it referred to in its submission, be verified against the recorded audio of the hearing and be rectified where necessary. To assess the timeliness of this request, the following must be assumed: proceedings for preliminary measures, such as the one at hand, serve to provide a temporary ruling in **urgent** cases until a final decision is reached during ordinary proceedings. Accordingly, in order to serve their purpose, preliminary proceedings must be conducted without delay. Courts and parties must adapt to this requirement. To this effect, in order to streamline proceedings, a hearing date of 31 January 2013 was tentatively scheduled with the parties even before the deadline (of 21 January 2013) set for the defendant's response to the application for preliminary measures had lapsed, in case a hearing was deemed necessary after receipt of the response. Subsequently, notwithstanding the considerable effort involved in preparing the minutes, in view of the subject matter and due to the defendant's missing pleading notes, as well as the volume of the minutes (49 pages), the minutes were delivered to the Parties on 11 February 2013. In view of the foregoing, if the defendant referred to passages in the minutes which it considered incorrect only on 28 February 2013, this was clearly not done **without delay**. Furthermore, the defendant did not, for example, state how exactly the passages about which it complained should be rectified, but instead simply asserted that the minutes did not correspond with the internal notes of its lawyers, and therefore should be verified – by whom the defendant did not say – against the audio recordings. The defendant, apparently lacking certain knowledge about the statements it made, is unable to say what the correct content of the minutes should be, and instead simply criticizes sections of the minutes as being inaccurate, because, for example, this or that topic was also discussed, or that an introduction was made, and it now demands that the minutes should be reconstructed using the audio recordings.

The defendant thus fails, on the one hand, to recognize that it is neither entitled to a reproduction of the exact wording nor to a comprehensive reproduction of its submissions at the hearing; instead, statements relating to the facts of the case are to be placed in the minutes only in their essence (Article 235 para. 2 CPC), and on the other hand to recognize that its request would result in delay, which would not be in conformity with the nature of the present proceedings. In proceedings for preliminary measures, any person who desires that the minutes be rectified must submit an application for correction, without delay upon receipt of the minutes, i.e. within a few days, and such application must contain references to the particular passages that the person considers incorrect and also to how exactly these passages ought to be rectified. The defendant failed to comply with these requirements. Its request for the correction of the minutes is therefore insufficient and also belated, which is why it will not be considered.

For purposes of clarification, we now turn to the defendant's argument that the reproduction of the technical judge's statement in the minutes of the hearing contains the depiction of chemical structural formulae even though the judge rendered his statement orally and without visual aids, so that the depiction of said structural chemical formulae shall be stricken from the minutes. These depictions in the minutes are visual representations of the structural formulae, which correspond to the abbreviations used in the patent in suit and, accordingly, in the technical judge's statement. Therefore, the technical judge's statement was, in terms of its **content**, correctly represented. The defendant itself did not assert anything to the contrary.

10.

The plaintiff applies for preliminary injunctive relief and also requests the recall of products already sold. By requesting an injunction, the seizure by the Federal Customs Administration, Customs Inspectorate Pratteln, is maintained (cf. Article 86c PatA). Nevertheless, what happened at customs and what may have led to that is – contrary to the defendant's assumption – irrelevant in the present proceedings. It is immaterial why and on whose application the customs authorities seized the goods. The only question to be assessed here is whether the plaintiff is entitled to a preliminary injunction according to Request No. 1 and to an order to remedy an unlawful situation pursuant to Request No. 2. To this end, it must be examined whether the patents in suit – provided that the defendant is unable to establish their invalidity – are infringed by the goods, and if so, whether the other requirements for the issuance of preliminary measures are also satisfied. If that is the case, then an injunction will be granted – completely independently of the reasons for the seizure by the Customs Authorities.

11.

The plaintiff asserts that its original requests are clear and enforceable after it showed probable cause that the pharmaceutical products D 1 - D 4, licensed by Swissmedic, which indisputably contain drospirenone, were manufactured for the defendant by the producer, in any case, by using one of the methods that are within the scope of the

patents in suit. The plaintiff further asserts that the defendant did not allege that any other method was applied, let alone did it show probable cause therefor. Consequently, the plaintiff concludes that its requests satisfy the requirements set out by the case law of the Federal Supreme Court for the issuance of injunctive relief in patent litigation.

According to the case law of the Federal Supreme Court, actions for injunctive relief must be aimed at enjoining precisely described behaviors. The infringing form or accused embodiment is to be described in such a way that, in the context of enforcement, it can easily be verified whether the enjoined embodiment is present. In principle, product names are insufficient because they can easily be changed (BGE 131 III 70 E. 3.3, 3.6; Decision of the FPC of 7 March 2012 in proceedings S2012_002; http://www.patentgericht.ch/fileadmin/entscheide/S2012_002.pdf)[6]. Product names or product license numbers as part of a request for relief can only suffice if it is guaranteed that no other products can be sold under said name or license number except those covered by the patent, which could be the case, for example, for products requiring official marketing approval (see decision of the FPC of 24 August 2012 in proceedings S2012_004, consid. 9; http://www.patentgericht.ch/fileadmin/entscheide/S2012_004.pdf)[7].

Therefore, with respect to medicines which require official marketing approval, the use of product names or license numbers only in requests for relief may be sufficient. However, this applies in principle only in cases in which the underlying patent is directed towards the active ingredient or a formulation per se (product protection), and where the approval unequivocally defines this active ingredient or formulation. If, as in the present case, the patent being relied on is a process patent for the manufacture of an active ingredient, and if it is not ascertainable from the publicly available approval documents that are in the court files that the product must imperatively be manufactured using a particular method which falls under the claims of the process patent, then the request for relief must contain a description of how exactly each and every process feature of the claim is concretely implemented in the accused embodiment, provided that these process features are not defined accordingly in the approval documents. Otherwise, a request for relief that refers solely to a product name would also encompass products manufactured by a different method that is not covered by the patent in question. Consequently, the product as defined in original Requests Nos. 1 and 2 would go beyond the scope of protection of the process patent, and would therefore encompass products which are not protected by the patent in suit (see criterion c in consideration 14 of the decision of the FPC of 2 February 2012 in proceedings S2012_003; http://www.patentgericht.ch/fileadmin/entscheide/S2012_003.pdf)[8].

The plaintiff did not sufficiently establish why, based on the marketing approval for the manufacture of the accused product, the first or the second method must imperatively

6 Translator's note: The original hyperlink in the judgment is outdated and was therefore updated.

7 Translator's note: The original hyperlink in the judgment is outdated and was therefore updated.

8 Translator's note: The original hyperlink in the judgment is outdated and was therefore updated.

be applied, respectively that no other product manufactured by a different method could also be sold under the name of the approved product.

Therefore, original Requests Nos. 1 and 2, which do not contain the required process features, will not be considered.

12.

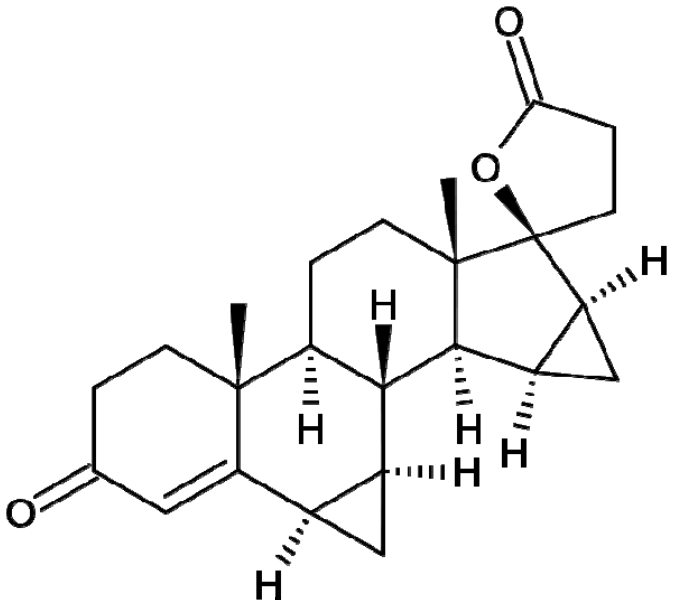
The plaintiff makes the following assertions regarding the amount in dispute: "The applicant estimates that the amount in dispute is CHF 500,000, which is common for preliminary measures involving pharmaceutical patents". This argument is beside the point. In the present proceedings, the amount in dispute is not to be determined by what might be common in such proceedings, but instead solely by the specific circumstances of the present proceedings. Regarding the amount in dispute, it should be borne in mind that it is not only the value of the seized products but primarily the value of the injunction that is decisive (BGE 92 II 62 E. 3; Leuenberger/Uffer-Tobler, Schweizerisches Zivilprozessrecht, Bern 2010, RZ 2.153). Furthermore, in assessing the amount in dispute, not only the interests of the plaintiff but also those of the defendant are to be taken into consideration (BGE 92 II 62 E. 3). In this respect, the defendant arrived at a substantiated estimate exceeding CHF 1 million. Contrary to the plaintiff's submissions, it cannot simply be assumed that the main proceedings in cases such as the present one will last for only one year, and one cannot ignore the fact that the decision on the request for preliminary measures may well have a prejudicial effect on the other proceedings pending elsewhere in Europe. Consequently, we assume the amount in dispute exceeds CHF 1 million.

13.

Issuing preliminary measures requires, on the one hand, that the alleged infringement is shown with the prerequisite degree of probability and, on the other hand, that the infringement is about to cause not easily reparable harm to the plaintiff (Article 66 lit. a PatA in connection with Article 72; Article 77 para. 1 lit. a PatA in connection with Article 261 CPC). In addition, a certain degree of urgency is required. The judge adjudicating the request for preliminary measures can confine himself to examining the legal issues summarily (BGE of 9.1.2012, 4A_508/2012 E. 4.2 with further references). Allegations are sufficiently probable if the judge considers them to be predominantly true, even though not all doubts are dissipated.

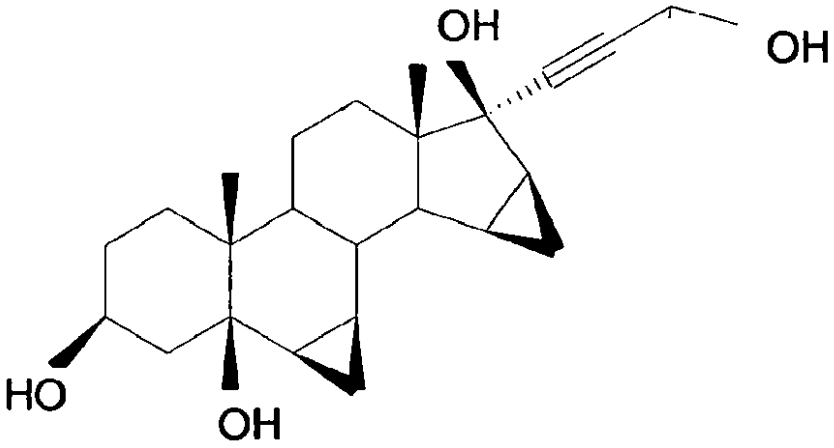
14.

According to the technical judge's statement, this case is about a method for manufacturing the component drospirenone (DRSP):



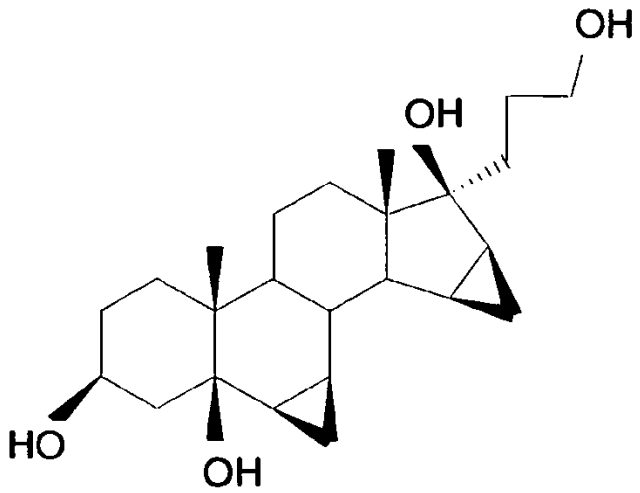
a steroidal active substance which belongs to the group of progestational hormones.

The starting point of the reaction for the production of this active substance is undisputedly always the alkaline molecule ZK 34506



ZK 34506

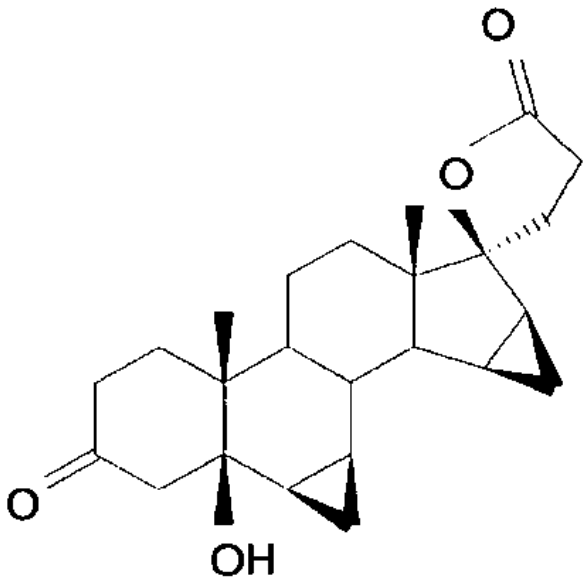
which, on the one hand, is to be transformed into the open-chain component ZK 92836 by hydrogenation of the triple bond (reaction step A)



ZK 92836

and transformed by subsequent oxidation and ring-closing into the cyclical lactone structure (implementation of the functionality shown at the top right of the drawing).

On the other hand, the 1,3-Propanediol is oxidized and water is eliminated to result in the corresponding enol structure (implementation of the functionality shown at the bottom left of the drawing), whereby this transformation is known to take place through an enol-intermediate form ZK 90965:



ZK 90965

The result of the reaction process is drospirenone (DRSP) as shown above earlier.

15.

Simply put, Patent '791 protects the following method of manufacture (claim 1, additions in parentheses by the Court):

Method for the production of drospirenone (DRSP) through

- catalytic hydrogenation of the alkaline ZK 34506 into the open-chained ZK 92836 (reaction step A),

- subsequent oxidation in the presence of a ruthenium salt into the enol ZK 90965 (reaction step B), and

- subsequent elimination of water under the formation of DRSP (reaction step C).

Simply put, Patent '840 protects only reaction step C; however, the patent specifies that, for the purpose of the elimination of water, p-toluenesulfonic acid is used.

16.

Assessment of the first method:

The plaintiff does not allege that the first method infringes Patent '791, even though the conditions for the oxidation step in Patent '791 by using a ruthenium salt (reaction step B), which is the main focus of the patent, are essentially the same as in the second method.

The plaintiff alleges the infringement of Patent '840 by the first method, i.e. by literal infringement of the claim's elements. The existence of such infringement is plausible, inter alia, in light of the decision of the District Court of Düsseldorf of 26 June 2012. Obviously, the first method literally reproduces all elements of the claim of Patent '840, as explained in the sworn affidavit of the executive director of Company K. According to the first method, using enol ZK 90965 as a starting point, the elimination of water and the formation of DRSP (reaction step C) takes place in the presence of p-toluenesulfonic acid, which literally corresponds to the principal claim of Patent '840 as maintained by the EPO Board of Appeal.

However, it does not seem plausible – also in light of the uncertain statements contained in the application for preliminary measures – that this first method was used at all. Such assumption has not been credibly established in view of the pre-trial correspondence with a corporate group member of the defendant, in considering the statements in the protective letter as well as the response to the request for preliminary measures, and in light of the information contained in the Drug Master File. Regarding this information from the Drug Master File, it should be noted, however, that it only concerns a manufacturing process referred to as "Option 2", and that not the entire Drug Master File Document was submitted. Therefore, it remains unclear to what extent the apparently existing "first option" deviates from "Option 2". It also seems unlikely that the first method was used at all given that the judgment of the District Court of Düsseldorf resulted in an injunction for the first method in Germany. It does not seem plausible that the defendant continued to use this first method without any modification, for example, by applying it selectively only for products delivered outside Germany.

As a result, regarding the first method – also having considered the plaintiff's statements during the hearing – probable cause has not been established that the defendant actually applies this method in the production of the active substance.

17.

Assessment of the second method:

17.1 First, we address one of the defendant's arguments. The defendant asserts the following: "What is characteristic about plaintiff's behavior is the fact that it did not even assert literal infringement of the patents in suit, at any rate not with respect to EP 0 918 791. Instead, plaintiff attempts to extend the scope of protection of its patents in suit to other methods by claiming that other means are equivalent, even though they are not listed in the patent claim. Yet it was plaintiff itself which refrained from mentioning these means in the patent claim and in the description. Therefore, the plaintiff is claiming a level of protection that goes far beyond the teachings of the inventions of the patents in suit".

This submission is incomprehensible. The fact that it is asserted that certain means are within the scope of the patent claim, even though they are not explicitly mentioned therein, is literally the prerequisite for the topic of equivalence. Furthermore, the fact that the means in question are not mentioned in the description is, in principle, an essential requirement for a successful assertion of equivalence. If the means were mentioned in the description but not in the claim, then one would presumably have to conclude that the patentee has refrained from claiming such means, and that it did not intend to protect that particular embodiment.

17.2 According to the case law of the Federal Supreme Court, imitation (infringement by equivalents, Article 51 PatA in connection with Article 66 let. a PatA and Article 69 EPC) exists if a process or product, while not reproducing one or more elements of the claim, replaces them with other elements that, within the framework of the problem underlying the patented solution, perform the same function as the elements in the claim (see BGE 97 II 85 E. 2; hereinafter "first question"). In order to qualify as imitation according to the case law of the Federal Supreme Court, the other elements which replace the ones contained in the claim must, moreover, be obvious to a person skilled in the art in light of the teaching of the patent (BGE 97 II 85 E. 1; BGE 125 III 29 E. 3b; 115 II 490 E. 2a; hereinafter "second question").

According to the "Schneidmesser" decisions of the German Federal Court of Justice (Schneidmesser I and II of 12 March 2002, GRUR 2002, 515 and 519), in order to determine whether equivalence exists, not only these two but rather three questions must be examined and answered cumulatively in the affirmative (cf. Meier-Beck in GRUR 2003, 905):

(1) Does the accused embodiment solve the problem underlying the invention with modified means that objectively achieve the same effect? (same effect, corresponds to first question above)

(2) If yes: Is a person skilled in the art by means of his or her general technical knowledge able to find the modified means as having the same effect? (obviousness to a person skilled in the art, corresponds to second question above)

(3) If yes: Are the considerations to be applied by the skilled person in the art in this regard so closely oriented to the meaning of the technical teaching protected by the patent claim that he or she considers the modified embodiment with its modified means as being of equal value to the solution provided by the invention as defined literally in the claim? (equal value).

In Great Britain, the three "Improver" questions are posed, namely as follows (Improver Corporation/Remington Consumer Products Ltd., R.P.C. 1990, 181[9]; GRUR Int. 1993, 245):

(1) does the variant have a material effect upon the way the invention works? If yes, the variant is outside of the claim. If no –

(2) Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes –

(3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

When determining the scope of protection of patents that goes beyond the wording of the claim (sphere of equivalence, sphere of imitation), while appreciating the contribution of the invention, legal certainty for third parties must also be taken into account. Third parties should, without unreasonable effort, be able to discern what is allowed and what is not allowed while studying the patent, which can be difficult, especially in the field of equivalence. The first question of same effect and the second question of discoverability or obviousness for a person skilled in the art take this interest into consideration. However, in light of the primacy of the claim language (cf. Article 51 PatA), they are insufficiently oriented towards the actual wording of the claim. Until now, the third question of equal value, which is oriented towards the actual wording of the claims, was unknown to Swiss case law in the assessment of the question of equivalence. In view of the objective of the European Patent Convention to provide for unity in connection with the interpretation of the scope of protection of European Patents – and such a patent is at issue presently –, relevant decisions by foreign courts should be taken into account, whereas decisions by supreme courts should be given more weight (see BGE 121 III 336 E. 5c S. 338; BGE 117 II 480 E. 2b S. 486 f.; BGE 137 III 170 E. 2.2). In this sense, Swiss courts also have to take into consideration the question of equal value as discussed above with respect to both European and Swiss patents. It is this third question that ensures that the scope of equivalence is limited – in a way understandable to a third party – to modifications to which a person skilled in the art, on the basis of the wording of the claims, has access and recognizes to have equal value.

[9] Translator's note: The proper citation for this case is *Improver Corp. v. Remington Consumer Products Ltd.*, [1990] F.S.R. 181 (Ch. 1989).

17.3 The second method is presented in the process description by patent attorney Cristina Biggi. It [the second method] is characterized by the fact that reaction step A involves the hydrogenation of the alkaline ZK 34506 under basic conditions (pyridine, palladium, THF [tetrahydrofolate]) in the open-chained component ZK 92836; that reaction step B involves the oxidation using TEMPO and calcium hypochlorite in a solvent, which results in enol ZK 90965; and that reaction step C involves water elimination by using pyridine/water.

The defendant does not dispute that this second method is used.

17.4 Infringement of Patent '791: Accordingly, the second method differs from the method claimed in Patent '791 only with respect to reaction step B, given that reaction step A requires catalytic hydrogenation, whereas the second method involves the use of palladium, and the claim indicates, without mentioning specific reagents, that in reaction step C the pharmaceutical product drospirenone is derived by means of water separation in the enol ZK 90965, which is also the case in the second method.

Reaction step B is defined in Patent '791 as an oxidation of the open-chained ZK 92836 in the presence of ruthenium salt into the enol ZK 90965. The question of which specific ruthenium salts can be applied is discussed in detail in paragraph [0011] of the patent, and it is indicated that, in combination with a catalytic amount of ruthenium salts, a conventional, simple oxidant may be applied. None of these [agents] is a calcium salt or hypochlorite, let alone a calcium hypochlorite $Ca(OCl)_2$. In addition, it is emphasized that the key reaction of the invented method is the ruthenium-catalyzed oxidation of the open-chained ZK 92836 into the enol ZK 90965 (cf. paragraph [0012], emphasis added by the Court). Relating to the advantages of the inventive method achieved by that, it is particularly indicated – apart from the mention of increased purity and yields (cf. paragraphs [0017] and [0018]) – that the toxic chromium compounds used thus far in the state of the art for oxidation are to be replaced with catalytic amounts of a metal (cf. paragraph [0019], emphasis added by the Court).

In the second method, reaction step B is carried out by using TEMPO, an organic radical, which is applied in combination with the oxidant calcium hypochlorite $Ca(OCl)_2$. As indicated in the plaintiff's own European patent specification EP 1 746 101 B1 (especially paragraphs [0007] and [0008]), TEMPO acts in catalytic amounts.

17.5 As regards the question of same effect (the first question with respect to equivalence):

The organic TEMPO carries out the same function as the claimed ruthenium salt. This is because it [TEMPO] is also used in catalytic amounts as an auxiliary oxidizing agent together with a second conventional oxidant, here calcium hypochlorite; just as catalytic amounts of ruthenium salt are used in Patent '791 in suit as an auxiliary oxidizing agent together with a second conventional oxidant, there sodium bromate is referred to as an example. Should another reaction mechanism possibly be passed through in the scope of fulfilling this function, this would be insignificant because, in connection with the

oxidation reaction, Patent '791 in suit does not mention any specific reaction mechanism.

It appears that there is objectively same effect.

17.6 As regards the question of discoverability and obviousness to a person skilled in the art (the second question with respect to equivalence):

It is unclear whether a person skilled in the art would be able to recognize TEMPO as a substitute which has the same effect as ruthenium salt. The fact that in its subsequent application EP 1 746 101, the plaintiff itself had argued in the same manner as it did in its original application, i.e. that it was, inter alia, in light of Patent '791 (cf. paragraph [0002]) surprising to find that for such an oxidation reaction TEMPO instead of ruthenium salt could be used, speaks against such an assumption. A further indication against [this assumption] is the fact that documents involved in the proceedings which relate to the oxidation of diols under the formation of lactones with TEMPO only reveal such reactions in ordinary molecules and not in connection with complex stereochemical molecules, let alone steroids. On the contrary, the fact that the Office, during the examination procedure, alleged that there was lack of an inventive step with regard to TEMPO, in light of the already known ruthenium salt, speaks in favor of such an assumption.

This question may remain open since equivalence fails because the person skilled in the art, following the wording of the claim and in light of the description of the protected invention, would not have considered TEMPO as a solution of equal value (the third question of recognizable equal value).

17.7 With regard to the question of whether the considerations by the person skilled in the art, concerning the replacement of ruthenium salt with TEMPO, are sufficiently oriented towards the meaning of the technical teaching protected by the patent claim for the person skilled in the art to consider the modified version TEMPO, with its modified means, as a solution of equal value to the literally claimed one (third question with respect to equivalence):

The use of ruthenium salt is described in Patent '791 as a key reaction (cf. paragraph [0012]). In the description of the advantages, it was indicated that the toxic chromium compounds could be replaced with catalytic amounts of a metal (cf. paragraph [0019]). There seems to be no suggestion thereby that an organic molecule is viewed as a replacement.

Even if, as an overarching concept of the invention of the technical teaching protected by the patent claim, the replacement of the toxic chromium compounds with a metal as a catalyzer were to be assumed, the person skilled in the art, given the specific mention of the importance of ruthenium salt as the key element of the invention in the description and in the claim, would perhaps consider another metal salt as a replacement for this ruthenium salt, but not an organic molecule and even more specifically not a radical, in particular TEMPO. Specifically, the choice of the specific system of using TEMPO, in

connection with the base frame of drospirenone and in connection with the separation of oxidation and water elimination, does not seem to be of recognizable equal value in view of the meaning of the technical teaching protected by the patent claim, because the documents concerning the use TEMPO for oxidation disclose such a reaction only with respect to small linear molecules, without taking into account the subsequent unstable dehydrating structural units.

Focusing on the wording of the claim and interpreting the protected technical teaching contained therein, also in light of the description (Article 69 EPC), an equal value recognizable to a person skilled in the art does not exist. As a result, imitation of the technical teaching of Patent '791 is ruled out.

17.8 Therefore, Patent '791 is not infringed, and the question of validity may remain open.

18.

Infringement of the Patent '840: The second method distinguishes itself from the method protected in Patent '840 in that for reaction step C, instead of p-toluenesulfonic acid, the base pyridine/water is used for water elimination from the enol ZK 90965 to form DRSP.

Hence, there is clearly no literal infringement (copying). In fact, the plaintiff itself does not assert such an infringement.

18.1 Hence, the first question to be decided is whether, within the framework of reaction step C, pyridine/water objectively performs the same function as p-toluenesulfonic acid. The applications of these two reagents cause water elimination in the enol ZK 90965 to take place in an enol structural unit. Even though the acid-catalyzed reaction represents a reaction mechanism which is different from the base-catalyzed reaction, the fact remains that both reagents perform the same function; namely to catalyze water elimination.

The defendant’s argument in this regard, that in the second method no separation of reaction steps B and C takes place, because an essential amount of DRSP already forms during the oxidation step, and therefore that there is no isolation of the intermediate product between these two steps, is not convincing. In the processes that are part of the prior art, reaction steps A and B always take place in a single step, that is, the reaction process continues until the end product DRSP is achieved (in this respect compare the decision of the EPO Board of Appeal, T 2505/11, consid. 9.3, third paragraph), whereas in the second method applied by the defendant, it is clear that reaction steps B and C are separate.

The defendant’s assertion of a partial water elimination, also recognizable in Gambaro’s opinion, proves to be unconvincing, because the formation of DRSP only commences after oxidation is completed, namely during distillation; hence this represents a thermal dehydration distinct from the process of oxidation. Further, such a distillation process is not mentioned explicitly in the Drug Master File, because the Drug Master File only

mentions the removal of the solvent; however, this only takes place after oxidation is completed and also not explicitly through the application of a distillation process. As was already established in the decision of the District Court of Düsseldorf, it is insignificant whether the isolation of a by-product occurs and to what extent this by-product is present before the addition of the catalyst for water elimination.

Hence, the different means objectively have the same effect.

18.2 The second question to be clarified is whether this objectively same effect was discoverable and obvious to a person skilled in the art. The plaintiff's submission, that the elimination of water from an enol-functionality belongs to the basic knowledge that students are equipped with during the first years of study in organic chemistry, can be concurred with. In these courses, chemists typically learn – based on this reaction – that catalytic water elimination can essentially be carried out equivalently under acid or base conditions. Based on his or her basic knowledge, a person skilled in the art is, therefore, aware of both possibilities, and he or she knows exactly the corresponding reaction mechanisms. Thus, the use of a base instead of an acid is obvious to the person skilled in the art precisely because this is a standard reaction which the person skilled in the art knows can be achieved through the two different methods mentioned above.

In the end though, the question becomes whether the replacement of the specific acid p-toluenesulfonic acid with the specific base pyridine/water is obvious to the person skilled in the art. Based on the patent in suit, the person skilled in the art knows that the system enol ZK 90965 is acid-labile and base-labile (cf. paragraph [0005], at the discussion on prior art in a one-step procedure). Moreover, the person skilled in the art, based on his or her basic knowledge as a chemist, knows that pyridine/water is a common and often used weak base. In view of the fact that, particularly during the one-step procedure in the prior art, water and pyridine are applied (cf. paragraphs [0003] and [0005] in the Patent '840 and also the prior art cited there), the person skilled in the art would basically not only take into consideration the replacement of the p-toluenesulfonic acid with a base, but instead he or she would, in an obvious manner, especially consider the replacement [of the p-toluenesulfonic acid] with the specific system of pyridine with water as a promising possibility. Consequently, the replacement of the acid p-toluenesulfonic acid with pyridine/water is obvious to the person skilled in the art.

18.3 As regards the question of whether the equal value of the solutions is recognizable in light of the patent claims and the specification: guided by the meaning of the technical teaching protected by the patent claim, a person skilled in the art can also recognize the equal value of p-toluenesulfonic acid and pyridine/water and would, therefore, have taken it into consideration. This is because he or she is able to recognize that the replacement of the specific acid p-toluenesulfonic acid with a suitable base would generate the same effect (see discussion above), and also because he or she precisely knows this base, pyridine/water, in connection with the present specific complex stereo-chemical molecule from the single-step procedure according to the prior art and he or she would accordingly also consider it as a base for the water elimination step in

connection with the separate oxidation and water elimination (two-step procedure). Thus, the person skilled in the art can assume that pyridine/water will bring about water separation without causing a rearrangement or any other unwanted side effect reactions on the molecule. Therefore, he or she would recognize the equal value. This conclusion is in no way invalidated by paragraph [0013] and the naming of stronger bases therein, in the sense of a description of an example of how the invention can be carried out but which is not claimed (see decision of the German Federal Court of Justice of 10 Mai 2011, X ZR 16/09 – Okklusionsvorrichtung; decision of the German Federal Court of Justice of 13 September 2011, X ZR 69/10 – Diglycidverbindung); this is because paragraph [0013] refers to a strong base, whereas the system of pyridine/water is well known to be a weak base.

Given that the parallel judgment from the Netherlands of 24 January 2013, which was submitted to the court, – if at all – treated the question of equal value only superficially and without reasoning, the differing opinion expressed therein is not convincing.

Consequently, equal value exists, and there is imitation.

19.

Furthermore, in connection with the question of imitation, the defendant submits that the scope of equivalence cannot be extended to embodiments which are known or obvious in light of the prior art (Formstein objection). In support of this argument, the defendant relies on Examples 1h and 5c in U.S. Patent 4 416 986 A, where it is stated that the oxidation of ZK 92863 in the presence of CrO_3 [chromium trioxide] in pyridine is a one-step reaction process for obtaining DRSP. Moreover, the defendant invokes [journal article] Angew. Chem. Int. Ed. Engl. 1982, 21, 696-697, in which the same one-step reaction with the reagents pyridinium dichromate is carried out in DMF. It [the defendant] thus claims that the attacked process is not novel in light of the prior art or at least that there is no inventive step given that analogous elimination reactions on analogous molecules under the influence of pyridine were already known in the prior art as referred to above.

This argument cannot be followed. According to the prior art, the course of the reaction in question is always a one-step reaction process, i.e., the reaction starts from the by-product ZK 92836 and proceeds directly to DRSP. In this process, the enol ZK 90965 presumably forms as a transient state (however, there is no revelation about this in the prior art). Obviously, though, this reaction process cannot be halted at this intermediate stage, even provided that such an intermediate stage actually exists. On the contrary, the invention according to Patent '840 is based on – as was also expressed in the relevant decision of the EPO Board of Appeal, in which exactly this state of prior art was also at issue (there, U.S. Patent 4 416 985 was even discussed as the closest piece of prior art D10) – adding an agent for the elimination of water, not already during the oxidation process, but only after oxidation into enol ZK 90965 is completed (see T 2505/11, consid. 9). According to the patent claim, the starting point of the reaction process is thus the ZK 90965, which – this must be the interpretation of the claim in light

of the description – is run as part of the oxidation process not as a hypothetical transient state, but presented as an actual stage and implemented with a separate catalytic active reagent for the purpose of water elimination. Therefore, in light of the one-step process in the prior art, the attacked process is not only novel, but also inventive, because the addition of pyridine already during oxidation – as known in the prior art – obviously does not allow at all for precisely the isolation of the intermediate stage ZK 90965 (at least there are no such indications in the prior art). Accordingly, the prior art provides neither an incentive nor a tangible suggestion as to how, and with what advantages enol-intermediate stage ZK 90965 (which is not revealed in the prior art) in light of the specifically disclosed oxidation reactions in the prior art (which always go all the way through to DRSP) is presented – and hence, as to how oxidation and elimination could be separated into two stages.

20.

In the event that imitation is found, the defendant raises, as an alternative, the defense of nullity. This defense needs only to be examined with respect to Patent '840, since no infringement of Patent '791 was found.

For the defense of nullity with respect to Patent '840, the defendant relies solely on lack of inventive step, and to this end, exclusively in light of a scientific publication by one of the inventors. It [the defendant] asserts that, in light of said publication, which was not considered in the relevant appeals proceedings, it is apparent that the invention does not solve the problem. The decision of the EPO Board of Appeal in T 1329/04, which was submitted in support of this argument, is not convincing because, on the one hand, this decision relates to the area of biochemistry, and, on the other hand, it only deals with the question of speculative application, which is common in that field but is not the case here. Hence, it is plausible that the reaction in question automatically leads to the indicated product. The question of whether the acids could subsequently rearrange the DRSP was never raised, neither during the EP proceedings in the matter of Patent '791, nor in connection with Patent '840. In addition, the defendant contradicts itself to a certain degree with this argument, because the defendant, respectively its suppliers, had obviously successfully applied a [manufacturing] method using p-toluenesulfonic acid; a fact which is revealed in the proceedings before the District Court of Düsseldorf and also in the international registration of Company K. Therefore, the defense of invalidity does not hold water.

21.

As mentioned above (consid. 6), the Parties have submitted their views on the expert report prepared by the [technical] judge-rapporteur. The following shall be said with regard to these views:

According to the plaintiff’s submission, the European Patent Office also granted a patent which does not require the use of ruthenium (Patent '840). The plaintiff, therefore, was of the opinion that protecting the interests of third parties made no sense and that the use of ruthenium in the claim cannot be read to give it such a limiting effect on the

scope of protection. It should be noted in this regard that Patent '791, including its specification, is to be read in the form in which it is presented. Remarkably, precisely those passages that specifically refer to ruthenium as an essential element were removed from the description of Patent '840, while those passages feature prominently in the description of Patent '791. This circumstance cannot be ignored.

Concerning the defendant's suggestion that the "Formstein objection" applies, it should be noted that it is precisely a one-step process that is used in the prior art. The separation of the two reaction steps is neither obvious in the prior art nor does the prior art contain any suggestion thereof (see the decision of the EPO Board of Appeal). Concerning the defendant's suggestion in connection with Patent '840 that with regard to the third "Schneidmesser question", one should only focus on the patent claim, and the fact that the bases are listed in the description leads to the exclusion of equivalence: it should be noted that section [0005] of Patent '840 mentions the bases for [water] elimination only in connection with a specific discussion of the prior art. Section [0013] of Patent '840 pertains to strong bases. In contrast, pyridine/water is not a strong base, but instead a weak base. Finally, the following should be noted regarding the defendant's suggestion that T 1329/04 obviously reveals that Patent '840 is not legally valid: said decision relates to a different technical field, namely biochemistry/ biotechnology. Moreover, it dealt with specific facts which are not present in the case at hand. Besides, the proceedings before the District Court of Düsseldorf show that the defendant's supplier could manufacture DRSP. On the other hand, the proceedings in the cases of Patent '840 and Patent '791 before the EPO reveal that there were obviously no problems with regard to the question of the effective solution of the problem.

22.

Concerning the defendant's denial of having committed an act of infringement by importing a product of which the ingredient directly derived from the [patented] process of the reaction is only one of its components, see [decision of the Federal Supreme Court] BGE 70 I 194, especially consid. 7, last paragraph. According to settled case law of the Federal Supreme Court, in situations in which not only the active ingredient is present in a product, it can be assumed that the product is directly derived from the [patented] process, if the active ingredient in question is crucial for the nature of the end product at issue. This is clearly the case here, because drospirenone is one of the two essential active ingredients contained in the final product. The defendant itself has not asserted any other plausible conclusion. Therefore, there is an act of infringement.

23.

As regards the requirement of not easily reparable harm, such harm can be affirmed in this case solely based on the difficulties of proving damages. The defendant's argument that it would have been easy for the plaintiff to substantiate the claimed decline in sales is unhelpful, because the plaintiff would then have been required to prove that the decline was due to the defendant's market presence. However, this is practically

impossible when multiple generic manufacturers are present on the market. The defendant itself admitted this fact, albeit only in connection with the difficulty involved in substantiating its own damages in the event a preliminary injunction were to be granted: "[However], if there are multiple other suppliers of a compound with identical composition on the market, it becomes impossible to even estimate the development of sales".

24.

Moreover, the question of proportionality of the ordered measures shall be considered.

24.1 In this regard, the defendant asserts that it would be unreasonable, if such complex and technical cases – such as the present case of alleged patent infringement by equivalents – were decided to the detriment of the defendant without a comprehensive assessment of the facts in ordinary proceedings. Such an assertion in a preliminary injunction proceeding is incomprehensible; according to the law, this type of proceeding simply requires establishing probable cause, and not a comprehensive examination of the facts. If the defendant further asserts (loc. cit.) that the deadline of ten days is too short and, therefore, does not allow enough time for an appropriate defense, such an assertion can also not be accepted, given that the defendant had been aware of this issue for a long time and that, on the occasion of the hearing, i.e. three weeks after it [the defendant] was served the request for preliminary injunction, the defendant did have a right to file an unlimited rejoinder.

24.2 Finally, the defendant argues that in the event the plaintiff's request were granted, the general public would be denied access to affordable medicine for the duration of the ordinary proceedings, and that such a result is all the more unacceptable as the plaintiff is once more attempting to hinder effective competition by requesting an illegitimate expansion of the scope of protection of the patent, on which said measures are based, to objects whose protection the plaintiff deliberately refrained from seeking in the granting procedures. The second argument – illegitimate expansion of the scope of protection – is not convincing, because if the Court were to arrive at the conclusion that there is an illegitimate expansion of the scope of protection, it would reject the plaintiff's request. As regards the argument that ordering preliminary injunctions would lead to the general public being denied access to affordable medicine: this might be true, it is, however, the result of the sole and exclusive rights accorded to the patentee for the duration of the patent as a reward for his contribution to the improvement of the state of the art.

25.

As regards the requirement of urgency, it must be held that the plaintiff cannot be blamed. The plaintiff reacted without delay as soon as the medicine was imported. The plaintiff showed probable cause in this regard in its submission of 27 February 2013, and also in connection with the injunction of 13 February 2013. Prior to these events, the plaintiff did not have a sufficient basis upon which to take appropriate steps. Moreover, the urgency results from the fact that the sale by the defendant of the

products in contention would create the impression that the plaintiff is unwilling to or incapable of enforcing its patent. In addition, in the event that the [defendant's] product were to be subsequently banned, women who had begun using these products would have had to change products, and from their perspective the plaintiff would have to be blamed. It follows that such an occurrence would damage the plaintiff's reputation.

26.

Given that the plaintiff has provided the required security in the amount of CHF 250,000.00 within the deadline, Order No. 1 of the injunction of 13 February 2013 is to be sustained. Order No. 2 of said injunction has become redundant after the defendant complied with the obligations contained therein.

For the sake of completeness, it remains to be said that it is not necessary to enter into the Parties' disagreement on whether the ex-parte preliminary injunction of 13 February 2013 was based on an accurate presentation of the facts by the plaintiff and therefore enter into the discussion whether it should or should not have been issued. Either way, said injunction remained valid until today's decision. As regards the future, the injunction is sustained based on the facts taken into consideration in today's decision.

27.

The plaintiff is given a deadline of 30 days within which it must file an action in an ordinary proceeding; otherwise the ordered preliminary injunction automatically expires (Article 263 CPC).

28.

According to Article 3(1) of the IR-PatC,[10] the Federal Patent Court shall publish its final decisions on the Internet ten days upon dispatching the same to the parties. The publication shall take place in non-anonymized form unless the protection of private or public interests necessitates anonymization. The anonymization may be carried out ex-officio, and in the case of private interests, anonymization may be done where this is requested and appears to be justified (para. 3).

In its rejoinder, the defendant forwarded a new request urging the Court to refrain from publishing this decision. In support of this request, the defendant submitted that there was no public interest because the controversial questions could only be answered temporarily, and there would be no comprehensive examination of the facts and the law. It further argued that mere anonymization would not protect its interests, because people who are familiar with this field of commerce will, within seconds of the publication, know who the parties are and what the subject matter is.

In a submission dated 4 March 2013, the defendant now clarifies that the information about the manufacturing method involved is a business secret of both the defendant and its suppliers. It further argues that the manufacturing process is not generally

[10] Translator's note: "IR-PatGer" refers to the Information Regulations for the Federal Patent Court of 28 September 2011 (SR 173.413.4).

known. Therefore, when publishing the judgment on the Internet, consideration should be given to the business secrets of the defendant and its suppliers. Should the Court, however, insist on publishing the judgment on the Internet, all relevant information in the grounds for the judgment about the business secret of the defendant and its suppliers should be blacked out or redacted by other means. Only in this manner would the defendant's business secret be protected. Relevant to the business secret are especially all remarks about the manufacturing process, namely the [technical] judge-rapporteur's expert report, specifically considerations 4 and 5, as well all the reasoning regarding the nullity of the patents in suit. This also concerns the agent used for oxidation, catalysis and elimination [of water] resp. water separation from the intermediate products and their names. If necessary, the defendant should be given the opportunity to indicate passages which should be kept secret before the Court releases its judgment.

Regarding the timing of this request, the reasoning contained in consideration 9 above applies. If the defendant wanted certain passages (obviously in its submissions and also from the [technical] judge-rapporteur's expert report) to be treated as confidential before the Court transmits the judgment to the Parties, then it had to make that request immediately, and it cannot request that the Court provide it with the opportunity to do so, which in effect means that the Court should grant it a deadline within which it will indicate the confidential sections. Therefore, this request will not be considered.

In accordance with Article 3(1) IR-PatC, the present decision will published on the Internet. Given that this a decision regarding preliminary injunctions, the names of the Parties involved shall be anonymized in accordance with standard practice [of the Federal Patent Court].

29.

The plaintiff shall bear the court fees. The final decision on who shall bear the costs of these preliminary injunction proceedings and attorney's fees relating thereto is reserved for decision in the ordinary proceedings. In the event that plaintiff does not file an action within the deadline set, it will be liable for paying party compensation to the defendant (Article 27 PatCA[11] in connection with Article 106(1) CPC).

The amount in dispute is estimated as exceeding CHF 1 million. Bearing in mind the complexity of the present proceedings, the court fee is set at CHF 40,000.00 (Article 31 and 33 PatCA in connection with 1 and 2 CostR-PatC).[12] The party compensation to be paid to the defendant is set at CHF 50,000.00 for attorney's fees (Article 32 and 33 PatCA in connection with Article 3 et seq. CostR-PatC); the compensation for consultation by patent attorneys is set at the same amount (Article 9[2] CostR-PatC).

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[11] Translator's note: "PatCA" refers to the Federal Act on the Federal Patent Court of 20 March 2009, as amended (SR 173.41).

[12] Translator's note: "CostR-PatC" refers to the Regulations about Costs of Proceedings before the Federal Patent Court of 28 September 2011 (SR 173.413.2).

The Federal Patent Court resolves:

1. In granting plaintiff's request of 14 February 2013 for the rectification of the minutes of the hearing, the minutes shall be rectified accordingly.

2. The defendant's request of 28 February 2013 for the rectification of the minutes shall not be considered.

The Federal Patent Court decides:

1. In confirmation of Order No. 1 of the Decision dated 13 February 2013, the defendant is hereby – subject to a disciplinary fine of CHF 1,000 per day pursuant to Article 343 para. 1 let. c CPC, but at minimum CHF 5,000 pursuant to Article 343 para 1 let. b CPC, and subject to criminal punishment by a fine against the members of its management pursuant to Article 292 SCC in the event of a violation of this order – preliminarily enjoined from importing into Switzerland, either on its own or through a third party, and from storing, offering for sale, selling or placing on the market by any other means contraceptives containing the active substance drospirenone "D 1" (Swissmedic license number a), "D 2" (Swissmedic license number b), "D 3" (Swissmedic license number c) and "D 4" (Swissmedic license number d), whereby the active substance drospirenone (6β, 7β; 15β, 16β -dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone) contained in the products in question was manufactured through eliminating water from 6β, 7β, 15β, 16β-dimethylene-5β-hydroxy-3-oxo-17α-androstane-21,17-carbolactone by adding p-Toluenesulfonic acid or pyridine/water mixture.

2. It is noted that Order No. 2 of the injunction of 13 February 2013 has become moot.

3. Otherwise, the plaintiff's requests are rejected, to the extent that they were to be considered.

4. The Customs Inspectorate Pratteln is hereby instructed to retain the units of the pharmaceutical product D which it had confiscated according to its letters of 19 and 21 December 2012, pending further instruction from the Federal Patent Court.

5. The plaintiff is hereby given a deadline – **7 March 2013** – by which it must file an action in ordinary proceedings; otherwise the preliminary measures ordered herewith will automatically expire.

6. The court fee is set at CHF 40,000.00.

7. Plaintiff shall bear the costs.

8. In the event that the plaintiff does not file an action in ordinary proceedings by the set deadline, it shall compensate the defendant with CHF 100,000.00.

This decision is transmitted to:

- Attorney Dr. Michael Ritscher; attached thereto is the Invoice No. (as court document); attachments: corrected minutes of the Hearing act. 39 as well as act. 36-39
- Attorney Dr. Christoph Willi (as court document); attachments: corrected minutes of the hearing act. 39
- Customs Inspectorate Pratteln (concerning Order No. 4; as court document)
- Federal Institute for Intellectual Property (after the decision becomes final; as court document)

Instructions on right of appeal:

This decision may be challenged, within 30 days after it was served, with an appeal in civil matters before the Federal Supreme Court; 1000 Lausanne 14 (Article 72 et seqq., Article 90 et seqq. and Article 100 Federal Supreme Court Act of 17 June 2005 [BGG, SR 173.110]). The legal brief must be in one of the official languages and it must contain requests supported by legal grounds, including a list of evidence and signatures. The decision against which the appeal is filed, and evidence available to the party filing the appeal, must be attached (see Article 42 Federal Supreme Court Act).

The suspension of deadlines according to Article 145(1) CPC does not apply.

St. Gallen, March 21, 2014

On behalf of the Federal Patent Court

President	**First Clerk**
Dr. iur. Dieter Brändle	lic.iur. Jakob Zellweger

Dispatched: 21 March 2013