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**Datasheet for the decision  
of 15 November 2019**

**Case Number:** T 1728/16 - 3.3.07

**Application Number:** 04816820.7

**Publication Number:** 1663183

**IPC:** A61K9/14, A61K9/20, A61K31/425

**Language of the proceedings:** EN

**Title of invention:**  
SOLID PHARMACEUTICAL DOSAGE FORM COMPRISING RITONAVIR

**Patent Proprietor:**  
ABBOTT LABORATORIES

**Opponents:**  
F.Hoffmann-La Roche AG  
Janssen Sciences Ireland UC  
Teva Pharmaceutical Industries LTD.

**Headword:**  
Solid pharmaceutical dosage form comprising ritonavir / ABBOTT

**Relevant legal provisions:**  
EPC Art. 107, 123(2), 54(3), 56, 100(b)  
RPBA Art. 12(4)

**Keyword:**

Amendments - added subject-matter (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

**Decisions cited:**

T 1061/16, T 0815/07, G 0001/15



**Beschwerdekammern**

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Case Number: T 1728/16 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 15 November 2019**

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**Decision under appeal:**      **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
25 May 2016 concerning maintenance of the  
European Patent No. 1663183 in amended form.**

**Composition of the Board:**

**Chairman**                    J. Riolo  
**Members:**                    E. Duval  
                                      P. Schmitz

## Summary of Facts and Submissions

- I. European patent 1 663 183 (hereinafter "the patent") was granted on the basis of 22 claims.

Claim 1 of the patent related to a solid pharmaceutical dosage form comprising a solid dispersion of at least one HIV protease inhibitor comprising ritonavir and at least one pharmaceutically acceptable water-soluble polymer having a Tg of at least 50 °C and at least one pharmaceutically acceptable surfactant.

- II. Five oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed, and it extended beyond the content of the application as filed.

- III. The appeals were filed by the patent proprietor and opponents 1, 3, 4 and 5 against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 2, the patent in suit met the requirements of the EPC.

The decision was based on a main request filed by letter dated 2 May 2013, a first auxiliary request filed by letter dated 17 October 2014 and a second auxiliary request filed by letter dated 22 December 2015.

- IV. In the decision under appeal, reference was made *inter alia* to the following documents:

D4: WO 01/34119 A2

D6: US 6599528 B1

- D10: Pharmaceutical Research (1996) Vol. 13, no. 9, S351, Abstract PDD 7475: Dias et al.
- D11: EP 1027886 A2
- D17: 28th Int. Symp. on Controlled Release of Bioactive Materials and 4th Consumer & Diversified Products Conference (2001), Vol. 1, pp. 738-739: Rosenberg et al.
- D18: Pharmaceutical Research (1996), Vol. 13, no. 9 suppl., p. S351, Abstract PDD 7474: D. Martin et al.
- D20: WO 00/57855 A1
- D22: Breitenbach et al. "Two Concepts, One Technology: Controlled-Release and Solid Dispersions with Meltrex" in *Drugs and the Pharmaceutical Sciences*, 2003 (126), pp. 125-134
- D23: Rosenberg et al. "Amorphous Embedding of a Lipophilic Drug Substance by Meltrex®-Technology" in *Abstract book 7th European Symposium on Controlled Drug Delivery*, 2002, pub. *Journal of Controlled Release* 87, (2003), pp. 264-267.
- D24: Leuner et al, *European Journal of Pharmaceutics and Biopharmaceutics* 50 (2000) 47-60
- D47: Perkin Elmer Application Note, "Tg and Melting Point of a Series of Polyethylene Glycols Using the Material Pocket" 2007.
- D48: EP 2 258 344, divisional of the contested patent.
- D51: study of the bioavailability of ritonavir.

- V. In particular, the opposition division decided that:
- (a) The main request and auxiliary request 1 contravened the requirements of Article 123(2) EPC.
  - (b) Document D51 was admitted into the proceedings.
  - (c) Auxiliary request 2 complied with the requirements of Article 123(2) EPC.

- (d) The existence of several methods for measuring the glass transition temperature (Tg) did not cause the subject-matter of auxiliary request 2 to be insufficiently disclosed.
- (e) The subject-matter of auxiliary request 2 was novel. In particular, since the priority was validly claimed, it was not anticipated by the divisional application D48.
- (f) Regarding inventive step, D4 was selected as closest prior art. The claimed solid dosage form differed from those of D4 by (i) a higher amount of water-soluble polymer with a Tg of at least 50°C and (ii) the presence of 2-20% of a non-ionic surfactant with an HLB value of 4-10. The effect resulting from feature (ii) was an increased drug bioavailability. The technical problem was the provision of a solid pharmaceutical dosage form comprising ritonavir with an increased drug bioavailability. Although surfactants with an HLB value below 10 were known to improve the bioavailability of low water soluble drugs, there was no suggestion in the prior art to add such surfactants to dosage forms comprising the low soluble *and* low permeable drug ritonavir. The requirements of inventive step were accordingly fulfilled.

VI. With its statement of grounds of appeal of 4 October 2016, the appellant - patent proprietor filed a main request and auxiliary requests 1 and 2. Auxiliary request 2 was identical to auxiliary request 2 found to comply with the EPC by the opposition division.

In reply to the statements of grounds of appeal filed by the appellants - opponents, the appellant - patent proprietor introduced 49 further auxiliary requests by letter dated 20 February 2017.

- VII. In a communication pursuant to Article 15(1) RPBA, the Board expressed *inter alia* the preliminary opinion that auxiliary request 2 complied with the requirements of Article 123(2) EPC, of novelty and of inventive step but that the requirements of sufficiency of disclosure were not fulfilled in respect of dependent claims 7 and 8.
- VIII. By letter dated 15 October 2019, the appellant - patent proprietor filed 11 further auxiliary requests "B", including auxiliary request AR2<sub>B</sub>, in which said dependent claims 7 and 8 were deleted.
- IX. Oral proceedings took place before the Board in the presence of the appellant - patent proprietor. The appellants - opponents 1, 4 and 5 had each announced by earlier letters that they would not attend the oral proceedings, and both opponent 2 and appellant - opponent 3 had withdrawn their oppositions.

During the oral proceedings, the appellant - patent proprietor made auxiliary request AR2<sub>B</sub> its main and sole request and withdrew all other requests. This new main request was handed over during the oral proceedings.

Claim 1 of this main request read as follows:

"A solid pharmaceutical dosage form which comprises a solid dispersion of at least one HIV protease inhibitor and at least one pharmaceutically acceptable water-



soluble polymer and at least one pharmaceutically acceptable non-ionic surfactant, wherein said HIV protease inhibitor comprises (2S,3S,5S)-5-(N-(N-((N-methyl-N-((2-isopropyl-4-thiazolyl)methyl)amino)carbonyl)-L-valinyl)amino-2-(N-((5-thiazolyl)methoxy-carbonyl)amino-1,6-diphenyl-3-hydroxyhexane (ritonavir), and said pharmaceutically acceptable water-soluble polymer has a Tg of at least 50°C, wherein the dosage form comprises, relative to the weight of the dosage form, from 50 to 85 % by weight of said water-soluble polymer, from 5 to 30 % by weight of said HIV protease inhibitor, from 2 to 20% by weight of said surfactant, and from 0 to 15% by weight of additives, and wherein said pharmaceutically acceptable non-ionic surfactant comprises a surfactant having an HLB value of from 4 to 10."

X. In addition to the documents submitted during the proceedings before the opposition division, reference is made to the following further documents submitted during the appeal proceedings:

(a) by the appellant - patent proprietor with its response to the statements of grounds of appeal of the opponents:

D58: Law et al., Journal of Pharmaceutical Sciences, 2001, 90(8), pages 1015-1025

(b) by the appellant - opponent 5 with its response to the statement of grounds of appeal of the patent proprietor:

D61: Annex 1, experimental data filed 20 February 2017

XI. The arguments of the appellants - opponents can be summarised as follows:

(a) The appellant - opponent 4 took the view that, to the extent that the appeal by the patent proprietor relied on auxiliary request 2 maintained by the opposition division, the appellant - patent proprietor was not adversely affected by the decision under appeal, and hence its appeal was not admissible.

(b) Claim 1 combined various embodiments from the application as filed which were not disclosed in combination therein, namely:

- the features relating to specific amounts of HIV protease inhibitor, polymer, surfactant and additives from page 3, lines 7-15,
- the presence of ritonavir as HIV protease inhibitor from page 4, lines 16-17, and
- the presence of a surfactant having an HLB value of 4-10 from page 6, lines 10-12.

Additionally, the absence of additive, i.e. the value 0% for the amount of additives, was not derivable from the expression "from about 0% to about 15%". Accordingly, the criteria of Article 123(2) EPC were not met.

(c) The subject-matter of claim 1 was insufficiently disclosed, because the parameter Tg was not reproducibly defined in the patent. As shown in e.g. D11, there were a variety of methods available for determining Tg values of organic polymers, resulting in significantly diverging Tg values for one and the same polymer. D47 also showed that some exemplary polymers recommended in paragraph [0026] actually had Tg values of less than -20°C. As set

out in T 815/07, the purpose of a parameter contained in a claim was to define an essential technical feature of the invention, and its method of determination should be such as to produce consistent values. This was not the case here. Accordingly, the criteria of sufficiency of disclosure were not met.

- (d) The subject-matter of claim 1 was not entitled to the claimed priority. The relevant date for the claimed invention was accordingly the filing date. The divisional application D48 formed part of the state of the art under Article 54(3) EPC to the extent that its disclosure was duly based on the priority document. Since the examples 2-5 disclosed in D48 were contained in the priority document, D48 was prejudicial to the novelty of all claims.
- (e) D4 qualified as a starting point for the assessment of inventive step. D4 was concerned with solid pharmaceutical dosage forms comprising a solid dispersion of ritonavir and water soluble polymers having high Tg (PVP, PEG). The presence of surfactant was also disclosed in claim 10 of D4.

Considering the ambiguity of the definition of the water soluble polymer, the feature relating to its amounts was not useful to delimit the invention from the prior art, and could anyway not contribute to an inventive nature of the claimed dosage forms since it was an obvious modification.

The second differentiating feature was the presence of 2-20% of a non-ionic surfactant comprising a surfactant with an HLB of 4-10. No valid conclusion could be drawn on any resulting effect on the

bioavailability of ritonavir, because the activity of the surfactant composition, which may contain further surfactants with an HLB outside the range 4-10, was determined by the net HLB value thereof (D41, D42). Furthermore, the comparisons with compositions lacking any surfactant given in the patent could not establish any technical effect over D4, since the closest prior art formulation described in D4 already included a surfactant.

The objective technical problem could only be defined as the provision of an alternative dosage form.

Considering that D4 emphasized that aqueous solubility was one of the most important factors affecting bioavailability, each of D6, D17 and D20 would have provided an incentive to use surfactants in the defined amounts and comprising a surfactant with an HLB of 4-10 in the expectation of providing an improved bioavailability for the drugs shown in D4. The use of solid dispersions, especially made by melt extrusion, was known from D22-D24, D10 and D18 as a technology of choice for addressing the problem of bioavailability, or at least the problem of low solubility of drugs such as ritonavir. In this respect, it was emphasized that the patent presented a poor aqueous solubility as the main problem in achieving bioavailability for oral dosage forms of HIV protease inhibitors.

Accordingly, the claimed subject-matter did not involve an inventive step.

XII. The arguments of the appellant - patent proprietor can be summarised as follows:

(a) Claim 1 met the requirements of Article 123(2) EPC. The use of ritonavir within the solid pharmaceutical dosage form of the invention, and its combination with a non-ionic surfactant having an HLB value of 4 to 10, would have been seriously contemplated by the skilled person reading the application as filed. In relation with the deletion of the term "about" before the value 0% for the amount of additives, the normal practice of the Boards of Appeal could be followed.

(b) Regarding sufficiency of disclosure in respect of the glass transition temperature  $T_g$ , there was only a small level of variability between the  $T_g$  values for a particular water soluble polymer, according to the different measuring methods, when compared with the size of the range recited in claim 1. Accordingly, the skilled person would be able to identify and select, without undue burden, water soluble polymers which were within the terms of the claim, irrespective of these different methods of measuring. The factual situation in case T 815/07 was markedly different, because the alleged ambiguity regarding the  $T_g$  parameter did not permeate the whole claim.

(c) The subject-matter of claim 1 of the main request was novel over the publication of the divisional application D48, because it was at least entitled to claim partial priority from the earlier application in light of decision G 1/15. The disclosure of the embodiments in D48 did not

benefit from an earlier effective date than the subject-matter in question.

- (d) D4 represented the closest prior art as it related to a solid oral dosage form of the HIV protease inhibitor ritonavir affording a good oral bioavailability and stability. D4 (see example 1B) disclosed a solid pharmaceutical dosage form comprising a solid dispersion of 30% ritonavir in a PEG8000 carrier incorporating a water soluble PVP polymer having a Tg of 138°C, in an amount of 10.5% relative to the weight of the dosage form.

The technical differences of the claimed invention were (a) the use of a much higher amount of the water soluble polymer having a Tg of at least 50°C (namely 50-85wt%); (b) the incorporation of a surfactant into the dosage form; (c) the presence of that surfactant within the solid dispersion component, and (d) the decision to use, as that surfactant, a non-ionic surfactant having an HLB value of from 4 to 10.

The positive effect on the bioavailability of ritonavir arising from the incorporation of a non-ionic surfactant having an HLB value of from 4 to 10 was established by the patent itself (comparative example and example 2 and 4) and confirmed by D51 and the additional *in vivo* tests submitted before the opposition division (see paragraph 158 of the letter filed on 2 May 2013). The objective technical problem was thus to improve the oral bioavailability of ritonavir.

D4 did not motivate the skilled person to increase the amount of PVP within the polymer matrix. In D4,

a surfactant was only mentioned as one of the possible optional additives, and without indication of its nature. There was no pointer in D4 to the use of a non-ionic surfactant having an HLB value of from 4 to 10, nor any suggestion of any ability to improve the oral bioavailability of ritonavir. This was not rendered obvious either by the further documents cited by the appellants - opponents. Thus the claimed subject-matter involved an inventive step.

XIII. The appellant - patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed during the oral proceedings before the Board (corresponding to auxiliary request AR2<sub>B</sub> filed by letter dated 15 October 2019).

XIV. The appellant - opponent 1, the appellant - opponent 4, and the appellant - opponent 5 each requested that the decision under appeal be set aside and the patent be revoked.

The appellant - opponent 4 additionally requested that the patent proprietor's appeal be held not admissible in view of Auxiliary request 2.

## **Reasons for the Decision**

### *Admissibility of the patent proprietor's appeal*

1. In the decision under appeal, the patent was found to meet the requirements of the EPC on the basis of auxiliary request 2. Since the appellant - patent proprietor's (then) higher ranking requests were not

found allowable by the opposition division, the appellant - patent proprietor is adversely affected and thus entitled to appeal the decision pursuant to Article 107 EPC. The admissibility of an appeal can only be assessed as a whole. There is no support in the EPC for a notion of "partial admissibility" of an appeal. The objection of appellant - opponent 4 to the admissibility of the patent proprietor's appeal in view of Auxiliary request 2 is thus not convincing. Moreover, auxiliary request 2 on which the decision under appeal was based formed the basis of the opponents appeals.

*Main request (filed during oral proceedings before the Board)*

2. Article 123(2) EPC

Claim 1 of the application as filed relates to a solid pharmaceutical dosage form comprising a solid dispersion of

- at least one HIV protease inhibitor and
- at least one pharmaceutically acceptable water-soluble polymer having a T<sub>g</sub> of at least 50 °C and
- at least one pharmaceutically acceptable surfactant.

By comparison, in claim 1 of the main request, the following features are introduced:

- (a) the HIV protease inhibitor comprises ritonavir,
- (b) the contents in said HIV protease inhibitor, surfactant and polymer as well as additives are defined by percentages weight ranges, and
- (c) the non-ionic surfactant comprises a surfactant having an HLB value of 4-10.



Each of the above amendments individually finds basis in the application as filed:

- (a) The HIV protease inhibitor ritonavir is disclosed e.g. on page 4.
- (b) The respective amounts for each components of claim 1 are disclosed in original claim 6, or page 3, lines 7-15. The deletion of "about" in respect of all values, including the value 0% for the additives, does not introduce added subject-matter: the lower limit of the range "from about 0 to about 15% by weight" is the value 0 or values just above it. Thus the expression directly and unambiguously discloses the value 0%, i.e. the absence of additive, which is not contradicted by the rest of the original disclosure.
- (c) The presence of a surfactant with an HLB value of 4-10 is disclosed on page 6, lines 9-12. Claim 3 of the application as filed clarifies that the surfactant referred to is the pharmaceutically acceptable surfactant present in the solid dispersion (and not simply in the solid dosage form).

The Board also agrees with the appellant - patent proprietor that the skilled person reading the application as filed would consider the combination of these features. The examples (see e.g. pages 17 and 18) show that the inclusion of a surfactant with an HLB value of 4-10 is preferable for the achievement of an enhanced bioavailability. Ritonavir is chosen among the two preferred HIV protease inhibitors (namely ritonavir and lopinavir). The fact that these features are

disclosed as being preferred is seen as a pointer to their combination with the generally disclosed percentage ranges.

Accordingly, the requirements of Article 123(2) EPC are fulfilled.

3. Sufficiency of disclosure

3.1 The objection of insufficiency of disclosure raised by the appellants - opponents is based on the parameter Tg present in claim 1. Similar issues were addressed by the same Board in a different composition in decision T 1061/16 relating to the patent stemming from a divisional application of the present case, and pertaining to solid dosage forms of ritonavir and lopinavir.

Claim 1 does not define the method for measuring the parameter Tg. It is established that different methods of measurement will lead to different Tg values, see for instance D11, page 6, [0037], according to which the different techniques may produce values falling within 10-30°C of each other.

A lack of clarity in relation with the Tg parameter is thus established. However, it is not shown that, as a result of this ambiguity, the patent as a whole does not enable the skilled person, relying on the description and on his common general knowledge, to carry out the invention. Considering the guidance given in paragraph [0024] of the specification, in particular the specific method of calculation of said parameter for copolymers from the Tg values of homopolymers given in a document cited in the same passage, the Board finds that the invention is sufficiently disclosed. The

Board sees in this respect no reason to depart from the similar considerations made in decision T 1061/16 (point 2. of the reasons).

In the Board's opinion, the circumstances of decision T 815/07 are not applicable in the present case, because the glass transition temperature is a well known parameter and the known methods for its measurement do not result in totally arbitrary values.

The requirements of sufficiency of disclosure are thus met.

4. Novelty

The appellant - opponent 4 contended that the subject-matter of claim 1 was not entitled to the claimed priority. The divisional application D48 therefore formed part of the state of the art under Article 54(3) EPC to the extent that its disclosure was duly based on the priority document. Since the examples 2-5 disclosed in D48 were contained in the priority document, D48 was prejudicial to the novelty of all claims.

However, in the Board's opinion, it follows from decision G 1/15 that, since examples 2-5 of D48 are contained in the priority document and are encompassed by the claims of the main request, these claims are entitled to a partial priority in respect of this alternative subject-matter. As a result, D48 is not part of the prior art pursuant to Article 54(3) EPC for this alternative subject-matter.

Accordingly, the claimed subject-matter is novel.

5. Inventive step

- 5.1 The claimed invention is directed to solid pharmaceutical dosage forms comprising at least ritonavir (see [0001]). It aims at addressing the need for improved oral solid dosage forms for HIV protease inhibitors which have suitable oral bioavailability and stability and which do not necessitate high vehicle volumes (see [0007]).
- 5.2 D4 relates to pharmaceutical compositions comprising a solid dispersion of ritonavir (see claim 5). D4 addresses the problems of bioavailability and stability. Accordingly, the Board considers D4 to represent the closest prior art.
- 5.3 The compositions of D4 comprise a water soluble carrier such as polyethylene glycol (PEG), and may comprise polyvinylpyrrolidone (PVP) in a broad range of 1-95% (see page 11 lines 5-6 of D4). In example 1B, a composition comprising 30% ritonavir (ABT-538) in 85:15 PEG8000:PVP ratio is described, corresponding to 30% ritonavir, 59.5% PEG8000 and 10.5% PVP.
- 5.4 PVP qualifies as a water-soluble polymer having a Tg of at least 50°C (according to the patent, see present claim 7). PEG8000 does not qualify as a water-soluble polymer having a Tg of at least 50°C, because the Tg of PEG8000 (about -100°C, see D58, page 1019) is far removed from the claimed range of 50° or above, even taking into account the ambiguities discussed above (see 3.1). No composition comprising 50-85% PVP is shown in D4. Accordingly, D4 does not disclose that the water-soluble polymer having a Tg of at least 50°C is present in an amount of 50%-85%.

The presence of a surfactant in the composition is mentioned in claim 10 of D4. However, D4 does not disclose that the solid dispersion contains a pharmaceutically acceptable non-ionic surfactant comprising a surfactant having an HLB value of from 4 to 10. The amount of 2-20% of a pharmaceutically acceptable non-ionic surfactant is also not disclosed in D4.

5.5 Regarding the technical effect resulting from the above differentiating features, and whether this effect arises over the whole scope of the claim, the Board comes to the following conclusions.

5.5.1 No effect is shown to arise from the presence of a higher amount (50%-85%) of water-soluble polymer having a Tg of at least 50°C.

5.5.2 As to the surfactant, the *in vivo* data presented in the patent (see comparative example vs. examples 2 and 4) credibly shows that the presence of 2-20% surfactant comprising a surfactant with an HLB value of 4-10 leads to an enhanced bioavailability of ritonavir, in comparison with a composition lacking any surfactant. A reproduction of example 1B of D4 is in this respect not needed, since the compositions compared in the patent differ only in respect of the differentiating feature.

The parties debated the relevance of the HLB parameter, relying in this respect on D51 and D61 (Annex 1). In the Board's opinion, D51 convincingly shows the surfactant with a HLB value of 4-10 (Span 20) to have a greater effect *in vivo* on bioavailability than surfactants with a HLB value outside this range (Cremophor RH40 and Tween 20). This is in apparent contradiction with the *in vitro* solubility data of D61,

in which Span 20 and Chremophor RH40 lead to comparable dissolution profiles of ritonavir. However, the bioavailability of a drug is affected not only by its aqueous solubility but also by a number of other factors, including permeation / drug absorption throughout the gastrointestinal tract, dosage strength and first pass effect (see paragraph [0004] of the patent). Consequently, the *in vitro* solubility data of D61 do not invalidate the above conclusion that Span 20 has an improved *in vivo* effect on bioavailability of ritonavir.

The Board concurs with the appellants - opponents that claim 1 defines the amount of surfactants in general but not the amount of surfactant having an HLB value of 4-10. Nonetheless, for the Board, in view of the above evidence, the presence of a given amount of surfactant with an HLB value of 4-10 can credibly be expected to correspondingly improve the bioavailability of ritonavir in comparison with the same composition lacking the surfactant with an HLB value of 4-10.

In this, the Board comes to the same conclusions as in decision T 1061/16 (point 3.5 of the reasons).

- 5.5.3 Accordingly, the problem to be solved may be formulated as the provision of a solid pharmaceutical dosage form comprising ritonavir with an improved bioavailability.
- 5.5.4 It remains to be assessed whether the claimed solution is obvious in light of the prior art, in particular D6, D10, D17, D18, D20, D22-D24.
- 5.5.5 D17 teaches that embedding a drug in molecular disperse form in a water-soluble polymer as solid solution by using the Meltrex®-technology, i.e by melt extrusion

with a PVP copolymer, enhanced the oral bioavailability in many cases significantly. D17 reports on the further effect of surfactants with HLB values of 4.7, 6.7 and 8.6 on the *in vitro* solubilisation of nearly insoluble drug compounds. However, the skilled person could not infer from D17 that surfactants with HLB values of 4-10 improve the bioavailability of a BCS class IV drug such as ritonavir (see D29, page 268), which has not only low solubility but also low permeability.

The same conclusions can be drawn regarding D23, in which the *in vitro* effect of an unknown liquid emulsifier with an HLB value of 4.0 on solubility is assessed.

- 5.5.6 D6 broadly considers the use of surfactants with an HLB value of 2 to 18, particularly preferably 10 to 14 (see page 2, lines 23-26) to formulate active ingredients of low solubility or low bioavailability. The only exemplified surfactant is polyoxyethylene glycol trihydroxystearate 40, i.e. chromophor RH40, which has an HLB value outside the range 4-10. For these reasons, the Board does not consider that D6 would lead the person skilled in the art towards the use of surfactants with HLB values of 4-10 to improve the bioavailability of the low-solubility and low-permeability drug ritonavir. Similar considerations apply to the related disclosure of D20.
- 5.5.7 Lastly, none of D10, D18, D22 and D24 show formulations comprising surfactants with HLB values of 4-10. Therefore these documents do not point to the claimed solution.
6. Accordingly, the main request fulfils the requirements of Article 56 EPC.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the set of claims of the main request filed during the oral proceedings before the Board and a description to be adapted.

The Registrar:

On behalf of the Chairman  
(according to Art. 8(3) RPBA):



B. Atienza Vivancos

P. Schmitz

Decision electronically authenticated