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**Datasheet for the decision  
of 7 July 2011**

**Case Number:** T 0007/07 - 3.3.02  
**Application Number:** 00953387.8  
**Publication Number:** 1214076  
**IPC:** A61K 31/565, A61K 31/585,  
A61P 15/00  
**Language of the proceedings:** EN

**Title of invention:**

Pharmaceutical combination of ethinylestradiol and  
drospirenone for use as a contraceptive

**Applicant:**

Bayer Pharma Aktiengesellschaft

**Opponent:**

Hexal AG

**Intervener:**

Ladee Pharma Baltics UAB

**Headword:**

Ethinylestradiol and drospirenone for use as a  
contraceptive/BAYER PHARMA AG

**Relevant legal provisions:**

EPC Art. 105(1)(a), 115  
Lithuanian Patent Law, Art. 50  
TRIPS, Art. 39

**Relevant legal provisions (EPC 1973):**

EPC Art. 2(1), 3, 54  
EPC R. 64(a)

**Keyword:**

"Admissibility of the appeal (yes): appellant clearly identifiable"

"Admissibility of the intervention (no): infringement proceedings instituted in extension state not based on the European patent in suit"

"Admissibility of auxiliary request 3 (no): prima facie clarity problems"

"Novelty of main request and auxiliary request 1 (no): not novel over public prior use"

"Auxiliary request 2 - Article 123(2) EPC (no): new combination of features"

**Decisions cited:**

G 0009/91, G 0001/92, G 0001/94, G 0002/02, G 0003/02,  
J 0014/00, J 0019/00, J 0009/04, J 0002/05, J 0004/05,  
T 0338/89, T 0867/91, T 0446/95, T 1071/00, T 0906/01,  
T 0152/03, T 0006/05, T 0425/05, T 1421/05, T 1196/08

**Catchword:**

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Case Number: T 0007/07 - 3.3.02

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.02**  
**of 7 July 2011**

**Appellant:** Hexal AG  
(Opponent) Industriestraße 25  
D-83607 Holzkirchen (DE)

**Representative:** Wittkopp, Alexander  
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**Respondent:** Bayer Pharma Aktiengesellschaft  
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**Representative:** Plougmann & Vingtoft A/S  
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**Intervener:** Ladee Pharma Baltics UAB  
Schön, Christoph  
Dr. Schön & Partner  
Bavariaring 26  
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**Representative:** -

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 17 November 2006  
rejecting the opposition filed against European  
patent No. 1214076 pursuant to Article 102(1)  
EPC 1973.

**Composition of the Board:**

**Chairman:** U. Oswald  
**Members:** A. Lindner  
R. Cramer

## Summary of Facts and Submissions

- I. European patent No. 1 214 076 based on application No. 00 953 387.8 was granted on the basis of 19 claims. The European patent specification mentions Lithuania as designated extension state.
- II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step.
- III. The documents cited during the opposition and appeal proceedings included the following:
- (4) WO 98/04269
  - (43) Judgement by the United States District Court for the District of New Jersey dated 3 March 2008.
- IV. In the decision pronounced on 23 October 2006, the opposition division rejected the opposition. The opposition division came to the conclusion that the subject-matter of the claims as granted was novel, as none of the cited prior-art documents unambiguously disclosed micronised drospirenone. As regards inventive step, the problem to be solved *vis-à-vis* document (4), which constituted the closest prior art, was to improve the bioavailability of drospirenone. This problem was solved by the use of micronised drospirenone. Although the skilled person would undoubtedly consider micronisation as a possible solution to the problem defined above, he would carry out additional experiments to check whether micronisation was suitable for the specific compound drospirenone. Being aware of the problem of isomerisation in an acidic environment,

he would in particular test drospirenone under the pH conditions of the gastrointestinal tract and thus find out that micronisation of drospirenone would not increase its bioavailability *in vitro*. The opposition division concluded therefrom that the good bioavailability of micronised drospirenone was surprising, so that the requirements of Article 56 EPC were met.

- V. The opponent (appellant) lodged an appeal against said decision.
- VI. With an observation pursuant to Article 115 EPC, a third party (Stragen Pharma) submitted document (43) and argued that the subject-matter claimed in the contested patent lacked novelty over the product Yasmin<sup>R</sup>, which according to document (43) had been put on the market before the priority date of the contested patent. In addition, the product Yasmin<sup>R</sup> had become publicly available through clinical trials carried out between 9 December 1996 and 16 July 1998 and in which the participating women had not signed any confidentiality agreements.
- VII. With a letter dated 4 May 2011, Ladee Pharma Baltics UAB (intervener) filed an intervention pursuant to Article 105 EPC following the institution of infringement proceedings in Lithuania.
- VIII. In a further observation pursuant to Article 115 EPC, another third party (Gedeon Richter Plc.) reiterated the novelty objections with regard to the clinical trials mentioned by Stragen Pharma (see point VI above).

- IX. In a communication dated 13 May 2011, which was issued pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal of the EPO (RPBA), the board informed the parties that according to its preliminary opinion the intervention of Ladee Pharma Baltics UAB appeared to be inadmissible.
- X. In a letter dated 6 July 2011 the respondent questioned the admissibility of the appeal, as the identity of the appellant was not clear from the notice of appeal and the grounds of appeal mentioned Hexal AG as opponent, whereas the opposition was filed by Hexal Pharmaforschung GmbH.
- XI. At the oral proceedings of 7 July 2011, the respondent submitted a new main request and auxiliary requests 1 to 3. The independent claims read as follows:
- (i) Main request:*
- "1. A pharmaceutical composition in an oral dosage form comprising, as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the composition, of from about 2 mg to 4 mg, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of from about 0.01 mg to 0.05 mg, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in micronized form.
6. A pharmaceutical preparation consisting of a number of separately packaged and individually removable daily dosage units placed in a packaging unit and intended for oral administration for a period of at least 21

consecutive days, wherein said daily dosage units comprises a combination of drospirenone in an amount of from about 2 mg to 4 mg and ethinylestradiol in an amount from about 0.01 to 0.05 mg, wherein said drospirenone is in micronized form.

16. Use of drospirenone combined with ethinylestradiol for preparing a pharmaceutical composition for the inhibition of ovulation in a mammal, in particular a human, the composition comprising an amount of drospirenone corresponding to a daily dosage, on administration of the composition, of from about 2 mg to 4 mg, and comprising an amount of ethinylestradiol corresponding to a daily dosage, on administration of the composition, of from about 0.01 to 0.05 mg, and wherein said drospirenone is in micronized form."

*(ii) Auxiliary request 1:*

"1. A pharmaceutical composition in form of a tablet, pill or capsule comprising, as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the composition, of from about 2 mg to 4 mg, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of from about 0.01 mg to 0.05 mg, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in micronized form."

Claim 6 is identical to claim 6 of the main request.

"16. Use of drospirenone combined with ethinylestradiol for preparing a pharmaceutical composition in form of a

tablet, pill or capsule for the inhibition of ovulation in a mammal, in particular a human, the composition comprising an amount of drospirenone corresponding to a daily dosage, on administration of the composition, of from about 2 mg to 4 mg, and comprising an amount of ethinylestradiol corresponding to a daily dosage, on administration of the composition, of from about 0.01 to 0.05 mg, and wherein said drospirenone is in micronized form."

*(iii) Auxiliary request 2:*

" 1. A tablet comprising, as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the tablet, of 3 mg, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of from 0.015 mg to 0.03 mg, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in micronized form, and wherein at least 70% of said drospirenone is dissolved from said tablet preparation containing 3 mg drospirenone within 30 minutes, as determined by the USP XXIII Paddle Method II using 900 ml water at 37°C as the dissolution media and 50 rpm as the stirring rate."

2. A pharmaceutical preparation consisting of a number of separately packaged and individually removable tablets placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said tablets are as defined in claim 1."



*(iv) Auxiliary request 3:*

" 1. A tablet comprising, as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the tablet, of 3 mg, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of from 0.015 mg to 0.03 mg, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in micronized form, so that particles of the drospirenone have a surface area of more than 10,000 cm<sup>2</sup>/g, and the following particle size distribution as determined under the microscope: not more than 2 particles in a given batch with a diameter of more than 30 µm, and preferably ≤ 20 particles with a diameter of ≥ 10 µm and ≤ 30 µm, and wherein at least 70% of said drospirenone is dissolved from said tablet preparation containing 3 mg drospirenone within 30 minutes, as determined by the USP XXIII Paddle Method II using 900 ml water at 37°C as the dissolution media and 50 rpm as the stirring rate."

XII. The appellant essentially argued as follows:

Regarding the admissibility of the appeal, the appellant argued that it was clear from the history of the file that the appeal had been filed on behalf of the only opponent in the proceedings. Moreover, Hexal Pharmaforschung GmbH had merged with Hexal AG on 24 August 2006 which meant that Hexal AG was the universal successor to Hexal Pharmaforschung GmbH and the appeal was filed on behalf of Hexal AG.

In connection with the prior use, the appellant emphasised that the women participating in the clinical trials according to document (43) had not been bound to secrecy. As a consequence, the prior use was public and destroyed the novelty of the claimed subject-matter. Novelty objections were also raised in connection with document (4).

XIII. The respondent essentially argued as follows:

Regarding the admissibility of the appeal, the respondent argued that the notice of appeal did not contain any identification of the appellant, which could mean that Maiwald Patentanwalts GmbH had filed the appeal in its own name, in which case the appeal would have to be rejected as inadmissible. Even if the appeal had not been filed by Maiwald Patentanwalts GmbH on its own behalf, it was not clear whether Hexal Pharmaforschung GmbH (name of the opponent which had filed the notice of opposition, or Hexal AG (defined as appellant in the letters of 24 September 2008, 8 January 2010, 6 June 2011 and 16 June 2011) was the real appellant. As a consequence, the appeal was inadmissible.

As far as the admissibility of the intervention was concerned, it was argued that the extension system was not part of the EPC and that the validity of the extended patent was governed solely by national law. As a consequence, an intervention based on an alleged infringement in Lithuania, where the patent had effects on the basis of an extension agreement, was not admissible.

The respondent did not contest the prior use in the form of clinical trials, but it did dispute that this prior use was public. The personnel conducting the clinical trials described in document (43) had signed a confidentiality agreement and the women participating in the trials, although not having signed such an agreement, were implicitly bound to secrecy. The US court had also found that it would have been unethical to ask the participants to sign such an agreement. Although the participants were informed about the active agents used in the clinical trials, they did not know that drospirenone was present in micronized form. The skilled person had no reason to analyse the particle size of any unreturned samples. Moreover, such an analysis could not be carried out without undue burden. In principle, an analysis of the particle size was possible via RAMAN spectroscopy, but such an analysis required a considerable amount of samples. As the number of unreturned samples was not known, it was not certain that such an analysis could be performed at all. Moreover, the clinical trials constituted "trade secrets" pursuant to Article 39 TRIPS.

With regard to auxiliary request 2, the respondent argued that Article 100(c) EPC had not been cited as ground for opposition. As a consequence, the objections raised under Article 123(2) EPC constituted a fresh case, which was not allowable in appeal proceedings.

Regarding auxiliary request 3, it held that the late filing was the consequence of objections raised for the first time at the oral proceedings before the board. The subject-matter claimed in claim 1 of auxiliary request 3 was clear, as the skilled person would

understand without any doubt that the terms "2 particles" and " $\leq 20$  particles" meant "2% of the particles" and " $\leq 20\%$  of the particles".

XIV. The intervener essentially argued as follows:

The intervention was admissible, as Article 105 EPC ruled that any third party could intervene if it could prove that proceedings for infringement of the same patent had been instituted against it. The term "same patent" meant a European patent granted under the EPC. The decisive question was whether said third party was being sued on the basis of said European patent. In this context, reference was made to the Extension Ordinance of Slovenia (EO), as according to the information given in OJ EPO 1994, 527, the Lithuanian rules governing extension corresponded to the Slovenian EO. The EO ruled that the effects of a granted European patent were extended to Slovenia. Furthermore, the effects of an extended European patent in Slovenia were deemed as not existing *ab initio* if the European patent was revoked in opposition proceedings before the EPO. The same rules could be found in Chapter 10 of the Lithuanian Patent Law. As a consequence, the contested patent formed the basis of the infringement proceedings instituted against Ladee Pharma Baltics UAB, so that the intervention was admissible.

XV. The intervener requested that the intervention be declared admissible. It further requested that the matter be submitted to the Enlarged Board of Appeal if the board were of the opinion that the intervention was inadmissible.

- XVI. The appellant requested that the decision under appeal be set aside and that the European patent No. 1 214 076 be revoked.
- XVII. The respondent requested that the appeal be declared inadmissible. It further requested that the intervention be declared inadmissible. Alternatively, it requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1 to 3 filed during the oral proceedings on 7 July 2011.

### **Reasons for the Decision**

1. Admissibility of the appeal

According to Rule 64(a) EPC 1973 the notice of appeal shall contain the name and address of the appellant. According to board of appeal case law (see e.g. T 0867/91 of 12 October 1993, point 1.1 of the reasons for the decision, and T 1071/00 of 26 January 2006) the requirements of Rule 64(a) EPC 1973 are met if the notice of appeal provides sufficient information to identify the appellant and his address.

The notice of appeal identifies the patent, the patent proprietor and the date of the decision. It was filed by one of the representatives of the opponent in oral proceedings before the opposition division. The representative belongs to the firm of representatives that represented the opponent throughout the opposition proceedings. It is therefore beyond doubt that the

appeal was filed on behalf of the (only) opponent, who was also the only party adversely affected by the decision under appeal.

The appellant has submitted evidence that the opponent Hexal Pharmaforschung GmbH merged with Hexal AG on 24 August 2006 and therefore ceased to exist with effect from that date. Due to the merger, Hexal AG is the universal successor to Hexal Pharmaforschung GmbH.

The universal successor to the opponent automatically acquires party status in proceedings pending before the EPO (see e.g. T 0425/05 of 23 May 2006, point 1.2 of the reasons for the decision). This happens on the date a merger becomes effective, irrespective of when supporting evidence is filed (see T 0006/05 of 9 October 2007, points 1.6.4 and 1.7 of the reasons for the decision). As the merger in the present case became effective on 24 August 2006, Hexal AG became a party to these proceedings on that date and acquired the right to file the appeal on 19 December 2006. The appeal could not have been filed by Hexal Pharmaforschung GmbH, as that legal entity no longer existed on 19 December 2006. As pointed out in T 0006/05, in the case of a universal succession there can only be one (legal) person who has rights and obligations, with the consequence that there is necessarily and automatically a continuation of the existing legal status as opponent from the date of the merger. Decision T 1421/05 of 18 January 2011, referred to by both parties, does not shed a different light on the matter.

As it was obvious that the appeal was filed on behalf of the only opponent, and Hexal AG had acquired

opponent status prior to the filing of the appeal, the statement of grounds correctly mentions the name of Hexal AG as opponent. It is therefore possible to identify the appellant as Hexal AG and the appeal is admissible.

2. Admissibility of the intervention

Under Article 105 EPC, any third party may intervene in opposition proceedings after the opposition period has expired if it proves that proceedings for infringement of the same patent have been instituted against it. Intervention is in principle also possible during appeal proceedings (G 1/94, OJ EPO 1994, 787). The term "same patent" means that the infringement proceedings must be based on the European patent in suit in the opposition proceedings for which intervention is sought (see T 0338/89 of 10 December 1990, T 0446/95 of 23 March 1999).

According to Article 99(1) EPC, within nine months of the publication of the mention of the grant of the European patent any person may give notice of opposition to that patent. The patent in suit in opposition proceedings before the EPO is thus a granted European patent. A European patent is a patent granted under the EPC for one or more EPC contracting states (Articles 2(1) and 3 EPC).

It follows that the term the "same patent" in Article 105(1)(a) EPC refers to a patent granted under the EPC for one or more EPC contracting states, and that for an intervention to be admissible, proceedings

for infringement of that patent must have been instituted.

The patent in suit in the present proceedings, European patent 1 214 076, was not granted for Lithuania under the EPC, as Lithuania was not an EPC contracting state on the (international) filing date and could therefore not be designated for a European patent.

Ladee Pharma Baltics UAB has filed evidence that Bayer Schering Pharma AG had instituted proceedings before the Vilnius District Court for infringement of patents Nos. 1214076 and 1380301, patents extended to Lithuania on the basis of the agreement signed on 25 January 1994 by the President of the European Patent Office and the head of the Lithuanian patent office (OJ EPO 1994, 201) that entered into force on 5 July 1994 (OJ EPO 1994, 527).

According to the "Basic principles" set out in OJ EPO 1994, 75, the extension system provides European patent applicants with a simple and cost-effective way of obtaining protection in the extension state. At the applicant's request, and on payment of the prescribed fee, European patent applications and patents can be extended to the extension state, where they will have the same effects as national applications and patents. The extension system largely corresponds to the EPC system operating in the EPC contracting states, except that it is not based on direct application of the EPC but on national law modelled on the EPC. These "Basic principles" apply not only to the extension agreement with Slovenia but also to the agreement with Lithuania (OJ EPO 1994, 201, last paragraph).



The national law of the extension state governs the extension proceedings and the legal effects of the extension. In Lithuania the rules governing the extension system are set out in Chapter 10 of the Lithuanian Patent Law (LPL). Article 50, first sentence, LPL states that "A European patent application and a European patent extending to the Republic of Lithuania shall, according to the following provisions of this Chapter, have the effect of and be subject to the same conditions as a national application filed and a national patent granted under the Patent Law of the Republic of Lithuania."

It follows that the extension procedure generates legal effects exclusively on the basis of Lithuanian national law, and no sovereign rights have been delegated to the EPO. As far as the extension procedure is concerned, the EPO is not acting within the framework of the EPC, but is simply assisting the extension state with the establishment of national property rights by receiving requests for extension and levying extension fees that are, after deduction of an amount to cover the EPO's expenses, forwarded to the patent office of the extension state (cf. J 0014/00 of 10 May 2001, OJ EPO 2002, 432, J 0019/00 of 10 May 2001, J 0009/04 of 1 March 2005, J 0002/05 of 1 March 2005 and J 0004/05 of 2 February 2006).

The infringement proceedings before the Vilnius District Court are therefore not based on a European patent within the meaning of Articles 2(1) and 3 EPC because the patent was not granted for Lithuania. The infringement proceedings are based on a patent granted

for a number of EPC contracting states that under Lithuanian law also has effects in Lithuania, but exclusively on the basis of Lithuanian national law that confers the same effect to this patent as to a national patent. The board thereby observes that any state can provide in its national law that patents granted in or for other states are effective on its territory, even without express agreement with that other state.

As a result, the infringement proceedings are not based on the European patent in suit in the opposition proceedings. The board agrees with the findings in T 1196/08 of 10 November 2010 that an intervention based on proceedings for infringement of a patent that has effect in a particular state solely on the basis of national law is inadmissible.

The submissions made by Ladee Pharma Baltics UAB with respect to the patentability of the invention to which the patent relates are consequently regarded as third-party observations under Article 115 EPC.

The board considers that there is no need to refer questions to the Enlarged Board of Appeal because there is no contradictory case law and the board itself is in a position to resolve the points of law without any doubt.

3. Main request - novelty

- 3.1 In April 2008 a third party, Stragen Pharma, submitted a copy of a judgement by the United States District Court for the District of New Jersey dated 3 March 2008

(document (43)). The judgement concerns the validity of US Patent No. 6 787 531, that corresponds to the patent in suit in the present appeal. The third party claims *inter alia* that claims 1-5 and 16-19 lack novelty over a prior use reflected in the US decision, namely the conduct of clinical trials with contraceptives containing the composition claimed in the patent in suit in the present appeal. These trials took place in the US between December 1996 and July 1998, i.e. before the priority date of the contested patent (31 August 1999). The participants were informed of the ingredients but had not signed a confidentiality agreement, and not all unused drugs had been returned. The third party claimed that as a result the drugs had become publicly available.

3.2 During the oral proceedings the appellant argued for the first time that the trials mentioned in the US decision establish a novelty-destroying public prior use. Although these arguments were brought forward at a very late stage, they are nevertheless admitted by the board as the allegation of a novelty-destroying prior use does not amount to a new ground for opposition, was as a result of the third-party observations known since April 2008, and has prompted the respondent to present counter-arguments in its written submissions.

3.3 The respondent did not contest that clinical trials were carried out prior to the priority date and that the principal investigators but not the participants entered into confidentiality agreements. The participants were informed about the active agents of the contraceptive, but were not told that the drospirenone was present in micronised form. Nor did

the respondent contest that the oral contraceptive used for the study comprised all the features of the subject-matter according to claim 1.

It is established board of appeal case law that if a single member of the public, who is not under an obligation to maintain secrecy, has the theoretical possibility to access particular information, this information is considered as being available to the public within the meaning of Article 54(2) EPC.

The respondent argued that the drug had not become publicly available before the priority date as according to established board of appeal case law any persons involved in clinical trials are (implicitly) bound to confidentiality.

The board does not agree with the respondent's interpretation of the case law. Both decisions cited by the respondent (T 0152/03 of 22 April 2004 and T 0906/01 of 28 September 2004) concern prototype devices that were to be implanted in a small number of patients. Therefore, even if the patients did not sign a confidentiality agreement, they would not have been in a position to pass the prototypes on or even inspect them themselves.

Such trials are to be distinguished from trials where a large number of patients are given tablets to take home with them and for use over a longer period of time. It has been acknowledged by the US court that not all of the unused study drugs were returned. Therefore, it appears that after having handed out the drugs the respondent effectively lost control over them as the

participants in the clinical trials were in no way barred from disposing of the drugs as they wanted.

In view of these circumstances, the board comes to the conclusion that the handing out of the drugs to the participants made them become publicly available.

- 3.4 The respondent has also argued that the participants could not be bound by confidentiality as this would have been "unethical". The US court had established that it would have been unethical to bind patients by confidentiality provisions as they should have been in a position to discuss the medication with their spouses and doctors.

The board has difficulties in reconciling this argument with the argument that there was an implicit secrecy agreement. Either there was an implicit secrecy agreement or there was not. The finding of the US court rather confirms that there was indeed no obligation of confidentiality.

Nor can the line of argument that it would have been unethical to have asked the participants to sign a secrecy agreement lead to a conclusion other than that the drugs had become publicly available before the priority date. If a product has become publicly available, it is irrelevant why it has so unless one of the exceptions in Article 55(1) EPC applies which is not the case here.

- 3.5 A further argument brought forward by the respondent is that the clinical trials were to be classified as "trade secrets" within the meaning of Article 39 TRIPS.

While the TRIPS agreement is not binding on the EPO, it is an element that can be taken into consideration when interpreting provisions of the EPC which admit of different interpretations (G 2/02 and G 3/02, OJ EPO 2004, 483). The respondent has not stated which provision of the EPC is so ambiguous that an interpretation in the light of TRIPS would be appropriate.

Even if the TRIPS agreement were applicable, the purpose of its Article 39 is to clarify the obligation of WTO members under Article 10bis of the Paris Convention to provide for protection against unfair competition. Article 39, paragraph 2, TRIPS merely states that "Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices...". This means that national authorities should allow natural and legal persons to keep particular information secret. In the present appeal the respondent was in a position to keep information secret, but decided to distribute the product to selected members of the public before it had secured patent protection.

Under Article 39, paragraph 3, TRIPS, the authorities of WTO members are obliged to keep information submitted to them confidential. This provision too is of no relevance for the present case as the prior use does not concern the disclosure of information by a national authority.

3.6 As the oral contraceptive used for the clinical trials was publicly available before the effective filing date of the contested patent and as the assertion that it comprises all the features of claim 1 of the main request was not contested by the respondent, it remains to be examined whether the skilled person was in a position to analyse its content and structure. In particular, it has to be evaluated whether he was able to determine the micronized state of drospirenone, which is an item of information that was not communicated to the women participating in the clinical trials.

According to G 1/92 (OJ EPO 1993, 277), the chemical composition of a product is state of the art when the product as such is available to the public and can be analysed and reproduced by the skilled person, irrespective of whether or not particular reasons can be identified for analysing the composition (see headnote 1). If it is possible for the skilled person to discover the composition or the internal structure of a product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art (see point 1.4 of the reasons for the opinion). The Enlarged Board emphasises that there is no support in the EPC that the public should have particular reasons for analysing a product put on the market in order to identify its composition or internal structure (see point 2 of the reasons for the opinion).

This means for the present case that, in order for the oral contraceptive used in the clinical trials to be publicly available, the skilled person does not need

any motivation for investigating the micronized structure of drospirenone. The only question is whether he is able to analyse the structure and composition of the product without undue burden. Regarding the composition of the prior use, the board notes that it belongs to the general knowledge of the skilled person to identify the active agents drospirenone and ethinylestradiol and to determine their concentrations within the tablet. This has not been contested by the respondent. On the contrary, the respondent has even acknowledged that this information had been passed on to the women participating in the clinical trials. Moreover, it does not require inventive skill to identify at least one excipient. However, there was a long discussion at the oral proceedings as to whether it was possible to determine the micronized structure of drospirenone which had undergone a compression step during tablet formation. The respondent argued that in principle such an analysis was possible via RAMAN spectroscopy. However, a large number of samples were necessary in order to calibrate the system. As the number of unreturned samples of the clinical trials was not known, there was no guarantee that the skilled person would have sufficient material for analysing the particle size of drospirenone. The board cannot agree with this argumentation. As was correctly pointed out by the appellant, it is not necessary to take tablets from the clinical studies for calibrating the system. This can also be done by using a different material. Once the system is calibrated, a single tablet from the clinical studies should be sufficient for determining the particle size of drospirenone.



The respondent further argued that the contraceptive used for the clinical trials comprised 21 hormone-containing tablets and 7 placebos. As a consequence, it was not certain that the unreturned samples contained any drospirenone at all. This argument is not convincing either, for the following reason: in view of the fact that the women participating in the clinical trials were not bound to secrecy, the public availability of the prior use was not restricted to the unreturned samples but included all the tablets handed out to them. As the tablets and placebos were not randomly administered but follow a well defined distribution scheme (e.g. 21 hormone containing tablets followed by 7 placebos), the participants had to be able to identify the two types of tablets. The skilled person therefore had no problems in selecting the hormone-containing specimens for his analysis. As a consequence, it was possible for the skilled person to discover the composition or the internal structure of the product product Yasmin<sup>R</sup> used in the clinical trials mentioned above and to reproduce it without undue burden. The subject-matter of claim 1 of the main request therefore does not meet the requirements of Article 54 EPC.

4. Auxiliary request 1 - novelty

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the oral dosage form claimed in the main request is restricted to tablets, pills or capsules. As the product Yasmin<sup>R</sup> used in the clinical trials mentioned above concerns tablets, the reasoning set out in point 3 above applies *mutatis mutandis* to the subject-matter defined in claim 1 of auxiliary

request 1. The requirements of Article 54 EPC are therefore not met.

5. Auxiliary request 2 - Article 123(2) EPC

5.1 The ground of opposition pursuant to Article 100(c) EPC was not invoked in the opposition proceedings. According to decision G 9/91 (OJ EPO 1993, 408), fresh grounds for opposition may not be introduced at the appeal stage unless the patentee agrees to their introduction (see point 18 of the reasons for the decision). However, amendments are to be fully examined as to their compatibility with the requirements of the EPC (see point 19 of the reasons for the decision). As the patentee did not give his consent, it has to be evaluated whether the objections raised under Article 123(2) EPC are based on amendments made in the course of the post-grant proceedings.

Claim 1 of auxiliary request 2 differs from claim 1 as granted as follows:

- (a) "pharmaceutical" composition was replaced by "tablet";
- (b) the concentration range of drospirenone was reduced from 2 mg to 4 mg to 3 mg;
- (c) the concentration range of ethinylestradiol was reduced from 0.01 mg to 0.05 mg to 0.015 mg to 0.03 mg;
- (d) the feature "wherein at least 70% of said drospirenone is dissolved from said tablet preparation containing 3 mg drospirenone within 30 minutes, as determined by the USP XXIII Paddle Method II using 900 ml water at 37°C as the

dissolution media and 50 rpm as the stirring rate" was added.

None of features (a) to (d) figures in the claims as granted. In this context it is noted that the USP XXIII Paddle Method II figuring in claims 3 and 18 as granted cannot serve as a basis for feature (d), which is more specific than the paddle method according to claims 3 and 18 as granted in that it additionally specifies a quantity of 900 ml of water to be used for determining the dissolution rate of drosiprenone. As a consequence, on the basis of Article 102(3) EPC 1973 the board is competent to examine whether these amendments are allowable under Article 123(2) EPC. The board is further competent to evaluate whether new combinations arising out of these amendments are in accordance with the requirements of Article 123(2) EPC.

Feature (a) :

Feature (a) is mentioned on page 9, lines 17-23 of the original application, where oral dosage forms such as tablets, pills or capsules are disclosed. In the last paragraph on page 9 of the original application, solutions, suspensions and emulsions are mentioned as further possible oral dosage forms. Of these six oral dosage forms, tablets are the preferred galenic form in view of the fact that all examples relate to them.

Feature (b) :

There are several passages in the original application in support of feature (b) including original claim 3 and the passages on page 4, lines 11-24 and page 5,

lines 18-20. Tablets comprising 3 mg drospirenone are also disclosed in all the examples of the original application.

Feature (c):

There are several passages in the original application in support of feature (c), including the passage on page 5, lines 18-24 and original claim 6, where compositions comprising 3 mg drospirenone (most preferred concentration) and 0.015 mg to 0.03 mg ethinylestradiol (preferred concentration range) are disclosed.

Feature (d):

Feature (d) is disclosed on page 4, lines 11-24 of the original application, however only in combination with a specific form of micronisation for drospirenone, which comprises a surface area and a particle size distribution as defined on page 4, lines 11-15 of the original application). As claim 1 of auxiliary request 2 does not comprise these limitations but relates to drospirenone in micronized form in general, the introduction of feature (d) into claim 1 of auxiliary request 2 amounts to an unallowable generalisation. The board would emphasise in this context that the passage in parenthesis on page 4, lines 11-15 of the original application (which corresponds to column 3, lines 42-48 of the patent specification) is not implicitly included in claim 1 of auxiliary request 2. The skilled person reading this claim concludes that any form of micronized

drospirenone having the required dissolution profile is included.

The USP XXIII Paddle Method is also cited in example 2 of the original application. However, example 2 cannot serve as a basis for feature (d) either, as the method described therein is more specific because it indicates that six covered glass vessels and six paddles were used, and, secondly, refers to the specific composition disclosed in example 1. As a consequence, feature (d) also constitutes an unallowable generalisation of example 2.

The subject-matter of claim 1 of auxiliary request 2 therefore does not meet the requirements of Article 123(2) EPC.

6. Auxiliary request 3 - admissibility

Auxiliary request 3 was filed at the oral proceedings before the board, i.e. at a late stage of the appeal proceedings. The admissibility of this request is therefore at the board's discretion and depends upon the overall circumstances of the case. According to Article 13(1) RPBA, this discretion depends *inter alia* upon the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy. As regards the need for procedural economy, the board notes that the introduction into claim 1 of the feature "and the following particle size distribution as determined under the microscope: not more than 2 particles in a given batch with a diameter of more than 30  $\mu\text{m}$ , and preferably  $\leq$  20 particles with a diameter of  $\geq$  10  $\mu\text{m}$

and  $\leq 30 \mu\text{m}$ " leads *prima facie* to a lack of clarity, as there is no point of reference other than the vague expression "given batch" for the features "2 particles" and " $\leq 20$  particles".

The board cannot follow the respondent's argument that the skilled person would inevitably read "2% of the particles" and " $\leq 20\%$  of the particles", as the particle size is measured under the microscope. It is therefore to be assumed that the particles having the required particle sizes are simply counted and that the term "given batch" refers to the totality of particles seen under the microscope, which is highly variable as it depends on factors such as degree of magnification (a higher magnification means that fewer particles can be seen) and concentration of particles on the slide. In the absence of a definition of the term "given batch", these features are therefore ambiguous and not in accordance with the requirements of Article 84 EPC. Although the filing of auxiliary request 3 can be seen as a reaction to objections raised for the first time against auxiliary request 2 at the oral proceedings before the board (see point 5 above), the board therefore decided not to admit auxiliary request 3 into the proceedings.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

N. Maslin

U. Oswald