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Datasheet for the decision of 26 November 2013

Case Number: T 1083/12 - 3.3.02

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Publication Number: 1598096

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Language of the proceedings: EN

Title of invention:
Pharmaceutical combination of ethinylestradiol and drospirenone for use as a contraceptive

Patent Proprietor:
Bayer Pharma Aktiengesellschaft

Opponents:
Laboratorios Léon Farma, S.A.
Sandoz International GmbH
Teva Pharmaceutical Industries Ltd.
Lupin Limited
Helm AG
Gedeon Richter Plc.
Effik Benelux N.V.

Headword:
Pharmaceutical composition containing ethinylestradiol and drospirenomne/BAYER PHARMA

Relevant legal provisions:
EPC Art. 100(c), 123(2), 76(1)

Keyword:
"Added matter (yes)"

Decisions cited:
T 0007/07

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1083/12 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 26 November 2013

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 29 March 2012 revoking European patent No. 1598069 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
L. Bühler

Summary of Facts and Submissions

I. European patent No. 1 598 069, based on European patent application No. 05076943.9 which was filed as a divisional application of application No. 03017743.0, which was filed as a divisional application of application No. 00953387.8, which was filed as an international patent application published as WO 01/15701 (root application as filed), was granted with twenty claims.

Claim 1 as granted read as follows:

"1. A pharmaceutical composition comprising ethinylestradiol and inert carrier particles containing drospirenone on their surface, wherein drospirenone is present in the composition in an amount corresponding to a daily dosage of from about 2 mg to about 4 mg; and ethinylestradiol is present in the composition in an amount corresponding to a daily dosage of from about 0.01 mg to about 0.05 mg."

Dependent claims 10 and 11 as granted read as follows:

"10. The composition according to any of the preceding claims, wherein said composition is in the form of an oral dosage unit."

"11. The composition according to claim 10, wherein said oral dosage unit is in the form of a tablet, a capsule or a pill."

II. Oppositions were filed and revocation of the patent in its entirety was requested, in particular pursuant to

Article 100(c) (the subject-matter of the patent extends beyond the content of the application, or earlier application, as filed), 100(a) (lack of novelty and lack of inventive step) and 100(b) EPC (lack of sufficiency of disclosure).

III. The following documents were cited *inter alia* in the opposition and appeal proceedings:

D5 R. Voigt, "Lehrbuch der Pharmazeutischen Technologie", 1987, 470-474

D11 Melia and Davis, Aliment. Pharmacol. Therap., 3, 513-525, 1989

D13 Remington's Pharmaceutical Sciences, 18th edition, 1990, Chapter 31, Dissolution, pages 589-602

D14 D. C. Monkhouse and J. L. Lach, J. Pharm. Sci., 61, 1430-1435, 1972

D15 S. M. Alsaidan et al., Drug Development and Industrial Pharmacy, 24(4), 389-394, 1998

D17 Cohen et al., Pharmaceutical Research, vol. 7, No 10, 983-987, 1990

D28 Pharmaceutical Dosage Forms 1980, 114, 150

D62 Teva's submission of 30 September 2011 in the opposition proceedings against EP 1 380 301, pages 1 and 11

D83 UK national decision "Gedeon Richter PLC v. Bayer Schering AG", High Court of Justice, Chancery Division, Patent Court, [2011] EWHC 583 (Pat), dated 17 March 2011

D87 Guidance for Industry. Dissolution Testing of Immediate Release Solid Oral Dosage Forms, US Department of Health and Human Services, Food and Drug Administration, 1997

D88 FIP Guidelines for Dissolution Testing of Solid Oral Products, Pharm. Ind., 57(5), 362-369, 1995

D113bR. Thilbert et al., MML series, 1991, volume 1, pages 327-328

IV. The present appeal lies from a decision of the opposition division revoking the patent (Article 101(3)(b) EPC).

V. The opposition division admitted into the proceedings the main request filed as MR3 at the oral proceedings which took place on 31 January and 1 February 2012, since the amendments complied with the requirements of Rule 80 EPC and were allowable under Article 123(3) EPC. Moreover, the opposition division was of the opinion that the amended claims complied with the requirements of Article 84 EPC (clarity), and Articles 123(2) and 76(1) EPC (added matter). The opposition division did not share the opponents' concerns in relation to a possible double patenting vis-à-vis EP-B1-1380301 (granted patent deriving from the parent application), which was revoked in first-instance proceedings and for which an appeal had been lodged (T 598/12, same board as in the present case).

The opposition division considered that the invention claimed in the main request was not sufficiently disclosed (Articles 100(b) and 83 EPC). According to the opposition division's findings, the patent disclosed, paragraph [00017], to dissolve DRSP (drospirenone) in a suitable solvent, e.g. methanol or ethyl acetate, and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing DRSP on their surface in the

composition, but gave no details about how to perform this technique and did not contain any examples concerning spray-coating. Therefore, there was no guidance in the patent in suit as to how to achieve the dissolution profile by means of a spray-coating technique.

The opposition division found that auxiliary requests 1 to 3 filed during the above-mentioned oral proceedings were not admissible since they were not suitable to overcome the deficiencies of the main request. As regards auxiliary request 4 filed on the second day of the oral proceedings before the opposition division, the opposition division considered that it failed to comply with Article 83 EPC for analogous reasons to those given for the main request.

VI. The patent proprietor (appellant) filed a notice of appeal on 7 May 2012. With its grounds of appeal dated 7 August 2012 it filed a main request (identical to the main request MR3 filed at the oral proceedings before the opposition division) and new auxiliary requests 1 and 2, as well as documents D5a, D113 and D114. The appellant requested that the decision under appeal be set aside and the case remitted to the department of first instance for examination of the grounds for opposition under Article 100(a) EPC.

Claim 1 of the main request reads as follows:

"1. A tablet comprising ethinylestradiol and inert carrier particles containing drospirenone on their surface obtainable by dissolving drospirenone in a suitable solvent and spray it onto the surface of inert

carrier particles followed by incorporation of the particles containing drospirenone on their surface in the tablet, wherein drospirenone is present in the tablet in an amount corresponding to a daily dosage of 3 mg; and ethinylestradiol is present in the tablet in an amount corresponding to a daily dosage of from about 0.01 mg to about 0.05 mg, together with one or more pharmaceutically acceptable carriers or excipients, and wherein at least 70% of said drospirenone is dissolved from said tablet within 30 minutes, as determined in 900 ml of water at 37°C by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm."

Auxiliary request 1 contains three independent product claims.

Claim 1 of auxiliary request 2 reads as follows:

"1. A tablet comprising ethinylestradiol and inert carrier particles containing drospirenone on their surface obtainable by dissolving drospirenone in a suitable solvent and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing drospirenone on their surface in the tablet, wherein drospirenone is present in the tablet in an amount corresponding to a daily dosage of 3 mg; and ethinylestradiol is present in the tablet in an amount corresponding to a daily dosage of from about 0.01 mg to about 0.05 mg, together with one or more pharmaceutically acceptable carriers or excipients, wherein polyvinylpyrrolidone is included, and wherein at least 70% of said drospirenone is dissolved from said tablet within 30 minutes, as determined in 900 ml

of water at 37°C by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm."

VII. Opponent O3 filed a notice of appeal with its letter of 31 May 2012, a second letter dated 3 August 2012 in order to clarify its position, and grounds of appeal on 7 August 2012. With its grounds of appeal it filed documents D113 and D114 which are renumbered as D113b and D114b. Opponent O3 stated that it was appealing the first-instance decision to the extent that the opposition division's findings adversely affected it. Opponent O3 also stated that it had filed an appeal in order to be able to contest the opposition division's decision in relation to added subject-matter (Article 123(2) EPC), since otherwise the principle of prohibition of *reformatio in peius* would not allow such discussion.

VIII. An intervention under Article 105 EPC was filed on 22 August 2012 by Effik Benelux N.V. together with a copy of the writ of summons dated 22 May 2012 and its English translation. The intervener submitted that the patentee had instituted proceedings for infringement against it which were pending before the Second Chamber of the Court of Commerce in Brussels. The intervener also filed a statement of grounds in support of its intervention and paid the opposition fee according to Rule 89(2) EPC.

IX. With a letter dated 21 September 2012 the appellant-patentee contested the admissibility of opponent O3's appeal, gave reasons thereto and cited several board of appeal decisions. It also requested a board

communication with a preliminary opinion about the admissibility of opponent's O3 appeal.

X. Opponents O1 (respondent 1), O2 (respondent 2), O3 (respondent 3), O5 (respondent 5) and O6 (respondent 6) filed counter-arguments to the patentee's appeal. They requested that the patentee's appeal be dismissed. Respondent 6 filed with its letter dated 20 December 2012 documents D111a and D115 to D124.

XI. With a letter dated 10 December 2012 opponent 4 (respondent 4) filed a reply to the patentee's grounds of appeal. Therein, it merely referred to the arguments in its notice of opposition (it also filed a copy of its notice of opposition as an annex). It requested that the patentee's appeal be dismissed.

XII. The board sent on 7 June 2013 a communication pursuant to Article 15(1) RPBA as an annex to the summons to oral proceedings.

In said communication the board expressed the opinion that opponent O3's appeal was inadmissible since opponent O3 was not adversely affected by the first-instance decision revoking the patent in suit (Article 107 EPC). The board pointed out that opponent O3 was not really seeking to challenge the decision of the opposition division revoking the patent in suit, but wanted the patent to be found invalid under Article 123(2) EPC (Article 76(1) EPC), in addition to Article 83 EPC.

Moreover, the board also clarified the following. The criteria governing the application of the principles of

prohibition of *reformatio in peius* in proceedings before the EPO are set out in Enlarged Board of Appeal decisions G 1/99, OJ EPO, 2001, 381 and G 9/92, OJ EPO 1994, 875 (issued together with G 4/93). In the case underlying the present appeal, the opposition division decided to revoke the patent after consideration of amended sets of claims (Article 101(3)(b) EPC). Therefore, a situation in which the principle of prohibition of *reformatio in peius* would apply did not arise in the present case.

In its communication the board expressed the opinion that the intervention filed by Effik Benelux N.V. under Article 105 EPC was admissible.

Additionally, the board expressed the view that auxiliary request 1 could not be admitted into the proceedings.

The board drew the parties' attention to the fact that before it could assess whether the subject-matter claimed met the requirements of sufficiency of disclosure (Articles 100(b) and 83 EPC), it had to assess whether the requirements of Articles 123(2) and (3), 76(1) and 84 EPC were met by the amended claims.

XIII. With a letter dated 17 June 2013 the appellant filed a further document, D125 (declaration of Mr Heller dated 12 April 2013).

XIV. With a letter dated 28 August 2013 the appellant filed a "response to the respondents' comments" to the grounds of appeal and to the observations on the board's communication. It also filed documents D54a,

D126 and D127 and submitted *inter alia* arguments in favour of the main request in relation to Articles 84, Article 76(1) and 83 EPC.

XV. With a letter dated 2 October 2013 respondent 2 filed comments and objections in relation to Article 76(1) EPC and Article 83 EPC.

XVI. With a letter dated 21 October 2013 respondent 4 informed the board that it would not attend the oral proceedings.

XVII. With a letter dated 24 October 2013 respondent 5 informed the board that it would not attend the oral proceedings.

XVIII. With a letter dated 25 October 2013 respondent 1 contested the admissibility of patentee's appeal and of auxiliary request 1 filed with the grounds of appeal. Furthermore it filed objections under Articles 100(c) and 123(3) and 76(1) EPC. It also filed objections under Article 84 EPC, and further arguments in relation to the ground pursuant to Article 100(b) EPC.

XIX. Oral proceedings took place on 26 November 2013 in the absence of respondents 4 and 5.

During the oral proceedings the appellant filed two further auxiliary requests, auxiliary requests 3 and 4.

Claim 1 of auxiliary request 3 reads as follows:

"1. **A pharmaceutical composition** comprising ethinylestradiol and inert carrier particles containing

drospirenone on their surface obtainable by dissolving drospirenone in a suitable solvent and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing drospirenone on their surface in the **composition**, wherein drospirenone is present in the **composition** in an amount corresponding to a daily dosage of **2-4 mg**; and ethinylestradiol is present in the **composition** in an amount corresponding to a daily dosage of from about 0.01 mg to about 0.05 mg, together with one or more pharmaceutically acceptable carriers or excipients, and ~~wherein at least 70% of said drospirenone is dissolved from said tablet within 30 minutes, as determined in 900 ml of water at 37°C by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm~~ **the composition is formulated in admixture with one or more pharmaceutically acceptable excipients that promote rapid dissolution of the drospirenone and ethinylestradiol so as to promote rapid dissolution of drospirenone on oral administration.**" (*emphasis added*)

Claim 1 of auxiliary request 4 differs from claim 1 of auxiliary request 3 in that the following has been added at the end of the claim:
", wherein said excipients that promote rapid dissolution of drospirenone and ethinylestradiol are carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, gelled starch, gelatin or polyvinylpyrrolidone."

XX. At the oral proceedings before the board opponent O3 (respondent 3) withdrew its appeal.

XXI. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows.

The appellant did not object the admissibility of the intervention *per se* but it objected to the introduction into the appeal proceedings of the intervener's objection under Article 100(a) EPC relying on public prior use in Europe, since this issue had not been duly substantiated as required by Rule 76 EPC. The appellant also relied in this respect on Article 14 RPBA.

(a) In relation to the objection raised by respondent 1 against the admissibility of its appeal, the appellant stated that respondent 1 had cited decision T 7/07 of 7 July 2011 in its written submissions, whereas in the oral proceedings it had cited decision T 598/12 of 5 November 2013. Apart from the fact that the written decision in appeal case T 598/12 was not yet issued, the facts were not the same, and the subject-matter of the claims was not the same. Therefore, the requirements mentioned in decision T 167/93 of 3 May 1996 were not fulfilled.

The appellant further argued that, contrary to respondent's 2 submissions, the claims serving as the basis for the board's of appeal decision in the patent deriving from the parent application did not contain the feature that DRSP should be present on the surface of inert carrier particles. Therefore, there was not a situation of *res judicata*.

(b) *Main request*

As regards the issue of added matter under Articles 123(2) and 76(1) EPC, the appellant further submitted that in the appeal case T 598/12, which dealt with the patent deriving from the parent application, the general knowledge of the skilled person in the field had been discussed. The appellant also referred to the principles set out in Enlarged Board of Appeal decision G 2/10, OJ EPO 2012, 376 and stated that the addressee was the skilled person and that he would use his common general knowledge to consider the content of the whole document (root application as filed). Literal support was not required. In this context the appellant cited board of appeal decision T 667/08 of 20 April 2012. Moreover, it referred to documents D17, D87 and D88 as relating to the common general knowledge in the field. The appellant submitted that what could be learned from these documents was that the dissolution profile defined in the root application as filed was exactly what the skilled person would expect since it was similar to the dissolution profile of rapid dissolution or immediate release forms in said documents. The appellant further cited documents D11, D13 and D28 which reflected the general knowledge that micronization was one among other methods for improving dissolution of poorly soluble drugs. The appellant also cited document D5 (a textbook which had not been cited in case T 598/12); the general considerations on pages 471-472 for improving the dissolution of sparingly soluble drugs ("*Löslichkeitsverbesserung*") were similar to those in documents D11, D13 and D28. In particular, document D5 mentioned that an increase in the surface area of the drug substance could be

attained by means of micronization or with spray-dried or sprayed products (page 472). The appellant further cited point 23.3.2.5 on pages 473-474 in document D5, including that deposition on solid carrier particles led to improvement of dissolution; it also mentioned the use of a fluidized bed. The appellant was of the opinion that document D5 presented the skilled person with the information that a poorly soluble drug sprayed onto the surface of inert carrier particles would have at least the dissolution profile of the micronized drug. It also cited document D113b, page 328, third paragraph, and stated that micronization was a generic term for micropulverization and micromilling, but was not the only method for improving dissolution of sparingly soluble drugs.

Therefore, it was in the light of this background knowledge that the description of the root application as filed had to be read.

Claim 1 of the main request derived from claim 1 of the root application as filed in that it specified that the pharmaceutical composition was a tablet containing 3 mg DRSP with the dissolution profile as defined on page 4 for tablets with 3 mg DRSP. The specification of the content of DRSP as 3 mg was disclosed on page 5, lines 19-20, independently of the amount of ethinylestradiol. As regards the specification of the dosage unit form as a tablet, the appellant pointed to page 9, lines 23 and 25 of the root application as filed and stated that tablets were the preferred dosage unit form disclosed. As regards the product feature that "inert carrier particles containing DRSP on their surface" were incorporated in the tablet, the appellant

mentioned page 4, lines 23-24 of the root application as filed. Therefore, there was explicit support in the root application as filed. As regards the product-by-process feature, the appellant stated that it was not relevant whether the product was obtainable by other processes such as ripping or product deposition, since the claim was a product claim not restricted by the process. It cited board of appeal decisions T 120/03 of 01 January 2005, point 6 of the reasons, and T 411/89 of 20 December 1990. The teaching on page 4 of the root application as filed could be divided in three parts: lines 11 to 16, when DRSP is issued in a defined micronized form, rapid dissolution in vitro arises; lines 16 to 20, the term "rapid dissolution" is defined by means of USP XXIII Paddle Method; lines 20 to 24, one can spray DRSP onto the surface of inert carrier particles instead of providing it in micronized form. The skilled person would read the sentence in lines 20 to 24 within the context of page 4 of the root application as filed, as meaning that this was an alternative rapid dissolution form for providing the *in vitro* dissolution profile of DRSP.

The skilled person would not give a meaning to rapid dissolution contrary to its ordinary meaning in textbooks and common general knowledge. Therefore, the teaching on page 4 of the root application as filed was that a particular micronized form could be replaced by DRSP sprayed onto the surface of inert carrier particles.

The appellant also stated that some opinions of the opponents had changed from one case to another (parent, divisional) and referred to documents D62 and D83, in

particular points 72 and 43. It also argued that the opponents' arguments were artificial and formalistic.

The appellant further stated that documents D14 and D15 were not common general knowledge and that they were not concerned with spraying. Documents D14 were scientific publications. Document D14 related to the preparation of a "minuscular drug sample" (page 1431), and document D15 related to sample preparation by solvent deposition (page 390). Spraying the drug from a solution was not the method employed in these documents. In fact, documents D14 and D15 related to deposition, and the passages quoted by respondent 1 from the appellant's letter dated 28 August 2013 related to sufficiency of disclosure.

As regards respondent 1's argument that the DRSP could be in a matrix, it had nothing to do with claim's 1 wording and Articles 123(2) and 76(1) EPC. The product-by-process wording found a literal basis on page 4, lines 21 to 24.

Additionally, the presence of the excipients mentioned on pages 5 or 9 of the root application as filed were not mandatory. Moreover, it was on page 5 and not on page 9 where the excipients which acted to promote dissolution of both active substances were defined. Additionally, the examples referred to "preparation of tablets containing drospirenone and ethinylestradiol".

(c) *Admission of auxiliary request 1*

The appellant submitted that it had filed auxiliary request 1 in view of the discussion about double

patenting before the opposition division. Double patenting was not a cause for opposition. If the board considered that double patenting was an issue then this request would be re-submitted.

(d) *Auxiliary request 2*

This auxiliary request had been filed as a direct reply to the objections by the opponents that PVP was an essential feature. The basis for the amendment was to be found on page 5, lines 15 and 16 of the root application as filed. When examining the content of the root application as filed, a literal interpretation should be avoided; the skilled person would seriously contemplate the addition of PVP. PVP was disclosed on page 5 as being particularly helpful as an excipient. This meant that this was a preferred feature. PVP was also mentioned on page 9, line 21 of the root application as filed.

(e) *Admission of auxiliary requests 3 and 4*

The appellant pointed to the differences between these two sets of claims and the main request.

The appellant stated that these auxiliary requests had been filed as a reaction to the discussions during the oral proceedings. The appellant argued that, in the written proceedings, the opponents had relied upon decision T 7/07, whereas at the oral proceedings they had objected for the first time to claim 1 of the main request as relating to an unallowable combination of features. Amendments had now been introduced in response. The amendments were allowable since they

found a basis on pages 2, 9 and 5 of the root application as filed.

The opposition division had found that the main request was allowable under Articles 123(2) and 76(1) EPC. This was the reason for not having filed these auxiliary requests earlier. From the beginning of the appeal proceedings, the appellant had requested remittal to the department of first instance for further prosecution. Therefore, the argument that the filing of these two auxiliary requests caused an unnecessary prolongation of proceedings did not hold.

The appellant denied that the amended claims of auxiliary requests 3 and 4 were *prima facie* not allowable and referred again to pages 2, 4, 5 and 9 of the root application as filed.

XXII. The respondents' arguments, as far as relevant for the present decision, may be summarised as follows.

At the beginning of the oral proceedings the representative for respondent 1 clarified that, since he was also representing respondent 7, he would made all submissions and requests simultaneously in the name of respondents 1 and 7. Therefore, the submissions and requests summarised below for respondent 1 were endorsed by respondent 7.

(a) Respondent 1 contested the admissibility of the patent proprietor's appeal since all the appellant's requests comprised the feature concerning the dissolution profile as had been the case in appeal case T 598/12 (same board as in the present case). The board

had decided in T 598/12 that the claims contravened the requirements of Article 123(2) EPC. Therefore, the appeal case T 598/12 represented *res judicata* for the present appeal case and all the requests had to be rejected as inadmissible. Moreover, the contested feature had been found not allowable in decision T 7/07, which directly applied.

(b) *Main request*

Respondent 1 objected to claim 1 of the main request under Articles 123(2) and 76(1) EPC. Claim 1 related to an unallowable combination of features not disclosed in the root application as filed. *Inter alia*, the claim related to a particular dosage unit form, namely a tablet, comprising ethinylestradiol and inert carrier particles containing drospirenone (DRSP) on their surface (these were defined by means of a product-by-process feature), the DRSP was present in an amount corresponding to a daily dosage of 3 mg and the tablet was characterised by means of a particular dissolution profile for DRSP.

The rapid dissolution profile was defined on page 4 of the root application as filed in connection with a particular micronized form of DRSP. The second sentence which started with the words "Instead of..." (page 4, line 20) did not refer back to the dissolution profile and did not require that DRSP had a particular dissolution profile. Page 4 of the root application as filed did not disclose the dissolution profile defined in lines 16 to 20 for tablets containing DRSP in which DRSP had been put in the physical form obtained by spraying a solution of DRSP onto the surface of inert

carrier particles. This was not only a linguistic approach but it was also in line with the interpretation the skilled person would give to the disclosure on page 4, since he knew from his general knowledge that many factors affected the dissolution profile, and thus, without defining parameters such as surface area or nature of the inert carrier, the dissolution profile attained by a particular micronized form of DRSP was not generally applicable to any other form. In this context respondent 1 cited documents D14 and D15. Moreover, respondent 1 pointed to page 9, lines 10 to 23, of the root application as filed and the particular excipients not mentioned in the claim, but which were required in oral administration for promoting rapid dissolution.

Respondent 1 further submitted that claim 2 of the root application as filed related to a composition in which DRSP was in micronized form or sprayed from a solution onto particles of an inert carrier. Claim 1 of the main request related to a tablet comprising inert carrier particles containing DRSP on their surface which were not necessarily obtained by spraying from a solution. The product-by-process feature "obtainable by..." was not delimitative of the inert carrier which could contain DRSP not only on its surface but also in the matrix.

Although the appellant had referred to contradictions in the opponents' submissions, this did not apply to all the opponents, and certainly not to respondent 1.

Moreover, respondent 1 argued that the appellant had submitted that documents D14 and D15 should be

disregarded since they did not relate to spray drying or spray coating. However, the appellant had stated in its letter dated 28 August 2013 (page 17) that claim 1 of the main request was a product claim and it was the product which had to be assessed and not the process. Respondent 1 pointed to said letter, wherein the appellant had stated that it did not matter whether the techniques *per se* were equivalent as long as they led to equivalent products. Respondent 1 submitted that since the products in claim 1 were not restricted by the process the claim related to an unallowable generalisation of the disclosure on page 4. Moreover, the skilled person was aware of the techniques in documents D14 and D15 and knew that the rate of dissolution of the drug varied depending on several parameters. This meant that depending on the choice of these parameters one could obtain different dissolution profiles and that it was not necessarily the case that the dissolution profile was at least that stated on page 4 of the root application as filed for a particular micronized form.

Respondent 2 also submitted that decision T 598/12 represented *res judicata* for the present appeal case since claim 1 was "essentially" the same. Respondent 2 submitted that the only difference was the feature "inert carrier particles containing drospirenone on their surface obtainable by dissolving..." and that the product-by-process feature was not to be considered.

Respondent 2 referred to the board's communication sent as an annex to summons to oral proceedings, in particular to point 14.1, and stated that the conditions for *res judicata* were given. Additionally,

in decision T 7/07 it had already been decided that the feature concerning the dissolution profile was disclosed only in connection with a particular micronized form.

Respondent 3 added that decision T 7/07 had considered the feature "tablet" as preferably disclosed in view of the examples, but the examples only related to micronized forms. Moreover, the mention of a tablet preparation containing 3 mg of DRSP was made on page 4, lines 18 and 19, of the root application as filed only in connection with the test method for determining a particular dissolution profile *in vitro*, and thus could not serve as a valid basis for the tablets claimed. The disclosure of tablets on page 9 of the root application as filed was linked to the incorporation of pharmaceutically acceptable excipients that promoted dissolution of the DRSP and ethinylestradiol on oral administration.

Respondent 6 stated that claim 1 included several unallowable amendments which concerned *inter alia* the administration form being a tablet without mentioning the particular excipients that promoted dissolution as required on page 9, lines 10 to 17 of the root application as filed. Tablets were only mentioned at the end of this paragraph on page 9 within such a context. Moreover, the broad range of amounts for ethinylestradiol was disclosed only in connection with a broad range of amounts for DRSP (page 5 of the root application as filed). The tablets now claimed comprised a combination of 3 mg DRSP with a particular range for ethinylestradiol which did not appear to be disclosed together on page 5. Additionally, the

dissolution profile was only disclosed on page 4 for a particular form of micronized DRSP as outlined in decision T 7/07.

The teaching in the root application as filed was that one could use DRSP sprayed onto the surface of inert carrier particles instead of micronized DRSP, but the root application as filed did not disclose that these other forms would lead to the dissolution profile of the particular micronized form mentioned on page 4. The dissolution profile was dependent on the surface area, which was why the dissolution profile was given on page 4 only for the particular micronized form having a particular surface area. Spraying DRSP from a solution onto the surface of inert carrier particles was disclosed as an alternative for micronization but it was not disclosed what the surface area would be or that the dissolution profile was that of a particular micronized form.

As regards the appellant's reference to the proceedings in relation to the UK national decision D83, respondent 6 stated that the passages quoted were a summary by the judge and not a *verbatim* statement by Gedeon Richter (respondent 6 in the present case). There was no disclosure of DRSP sprayed onto the surface of inert carrier particles in conjunction with a particular dissolution profile.

Respondent 6 also argued that it was unallowable to make a combination of features from the reservoir of features in the root application as filed. It cited *inter alia* decision T 330/05 of 30 August 2005. Moreover, the passage on page 4 of the root application

as filed mentioning a tablet concerned a dissolution test and did not serve as a basis for the tablet now claimed. In respect of the disclosure of tablets on page 9 of the root application as filed, respondent 6 shared the views of respondent 3.

(c) *Admission of auxiliary request 1*

Respondent 1 objected to the admission of auxiliary request 1 and referred to its letter dated 25 October 2013 (paragraph bridging pages 2 and 3) and to the board's communication sent as an annex to the summons. Auxiliary request 1 was inadmissible since the introduction of three independent product claims was not allowable as a valid response to the decision of the opposition division or to the grounds for opposition.

Respondent 2 submitted that auxiliary request 1 was inadmissible. Auxiliary request 1 was similar to auxiliary request 8 filed in the course of opposition proceedings and then no longer prosecuted. Auxiliary request 1 could have been filed earlier in the proceedings (Article 12(4) RPBA). Moreover, the incorporation of three independent product claims was not an allowable response to the objections of the opponents (Rule 80 EPC).

(d) *Auxiliary request 2*

Respondent 1 stated that all the arguments submitted in relation to claim 1 of the main request applied by analogy to claim 1 of auxiliary request 2. The difference was the incorporation as excipient of

polyvinylpyrrolidone. Polyvinylpyrrolidone (PVP) was mentioned on page 5, line 16 of the root application as filed. But the combination of features in claim 1 did not directly and unambiguously derive from the root application as filed (Articles 123(2) and 76(1) EPC).

Respondents 2 and 3 submitted that their arguments for the main request applied *mutatis mutandis* to auxiliary request 2.

Respondent 6 stated that the combination of DRSP on the surface of inert carrier particles and PVP, together with the dissolution profile, found no basis in the root application as filed.

(e) *Admission of auxiliary requests 3 and 4*

Respondent 1 submitted that auxiliary requests 3 and 4 should not be admitted into the proceedings since they had been filed too late and were *prima facie* not allowable, in particular in relation to Articles 123(2), 76(1) and 84 EPC. DRSP could not be on the surface but in the matrix of a carrier. Moreover, the appellant had known for a long time about the problems of added matter of the main request. The board's communication sent as annex to the summons for oral proceedings had informed the parties that at the oral proceedings it would be assessed whether the requirements of Articles 123(2) and 76(1) EPC were met. Therefore, these auxiliary requests could have been filed earlier, at the latest with the response to the board's communication.

Respondent 2 argued that during the whole appeal proceedings the claims had been directed to tablets with a particular dissolution profile and now in auxiliary requests 3 and 4 the claims were directed to pharmaceutical compositions without any particular dissolution profile. Such requests could have been filed earlier. The sets of claims relating to pharmaceutical compositions in the form of dosage forms or tablets, without any particular dissolution profile, had no longer been prosecuted in the written appeal proceedings. The appellant knew about the problems of the main request, but had waited until this late stage to file these two requests. This very late filing of these two auxiliary requests was inadmissible and represented an abuse of proceedings.

Respondent 3 endorsed respondent 2's submissions. The deletion of the dissolution profile at such a late stage was unjustified. The appellant had known from decision T 7/07 about the lack of disclosure of this feature in relation to forms other than a particular micronized form of DRSP. Moreover, respondent 6 had already objected under Articles 123(2) and 76(1) EPC to the combination of features in claim 1 of the main request with its letter dated 20 December 2012 and had also objected to the feature concerning the dissolution profile. Therefore, the filing of these two auxiliary requests at the oral proceedings could not be justified. Additionally, choosing some of the excipients mentioned in the root application as filed was an unallowable singling out.

Respondent 6 also objected to the admission of auxiliary requests 3 and 4 for analogous reasons as

those submitted by respondents 1, 2 and 3. Respondent 6 further stressed that the claims of auxiliary requests 3 and 4 were clearly not allowable under Articles 123(2), 76(1) and 84 EPC (it mentioned the expressions "rapid dissolution", "to promote rapid dissolution"). The amended claims opened new issues which could not be dealt with without undue delay.

Moreover, respondent 6 submitted that the appellant's argument that auxiliary requests 3 and 4 should be admitted since remittal to the first instance would occur if the claims were found allowable under Article 83 EPC did not hold, since the new claims of auxiliary requests 3 and 4 opened new issues to be discussed in relation to Article 83 EPC for which the respondents could not have been prepared.

XXIII. The arguments submitted by respondent 5 in writing (see letter dated 10 December 2012) in relation to the main request and Articles 100(c), 123(2) and 76(1) EPC are analogous to those submitted by the respondents who attended the oral proceedings before the board of appeal.

XXIV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution on the basis of the main request or, alternatively, of one of auxiliary requests 1 and 2 filed with the statement of grounds of appeal, or of one of auxiliary requests 3 and 4 submitted during the oral proceedings.

The respondents requested that the appeal be dismissed.

Reasons for the Decision

1. The patent proprietor, who was adversely affected by the first-instance decision dated 29 March 2012 revoking the patent (Article 107 EPC), filed a notice of appeal and a statement of grounds of appeal, and paid the fee for appeal (Article 108, Rule 99 EPC). Therefore, its appeal is admissible.

The subject-matter in the claims serving as the basis for the decision in appeal case T 598/12 is not identical to the subject-matter in the claims serving as the basis for the present decision. Additionally, the parties are not the same and the facts and evidence submitted in both cases are not identical. Therefore, *res judicata* does not apply in relation to appeal case T 598/12.

As regards appeal case T 7/07 (same board in another composition), again there is no situation of *res judicata*. The parties are not the same, the claims serving as the basis for the decision T 7/07 are not the same as the present claims, and the facts and evidence are not identical in both cases.

2. The intervention filed by Effix Benelux N.V. under Article 105 EPC is admissible. The appellant did not contest the admissibility of the intervention and the board sees no reason not to admit it.

Whether or not the public availability of the product Yasmin^{R} had been sufficiently substantiated in the reasons given with the notice of intervention dated

22 August 2012 does not affect the admissibility of the intervention under Article 105 EPC, since *inter alia* the ground of opposition pursuant to Article 100(c) EPC was also invoked and sufficiently substantiated with said notice of intervention. Therefore, the intervention contains reasons which substantiate grounds for opposition under Article 100 EPC and respondent 7's request that the patentee's appeal be dismissed.

Therefore, the intervention filed by Effix Benelux N.V. is admissible (Article 105 EPC).

3. Although respondents 4 and 5 were duly summoned, they did not attend the oral proceedings, as announced with their letters of 21 and 24 October 2013, respectively. As stipulated by Article 15(3) RPBA the board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

4. *Admission of auxiliary requests 1, 3 and 4*

4.1 *Auxiliary request 1*

Auxiliary request 1, which was filed with the grounds of appeal, contains three independent product-category claims directed to tablets, which derive from independent claim 1 as granted. The main request filed with the grounds of appeal (which is identical to MR3 filed at the oral proceedings before the opposition division) contains one independent claim directed to a tablet. The filing of an auxiliary request containing

three independent claims directed to tablets cannot be justified as an admissible procedural step to redress the first-instance decision against the main request. Therefore, auxiliary request 1 is not admissible.

The opposition division did not consider that there was any problem in relation to double patenting and was of the opinion that a possible double patenting was not a ground for opposition (point 2.3 of the reasons for the decision). Therefore, the appellant's arguments in favour of the admission of auxiliary request 1 do not hold.

4.2 *Auxiliary requests 3 and 4*

The appellant filed auxiliary requests 3 and 4 at the oral proceedings before the board, after the discussion of the main request and auxiliary requests 1 and 2 had taken place.

During the written appeal proceedings the claims were directed to tablets with a particular dissolution profile and the claims concerning pharmaceutical compositions without any particular dissolution profile were no longer prosecuted. The claims in auxiliary requests 3 and 4 no longer concern the tablets but are directed to pharmaceutical compositions without any particular dissolution profile and incorporating features which derive from the description.
Moreover, the objections in relation to added subject-matter (Articles 100(c), 123(2) and 76(1) EPC) in relation to the requests filed with the grounds of appeal were not raised for the first time at the oral proceedings before the board. With its letter dated

20 December 2012, respondent 6 had objected to claim 1 of the main request under Articles 100(c), 123(2) and 76(1) EPC, in particular, on the grounds that it related to an unallowable combination of features and because the dissolution profile was undisclosed for the tablets claimed.

Additionally, with the communication pursuant to Article 15(1) RPBA, which was sent on 7 June 2013 as an annex to the summons to oral proceedings, the board informed the parties that the assessment of the requirements of Articles 123(2) and 76(1) EPC would take place at the oral proceedings for the requests on file.

Therefore, auxiliary requests 3 and 4 could have been filed much earlier, at the latest in reply to the board's communication sent on 7 June 2013.

Additionally, the amendments introduced in auxiliary requests 3 and 4 diverge from those of the requests previously prosecuted on the appeal file and seek to introduce features deriving from the description at a very late stage of the proceedings. These amendments open new issues for discussion and delay the proceedings unduly. Oral proceedings were scheduled in order to attain a final decision. As explained in the board's communication sent as an annex to the summons to oral proceedings, the grounds of opposition pursuant to Article 100(c) (in conjunction with Articles 123(2) and 76(1) EPC) and Article 100(b) EPC were to be assessed. Therefore, in view of the need for procedural economy and fairness of proceedings the admission at the oral proceedings of new sets of claims which would

have required remittal for a discussion on grounds under Article 100(c) and (b) EPC was not justified.

Therefore, auxiliary requests 3 and 4 are not admitted into the proceedings.

5. *General remarks*

5.1 The patent in suit derives from European patent application No. 00953387.8, filed as an international application which was published as WO 01/15701 (parent application as filed).

The parent application, which was granted as EP-B1-1214076, underwent opposition proceedings and was revoked by decision T 7/07 of 7 July 2011 (taken by board 3302 in another composition).

5.2 The documents concerning the description and examples as originally filed are identical for the parent application and its divisional (i.e. the application from which the patent in suit derives). However, the sets of claims of the two applications as filed differ from each other.

5.3 *Main request*

Claim 1 of the main request relates to a tablet comprising ethinylestradiol (in an amount of from about 0.01 mg to about 0.05 mg) and inert carrier particles containing drospirenone (DRSP) (DRSP in an amount of 3 mg) sprayed onto their surface, together with one or more pharmaceutically acceptable carriers or excipients. The tablets are further characterised by a functional

feature, namely the following *in vitro* dissolution profile: "wherein at least 70% of said drospirenone is dissolved from said tablet within 30 minutes, as determined in 900 ml of water at 37°C by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm".

Therefore, it has to be investigated whether or not such tablets are directly and unambiguously disclosed in the root application as filed.

The root application discloses pharmaceutical compositions containing two active substances, namely DRSP and ethinylestradiol, in particular ranges of amounts (from 2 mg to 4 mg and from 0.01 mg to 0.05 mg, respectively), together with one or more pharmaceutically acceptable carriers or excipients (claim 1 of the root application as filed). According to the description in the root application as filed, the active substances DRSP and ethinylestradiol may be provided in micronized form or sprayed onto the surface of inert carrier particles from a solution (pages 4 and 5). Additionally, according to the description in the root application, the pharmaceutical compositions may be formulated in the form of oral dosage forms such as tablets, pills and capsules (page 9, lines 22-23) or in liquid form, e.g. as a solution, suspension or emulsion (page 9, lines 31-32).

Therefore, in order to arrive at the subject-matter claimed in claim 1 of the main request the skilled person has to select the dosage form as being a tablet, the form in which DRSP is present (inert carrier particles containing DRSP sprayed onto their surface)

and its amount (3 mg). Moreover, the tablet claimed has to provide the particular dissolution profile *in vitro* defined in the claim.

However, there is no pointer in the application as filed to such tablets. The examples illustrate tablets containing DRSP (3 mg) and ethinyl estradiol (0.03 mg), but both active substances are in **micronized** form (examples 1, 2, 3). The tablets employed in the bioavailability studies in example 4 are not explicitly characterised in relation to the physical form in which DRSP is present.

The amount of 3 mg DRSP present in the **pharmaceutical composition** is defined on page 5, line 20 of the root application as filed, but the passage dedicated to oral dosage forms on page 9, second paragraph, stresses that the pharmaceutically acceptable excipients should be those "that promote dissolution of the drospirenone and ethinylestradiol", and tablets are not explicitly mentioned as a preferred embodiment. Tablets are mentioned in the next paragraph on page 6 (lines 25-29) with the information that they "may conveniently be coated", but the subsequent paragraph on page 9 states clearly that liquid dosage forms are possible options for oral dosage forms.

Additionally, the "tablet preparation" containing 3 mg DRSP expressly mentioned with the test method for determining the dissolution profile *in vitro* on page 4, lines 16-20 of the root application as filed cannot serve as an allowable basis for the tablets in claim 1, since it is not specified that the "tablet preparation"

is a tablet containing the DRSP sprayed onto the surface of inert carrier particles.

5.3.1 Moreover, the root application as filed discloses that when DRSP is provided in a particular micronized form, namely "so that particles of the active substance have a surface area of more than 10,000 cm^2/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, in a pharmaceutical composition, rapid dissolution of the active compound from the composition occurs in vitro" (page 4, lines 11 to 16). However, the root application as filed does not disclose that when DRSP is provided sprayed onto the surface of inert carrier particles rapid dissolution always occurs, independently of *inter alia* the nature and physical form of the carrier. The specification in the root application as filed informs the skilled person that providing DRSP by spraying it from a solution onto the surface of inert carrier particles is an alternative to providing DRSP in micronized form (page 4, lines 20-24). However, the root application as filed does not disclose that tablets containing inert carrier particles onto which surface DRSP has been sprayed would necessarily provide the rapid dissolution profile defined in lines 16 to 20 on page 4 of the root application as filed.

It appertains to the common general knowledge in the field (documents D11, D13, D28, D113b) that through reduction of particle size (such as by micronization) dissolution of poorly soluble drugs may be promoted.

The surface area (which is a distinct characteristic of any specific solid form of a drug) is one factor having a major bearing on the dissolution profile (document D13, page 591, right-hand column). However, it is not technically meaningful to maintain that any increase in surface area always achieves the same effects in terms of dissolution behaviour, or guarantees an equivalent increase in dissolution rate (document D13, page 591, right-hand column, last paragraph). It is the increase in "the *effective* surface area of the drug, or the area exposed to the dissolution medium and not the absolute surface area, that is directly proportional to the dissolution rate" (document D13, page 591, right-hand column, last paragraph). These general principles apply to drug particles obtained by micronization, but are also applicable to products obtained by other methods for increasing the surface area of a drug, such as deposition of the drug on the surface of inert carrier particles or spraying of the drug from a solution onto the surface of inert carrier particles (document D5, page 472). The dissolution profile of the drug in the products will vary depending on factors such as the effective surface area, and this will be dependent in each particular case *inter alia* on the nature and form of the inert carrier particles onto which the drug has been sprayed, and the actual physical form taken by the drug particles on the surface of the carrier.

The root application as filed discloses that the dissolution of the poorly soluble drug DRSP may be promoted by spraying DRSP from a solution in a suitable solvent onto the surface of inert carrier particles. However, it is not directly and unambiguously derivable from the content of the root application as filed, even

considering the general knowledge in the field, that any of the tablets comprising inert carrier particles containing DRSP on their surface will provide the rapid dissolution profile *in vitro* defined on page 4, lines 16 to 20, which appears in claim 1 of the main request. These findings apply irrespective of whether or not the dissolution profile *in vitro* defined on page 4 is comparable or equivalent to the "rapid" dissolution profile obtained following the general recommendations in the general prior-art documents D17, D87 and D88.

As regards the appellant's argument that the spraying techniques disclosed in document D5, point 23.3.2.5 are able to provide products which will always have at least the dissolution profile *in vitro* obtained by micronization, the following has to be said. Apart from the fact that the particular process disclosed in point 23.3.2.5 of document D5 is not part of the disclosure of the root application as filed, a "product-by-process" feature does not restrict the product to only those products directly obtained by a certain process. The only characteristic which is mentioned in the root application as filed as directly derivable from the process is that the inert carrier particles contain DRSP on their surface. There is, however, no disclosure in terms of the specific surface area of the products so obtained, and thus, the dissolution profile *in vitro* is not specifically disclosed for the alternative now claimed.

Therefore, for the reasons given above, the main request fails since claim 1 contains added subject-

matter within the meaning of Articles 100(c), 123(2) and 76(1) EPC.

5.4 *Auxiliary request 2*

Claim 1 of auxiliary request 2 differs from claim 1 of the main request essentially in that polyvinylpyrrolidone is included as one of the excipients additionally present in the tablets. Therefore, the reasons given above for the main request apply *mutatis mutandis* to auxiliary request 2. Polyvinylpyrrolidone is disclosed in the root application as filed as an excipient which might be particularly helpful to promote dissolution (page 5, lines 15-16). However, this disclosure does not contain any pointer or reference to a particular dissolution profile *in vitro*, or to the choice of a particular dosage form or a particular physical form for DRSP.

Therefore, auxiliary request 2 fails since it contains added subject-matter within the meaning of Articles 100(c), 123(2) and 76(1) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald