Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 5 November 2020

Case Number: T 0401/16 - 3.3.07

Application Number: 10179142.4

Publication Number: 2260833

IPC: A61K9/16, A61K9/20, A61K31/635, A61K31/54, A61K31/495, A61K31/415

Language of the proceedings: EN

Title of invention:
Bilayer pharmaceutical tablet comprising telmisartan and a diuretic

Patent Proprietor:
Boehringer Ingelheim Pharma GmbH & Co. KG

Opponents:
reuteler & cie SA
Laboratorios Liconsa, S.A.
Generics [UK] Limited
LEK Pharmaceuticals d.d.

Headword:
Bilayer pharmaceutical tablet / BOEHRINGER INGELHEIM

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 13(1), 25(2)
EPC Art. 114(2), 76(1), 123(2), 83, 54, 56

Keyword:
Late-filed evidence - admittance of documents filed in appeal proceedings
Amendments - extension beyond the content of the (earliest) application as filed (no)
Sufficiency of disclosure - (yes)
Public prior use - (no)
Novelty - (yes)
Inventive step - (yes)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0401/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 November 2020

Appellant: (Opponent 2)	Laboratorios Liconsa, S.A. Gran Via Carlos III, 98, 7th floor 08028 Barcelona (ES)
Representative:	Schön, Christoph Dr. Schön, Neymeyr & Partner mbB Bavariaring 26 80336 München (DE)
Appellant: (Opponent 3)	Generics [UK] Limited (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1AG (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Respondent: (Patent Proprietor)	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Party as of right: (Opponent 1)	reuteler & cie SA Chemin de la Vuarpillière 29 1260 Nyon (CH)

Party as of right: (Opponent 4)	LEK Pharmaceuticals d.d. Verovskova 57 1526 Ljubljana (SI)
Representative:	Prüfer & Partner mbB Patentanwälte · Rechtsanwälte Sohnckestraße 12 81479 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 22 December 2015 rejecting the opposition filed against European patent No. 2260833 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	C. Schmidt

Summary of Facts and Submissions

I. European patent 2 260 833 (hereinafter "the patent") was granted on the basis of 13 claims. The independent claim of the patent as granted reads as follows:

"1. A bilayer pharmaceutical tablet for use in a method for the treatment of hypertension comprising a first layer containing telmisartan in at least 90% amorphous form as determined by X-ray powder diffraction measurement in a dissolving tablet matrix comprising a basic agent and a water-soluble diluent, and a second layer containing a thiazide diuretic in a disintegrating tablet matrix."

II. Four 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 earliest application as originally filed.

III. The opposition division took the decision to reject the oppositions.

IV. The decision of the opposition division dated 22 December 2015 cited among others the following documents:

F2: J. Pharm. Sci. 1969, 58(5), pages 635-636
F15: Physician's Desk Reference® (PDR), 54th edition, 2000, pages 120, 130, 308, 804-806
F17: WO 00/27397
F18: WO 00/43370
F20: Submissions relating to FDA approval of Micardis® HCT as follows:

F20d: NDA 21-162, Micardis® HCT Clinical Pharmacology and Biopharmaceutics2ws (38 pages)
F22: F-D-C Reports, Pharmaceutical Approvals Monthly, 2000, 5(12), pages 1-48
F24: Physician's Desk Reference® (PDR), 55th edition 2001,pages 979-981
F25: Physician's Desk Reference® (PDR), 55th edition 2001, pages 1941-1942
F26: Physician's Desk Reference® (PDR), 55th edition 2001, Supplement A
F27: F-D-C Reports, Pharmaceutical Approvals Monthly, 2001 , 6(1), pages 1 -44
F28: F-D-C Reports, The NDA Pipeline® - 2000, Inc., 2001
F29: Physician's Desk Reference® (PDR), 56th edition, 2002, pages 1051 -1054
F33: WO 03/059327
F35: US2005/0089575
F41: USPTO Office Action regarding US No.10/892,425 dated January 31,2013
F43: Manual of Patent Examination Procedure (MPEP) at USPTO, Sth edition, Rev. 9, pages 2100-75 to 2100-86
F44: Hobbs v. United States Atomic Energy Commission, 451 F.2d 849 (5th Cir. 1971)

V. The opposition division decided in particular as follows:

(a) The main request complied with the requirements of Articles 123(2) and 76(1) EPC.

(b) The subject-matter of the main request was sufficiently disclosed. The patent specification together with common general knowledge provided indications for the preparation of amorphous telmisartan, its quantification and formulation

into the claimed tablets, including the amounts of active ingredients to be included to achieve the claimed therapeutic use.

(c) The main request fulfilled the requirements of Article 54 EPC. Document F26 did not describe bilayer tablets containing specifically amorphous telmisartan and a basic agent. There was furthermore no evidence that the tablets of the prior use alleged by the opponents were freely available to the public prior to the filing date of the opposed patent.

(d) F26 was the closest prior art to the granted claims. The distinguishing features lay in the presence of telmisartan in at least 90% amorphous form and in the presence of a basic agent in the dissolving matrix of the telmisartan layer. This resulted in enhanced dissolution and immediate drug release profile. The objective technical problem to be solved was thus the provision of an implementation of the teaching of F26 providing enhanced dissolution and immediate drug release of telmisartan with respect to otherwise similarly formulated individual tablets containing the active agents. The claimed solution was not obvious in light of the prior art.

VI. Opponent 2 (appellant 1) and opponent 3 (appellant 2) lodged an appeal against the above decision of the opposition division.

VII. The following items of evidence were filed by the parties during the appeal proceedings:

(a) Documents filed by the appellant 1 with its statement setting out the grounds of appeal:

F54: Newport-Thomson database information
F55: Yakugaku Zasshi Vol. 85 (1965), No. 12, T. Yamana et al. "Studies on the stability of Drugs. XIV. Stability of Benzothiadiazine. (6). On the Decomposition of Hydrochlorothiazide in Alkaline Solution"
F56: Pharmazie 1974, Apr. 29(4): 286-90

(b) Documents filed by the appellant 2 on 24 April 2017 and 30 May 2018, respectively:

F57: U.S. sales data for Micardis®-HCT provided by IMSHealth
F58: Handbook of Pharmaceutical Excipients, povidone chapter, page 433

(c) Documents filed by the respondent on 22 March 2018:

HE1: Wikipedia entry on the Physicians' Desk Reference
HE2: Wikipedia entry on IMS Health

(d) Documents filed by the appellant 1 on 8 February 2019:

F59: Certificate of IQVIA on the availability of Micardis® HCT in the US starting from 2001
F60: Sales data in the US for Micardis® HCT in 2001 and 2002

VIII. With its reply to the appellants' statements setting out the grounds of appeal the patent proprietor (respondent) defended its case on the basis of the patent as granted as main request, and on the basis of an auxiliary request.

IX. Oral proceedings were held before the Board. They were not attended by appellant 2 who had informed the Board accordingly.

X. Appellant 1 and appellant 2 requested that the decision under appeal be set aside and the patent be revoked.

XI. The respondent requested that the patent be maintained as granted (main request), or that the patent be maintained on the basis of the auxiliary request filed with the reply to the statements setting out the grounds of appeal on 18 November 2016.

The respondent further requested that F54-F60 not be admitted into the appeal proceedings.

XII. The arguments of the appellants, as far as relevant for the present decision, can be summarised as follows:

(a) Admittance of items of evidence

The reasons provided by the opposition division not to admit F54 did not demonstrate that the opposition division applied the correct criteria for not admitting F54. F54 was highly relevant to the prior use issue and should be admitted.

F55-F56 were filed with the statement setting out the grounds of appeal as required by Article 12(2)

RPBA 2007. These documents were to be admitted in the appeal proceedings.

F57 and F59-F60 were provided as further evidence of the public prior use. They were to be admitted in the appeal proceedings because they were highly relevant.

F58 was filed in support of the fact that povidone has properties as disintegrant and cannot be seen only as a binder. F58 was to be admitted in the appeal proceedings.

(b) The features introduced in claim 1 of the main request were not disclosed in combination in the earliest original application (F33). In particular, the treatment of hypertension was not disclosed in relation with the claimed specific tablets containing thiazide diuretics. The main request did thus not comply with the requirements of Articles 76(1) and 123(2) EPC.

(c) The patent did not provide sufficient information to perform the invention over the whole breadth of the claims. In particular the claimed therapeutic use, being a functional feature of the claims, was not achievable for any amount of active agents and for any thiazide diuretic.

(d) Micardis® HCT consisted of a bilayer tablet containing telmisartan and HCTZ useful in the treatment of hypertension. This product was commercially available before the filing date of the patent in suit as revealed by F22 and F26-F29. This constituted a public prior use of the claimed invention prejudicial to the novelty thereof.

Furthermore, a prior sale under 35 U.S.C. §102 (b) of compositions falling under the scope of present claim 1 had been acknowledged by the patent proprietor (see F41 and F35). Finally, the disclosure of F26 itself anticipated the subject-matter of claim 1 of the main request, as the features not explicitly disclosed were implicit for the skilled person.

(e) F26 represented the closest prior art. The distinguishing features of claim 1 of the main request over F26 were mainly the presence of telmisartan in 90% amorphous form, and the specific presence of a basic agent and a water-soluble diluent in the telmisartan layer. During oral proceedings, the presence of the thiazide diuretic in a disintegrating layer was cited as further distinguishing feature. No effect had been substantiated compared to the generally defined bilayer tablets of F26. The objective technical problem to be solved was therefore the provision of an alternative bilayer tablet comprising telmisartan and HCTZ. The use of amorphous telmisartan as well as the formulations of individual tablets corresponding to each of the present layers were already disclosed in F17, F18, F24, F15 and F25. It would therefore have appeared obvious to the skilled person to formulate each layer of the tablet described in F26 according to those disclosures. Claim 1 of the main request did thus not fulfill the requirements of Article 56 EPC.

XIII. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

(a) Admittance of items of evidence

The opposition division did correctly exercise its discretion not to admit F54. Hence, F54 was to be excluded from the appeal proceedings.

Appellant 1 did not provide any reason for the late-filing of F55-F56. Besides these documents were not pertinent to the present proceedings, nor did F55 support common general knowledge. Furthermore, concerning F55, F2 did already quote F55 and the issue of HCTZ stability had been discussed in first instance proceedings. Besides F55 had been filed merely in Japanese. F55 and F56 were thus not to be admitted in the appeal proceedings.

No reason for the late-filing of F57-F60 was provided and these documents could have been filed earlier. Furthermore F57 as well as F59-F60 introduced complexity to the case, in particular as the source of the provided data were not specified, and were thus not suitable to prove the case of the appellants. F57-F60 were consequently to be excluded from the appeal proceedings.

(b) The new features of claim 1 of the main request found basis in the original earliest application (F33, in particular on pages 2 and 4) and were not taken in isolation from the description. Hence, the main request complied with the requirements of Articles 76(1) and 123(2) EPC.

(c) Contrary to the appellant 1's assertion, the patent in suit actually provided guidance on the dose of active ingredients to be used. Furthermore, the objection of appellant 1 concerning thiazide diuretics other than HCTZ was unsubstantiated. Accordingly, the main request fulfilled the requirements of Article 83 EPC.

(d) There was no evidence that Micardis® HCT was commercially available at the filing date of the patent. Furthermore, a prior sale under 35 U.S.C. §102 (b) did not equate to a public prior use, as revealed by F43 and F44. Finally Micardis® HCT as disclosed in F26 did not fall under the scope of claim 1, as there was no indication in F26 that the telmisartan was at 90% in amorphous form nor that the basic agent and water-soluble diluent were present in the telmisartan layer. Hence, the main request was novel.

(e) F26 represented the closest prior art. The present tablets differed from the tablets described in F26 in the composition of the two layers. The claimed tablets had a fast dissolution profile and an immediate drug release as substantiated by F20d. The objective technical problem to be solved was therefore the provision of a stable bilayer tablet containing telmisartan and HCTZ with good dissolution profile. None of the prior art taught the present specific composition of each layer. Claim 1 of the main request did thus involve an inventive step.

Reasons for the Decision

1. Admittance of items of evidence

1.1 Document F54

Document F54 was filed by appellant 1 during the first instance oral proceedings as a further evidence of a public prior use. The opposition division did not admit said late-filed document into the opposition proceedings because it was not *prima facie* relevant as it did not allow to establish the date of actual public availability of the relevant product. The Board considers that the opposition division exercised its discretion under Article 114 (2) EPC by applying the correct criteria. There is furthermore no indication that this has been done in an unreasonable way. Hence, the Board sees no reason to overrule the decision not to admit document F54.

1.2 Documents F55-F56

Documents F55-F56 were filed by appellant 1 with its statement setting out the grounds of appeal, submitted before 1 January 2020. Following the transitional provisions set out in Article 25(2) RBPA 2020, their admittance must be decided on the basis Article 12(4) RPBA 2007.

According to the first instance's decision, inventive step was acknowledged based on a technical problem to be solved which, following the problem and solution approach, did not take into account issues of solubility and stability of HCTZ. Documents F55-F56 were filed in reaction to this reasoning in order to

support of the fact that the skilled person would have been aware of the solubility and stability issues of hydrochlorothiazide (HCTZ).
Hence, the Board considers that there were no compelling reasons for appellant 1 to file these documents in first instance proceedings.

1.3 Documents F57-F60

Documents F57-F60 were submitted after the statements setting out the grounds of appeal and before notification of the invitation to oral proceedings. Their admittance must be decided on the basis Article 13(1) RPBA 2020. In the exercise of its discretion the Board shall consider *inter alia* the suitability of the new evidence to resolve the issues admissibly raised by another party.

Document F57 and F59-60 were submitted by appellant 2 and appellant 1, respectively, as further evidences of an alleged public prior use.

Appellant 2 has not explained to which extent F57 would support any date of public availability. In F59-F60 submitted by appellant 1, some explanations as to the collection and treatment of the data usually used by IQVIA (F59) as well as some sales dates (F60) are provided. The Board however notes that the data presented in F60 belong to a database, for which actually no details are provided. The assessment of the provided data is therefore problematic. Moreover, the Board notes that these documents are based on data relating to sales period going back to 2001-2002. The data have thus been available for a long time. Furthermore, contrary to the requirements of Article 13(1) RPBA 2020, none of the appellants did provide any

reason for submitting the data at this late stage of the proceedings.

Document F58, relating to the excipient povidone and its properties was submitted by appellant 2 to counter the argument brought forward by the respondent with its letter dated 22 March 2018 and relating to the difference between dissolution matrix and disintegrating matrix. The Board notes that the respondent recognises that povidone may have various properties. The point of dispute therefore does not appear to lie in the properties of povidone *per se* but rather in the intended/actual use thereof in the patent, to which F58 is irrelevant.

For these reasons documents F57-F60 are not admitted into the appeal proceedings.

Main request

2. Amendments - Articles 76(1) and 123(2) EPC

2.1 The patent in suit is based on European patent application EP10179142.4, which was filed as a divisional application of European patent application EP07115060.1, itself being a divisional application of European patent application EP02708290.8, published as WO 03/059327 (F33).

2.2 Claim 1 of the main request is based on original claim 5 of the earliest previous application (F33) wherein the following features have been introduced:

(a) "at least 90% amorphous form as determined by X-ray powder diffraction measurement",

(b) "for use in a method for the treatment of hypertension", and
(c) "thiazide" diuretic.

2.3 Feature (a) was introduced to replace the terms "substantially amorphous form" and finds basis on page 4 of F33. The appellants did not object to this feature.

2.4 The Board further observes that features (b) and (c) are disclosed on pages 2 and 4 of F33, respectively.

2.4.1 Contrary to the appellants' views, the Board considers that a medical use in the treatment of hypertension for any of the disclosed combinations is directly and unambiguously derivable from F33, for the following reasons:

Page 2 of F33 directly and unambiguously discloses, under the heading "objects of the invention", the use of a combination of telmisartan and a diuretic like HCTZ in the treatment of hypertension. The skilled person would understand said passage as referring to any combination of telmisartan and any diuretic, thus also the more specific tablets disclosed in F33. The mention of HCTZ as an example of a diuretic cannot be interpreted as limiting the disclosed subject-matter to a combination of telmisartan and HCTZ. The Board furthermore considers that the reference in said passage to an "expected" effect relates merely to the mentioned synergistic efficacy independently of the usefulness of the combination in the treatment of hypertension *per se*.

2.4.2 Furthermore, the Board notes that the original claims of F33 (in particular claims 1 and 5) relate merely to

a bilayer tablet containing a diuretic. The diuretic is further defined on page 4 of F33. The selection of "thiazide diuretic" from the list of possible diuretics constitutes a one-dimensional limitation of original claim 5, which does not introduce subject-matter extending beyond the original disclosure. The fact that, as argued by the appellants, the effects reported in the specification were substantiated in the examples only with one preferred thiazide diuretic (HCTZ) is irrelevant for the assessment of compliance with the requirements of Articles 123(2)/76(1) EPC.

2.5 Finally, in relation with the argument of the appellants that there would be no disclosure of the presently claimed combination of features in F33, the Board notes that claims 1 and 5 of F33 already disclosed a bilayer tablet with the presently claimed first and second layers wherein the first layer contained telmisartan in "substantially amorphous form" and the second layer contained "a" diuretic. As detailed above (see 2.4.1), the Board considers that the presently claimed medical use is directly and unambiguously derivable from F33 for any disclosed combinations. The presently alleged new combination was thus already generally encompassed by the original disclosure of the earliest filed application. The one-dimensional limitation of the diuretic cannot be seen to result in the formation of any new combination.

2.6 Accordingly, claim 1 of the main request fulfills the requirements of Article 76(1) EPC. The appellants objected to dependent claims 2-13 based only on their dependency on claim 1. No other objections were raised in relation to Article 76(1) EPC. It follows that also claims 2-13 of the main request meet the requirements of Article 76(1) EPC.

2.7 Furthermore, appellant 1 did not provide any detailed reasoning to support its objection of lack of compliance with the requirements of Article 123(2) EPC beyond the reasoning developed in relation with Article 76(1) EPC. Appellant 2 did not raise any objection under Article 123(2) EPC.

Claim 1 of the main request differs from claim 4 of the original application in that the measurement of amorphous content was specified as being by X-ray powder diffraction. This feature finds basis in the original description as stated above (see 2.3), since the original description and the one of F33 are identical.

Accordingly the main request also fulfills the requirements of Article 123(2) EPC.

3. Sufficiency of disclosure

3.1 Claim 1 of the main request is a purpose limited product claim. It is a general principle when assessing compliance with the requirements of Article 83 EPC that, when the therapeutic effect is a functional feature of the claims, the suitability of the claimed product to achieve said effect must be disclosed.

3.2 In the present case, the Board is satisfied that the skilled person would be in a position to prepare the claimed bilayer tablet *per se*. This issue was not disputed by the parties.

3.3 The question which remains to be answered is thus whether the patent provides suitable evidence of the effectiveness of the claimed combination in the

treatment of hypertension. In this regard, the Board notes that both active pharmaceutical agents used in combination in the claimed tablets are known in the prior art as useful in the treatment of hypertension (see paragraphs [0002]-[0007] and [0019] of the patent in suit). There is thus *a priori* no reason to doubt that a combination of both agents would also be useful in the treatment of hypertension.

3.4 In this context, appellant 1 argued that, in the present case, there were actually doubts that the effect would be achieved because the doses taught for each of the active ingredients (telmisartan and the thiazide diuretic) in the patent in suit were lower than the "usual" doses mentioned for each individual active agent in F24 and F25 (see paragraph [0025] of the patent in suit). This argument is however not convincing. The fact that the patent teaches to use doses lower than "usual" doses of each active agent when used individually, does indeed not substantiate that a combination of said lower doses would not be useful in the treatment of hypertension.

3.5 The Board finally observes that the argument of appellant 1 that the claimed therapeutic effect would not be achievable with any thiazide diuretic has not been substantiated by any evidence.

3.6 Accordingly, in the absence of serious doubts substantiated by verifiable facts that the claimed therapeutic effect would not be achieved by the claimed tablets, the Board considers that the criteria of sufficiency of disclosure are fulfilled.

4. Public prior use

4.1 The appellants argued that a public prior use of the claimed invention occurred through the commercial availability of Micardis® HCT in the US before the filing date of the patent in suit.

4.2 One of the issues to be clarified when a public prior use is alleged, is when the prior use occurred (see Case Law of the Boards of Appeal, 9th edition 2019, I.C.3.2.4 a)).

4.3 Several documents in support of the public availability of Micardis® HCT before the filing date of the patent in suit were submitted by the appellants. In relation to these documents, the Board observes the following:

(a) F22, dated December 2000, merely states that Boehringer Ingelheim "will begin shipping" Micardis® HCT "after the new year". This indication of an intention to commercialise the tablets is not an evidence of the actual public availability thereof in 2001.

(b) F26 and F29 cannot constitute an evidence of the actual availability of the drug to the public, as they merely provide the same information as the label approved by the FDA for a given drug. In this context the appellants argued that the Physicians' Desk Reference (PDR), from which F26 and F29 are extracted, is a publication aimed at physicians to provide them with prescription informations on a drug. The addition in said PDR of a drug not commercially available would be of no interest for the physicians, so that Micardis® HCT must have been commercially available at the publication date of F26. This argument is not convincing because the PDR merely contains authorized prescribing

informations on an approved drug, which cannot constitute an indication of factual commercial availability.

(c) F27-F28 are merely indicative of the FDA approval date for Micardis® HCT and cannot either constitute an evidence that the tablets were indeed available to the public before the filing date of the patent in suit.

4.4 Appellant 2 furthermore argued that, in the US proceedings concerning F35, the respondent acknowledged a prior sale under 35 U.S.C. §102 (b) of compositions according to example 4 of F35 obtained according to the process of claim 19 of F35 (see F41). Said compositions fall under the scope of present claim 1. The Board considers however that, as noticed by the opposition division, in view of F43 and F44, this acknowledgement does not necessarily correspond to an actual public prior use of the product.

4.5 It follows that, even when applying the balance of probabilities as standard of proof, the evidences on file are not sufficient to substantiate the occurrence of a public prior use before the filing date of the patent in suit. The alleged public prior use does accordingly not form part of the state of the art according to Article 54 EPC.

4.6 In this context it is noticed that, in view of the lack of sufficient evidence of the public availability of Micardis® HCT before the filing date of the patent in suit, the issue of the possibility of analysing Micardis® HCT and determine its composition, raised by the appellants in line with G1/92, does not need to be discussed.

5. Novelty

5.1 The appellants based their objection of lack of novelty of the main request on (i) a public prior use of the product Micardis® HCT and (ii) the disclosure of F26 *per se*.

5.2 Regarding (i), as detailed above (see 4.) the alleged public prior use of tablets falling under the scope of claim 1 of the main request is not part of the state of the art.

5.3 Concerning (ii), F26, which contains the manufacturer's prescribing information on Micardis® HCT, discloses that Micardis® HCT are bilayer tablets containing telmisartan, HCTZ and the same excipients as those listed in example 4 of the patent in suit (see F26, A12, 2nd column, 1st full paragraph) useful in the treatment of hypertension. There is however no information in F26 on the physical form of telmisartan nor the distribution of the excipients in each layer.

5.4 The appellants argued that the presence of telmisartan in amorphous form as well as the presence of the basic agent and the water-soluble diluent in the telmisartan layer would be implicitly disclosed. The Board does not share this view. The commonly known incompatibility between HCTZ and basic agents is not sufficient to conclude that the skilled person would have necessarily considered the basic agent in F26 to be in the telmisartan layer, because, in the absence of any details as to the structure of the layers in F26, any other measure circumventing this incompatibility issue could have been used. Furthermore the fact that Micardis® HCT tablets disclosed in F26 have similar composition and PK profile as Micardis® tablets

containing amorphous telmisartan as sole active agent (see F15 and F24), cannot constitute an evidence that telmisartan in the Micardis® HCT tablets of F26 is indeed in amorphous form, as many different factors may influence the PK profile.

5.5 Hence, it cannot be concluded that the product disclosed in F26 does indeed fall under the scope of the present claim 1, as the presence of 90% of the telmisartan in an amorphous form and the specific distribution of the excipients amongst each layer is not directly and unambiguously derivable from F26.

5.6 Accordingly the subject-matter of the main request is novel.

6. Inventive step

6.1 In agreement with both parties, the Board considers F26 to represent the closest prior art.

F26 relates to bilayer tablets containing telmisartan and HCTZ in two different layers for use in the treatment of hypertension. The tablets of F26 further contain the same excipients as those listed in example 4 of the patent in suit (see F26, A12, 2nd column, 1st full paragraph).

6.2 However, F26 does not disclose the specific structure of each layer, in particular the following features of claim 1 of the main request are not directly and unambiguously derivable from F26:
(i) at least 90% of telmisartan is in amorphous form,
(ii) telmisartan is in a dissolving matrix which contains a basic agent and a water-soluble diluent, and
(iii) HCTZ is in a disintegrating matrix.

In this context, appellant 2 argued that there would be no difference between a "dissolving" matrix and a "disintegrating" matrix. The Board considers that, in view of the definition of each term as provided in the patent in suit (see paragraphs [0018] and [0020]), the skilled person would recognise that, while both matrixes indeed have immediate release and are both eventually in a dissolved state, the disintegrating matrix first swells and then disintegrates. Moreover disintegrating matrixes are well-known in the field of drug formulation. The skilled person would thus make a distinction between both types of matrixes.

6.3 According to the respondent, the claimed tablets have a good dissolution and immediate release profile as stated in paragraph 9 of the patent in suit and substantiated by the results provided in F20d (see F20d Figure 1 on page 21 and pages 10 and 22, according to the PDF page numbering). The Board observes that, as argued by the appellants, no improved dissolution or release profile has been shown compared to bilayer tablets as described in F26 differing from the present ones only in the above defined features (i)-(iii). The results disclosed in F20d are indeed based on a comparison with individual tablets containing each of the active agents separately. It follows that, for the purpose of formulating the objective technical problem to be solved, no improvement compared to the closest prior art can be taken into account. The Board considers however, in line with the decision of the opposition division (see page 16, line 10 from the bottom onwards), that the effects shown in F20d for the claimed tablets, namely good dissolution and immediate release profile, still constitute a property of the tablets which cannot be ignored. Furthermore the Board

considers that, thanks to the comparison with the individual tablets and in the absence of any evidence of the contrary, these results can reasonably be extrapolated to tablets containing a different thiazide diuretic, so that said property is considered to credibly occur over the entire claimed range.

In this context, the appellants argued that the results provided in F20d would not even substantiate the presence of an improvement compared to the individual tablets over the entire breadth of the present claims (no improvement for the 40 mg dose of telmisartan ,see page 35 table 8, according to the PDF page numbering; no improvement for male subjects, see Figure 1 on page 21, according to the PDF page numbering; no direct advantage in terms of medical treatment of an increased Cmax for telmisartan, see F20d, page 4, according to PDF numbering). The Board considers that the entire data provided in F20d do substantiate that the claimed bilayer tablets achieve at least as good dissolution and immediate release profile as the individual tablets each containing one of the active agents. As already mentioned above, any improvement compared to the individual tablets would anyway not be relevant when formulating the technical problem to be solved starting from the closest prior art.

6.4 Accordingly, starting from F26, the objective technical problem lies in the provision of further bilayer tablets containing telmisartan and HCTZ with good dissolution and immediate drug release for use in the treatment of hypertension.

6.5 The Board considers that this problem has been credibly solved for the reasons provided above (see 6.3).

6.6 F26 does not provide any indication of how each layer should be formulated, in particular not in order to achieve good dissolution and immediate release profile.

The appellants considered that the skilled person would have found in F24 (or F15) and F25, which disclose individual tablets containing telmisartan and HCTZ respectively, indications as to the formulation of each of the layers. In particular the appellants argued that, in so far as the distribution of excipients is concerned, the thiazide layer according to claim 1 of the main request is merely limited by the feature of a disintegrating matrix. The appellants then stated that F25 taught to formulate HCTZ with lactose, which was a disintegrant. Accordingly, it would have been straightforward to formulate the thiazide agent in a disintegrating matrix. Finally, amorphous telmisartan was already known from F17-F18 and it was common general knowledge that amorphous forms were advantageous in terms of bioavailability.

The Board cannot share this view. While F24 provides indeed indication of how to formulate a telmisartan layer with excipients as disclosed in F26, the Board observes, as indicated by the respondent, that the HCTZ formulation disclosed in F25 contains different excipients than those listed in F26 (in particular calcium phosphate, gelatin and talc are not disclosed in F26). The skilled person would thus not have found in F25 an example of formulation of an HCTZ layer which he could have indeed directly applied to the generally defined formulation of F26. The extra step of replacing lactose of F25 by another disintegrant listed in F26 appears to be based on hindsights. Alone for this reason, the skilled person would not have arrived to the subject-matter of claim 1 in an obvious manner on

the basis of the teaching of the documents considered by the appellant.

Furthermore none of the prior art documents provide any hint to a formulation which would aim at providing good dissolution and immediate release of the active ingredients, let alone such a formulation comprising a dissolving matrix containing telmisartan at 90% amorphous, a basic agent and a water-soluble diluent, and a disintegrating matrix containing a thiazide diuretic. The combination of all the distinguishing features cannot thus be considered as a juxtaposition of mere arbitrary choices, as argued by the appellants. While, starting from F26, the skilled person could possibly have prepared a bilayer tablet according to the present claim 1, there is no indication in the prior art which would have prompted it to do so in order to obtain good dissolution and immediate release.

6.7 Accordingly the subject-matter of claim 1 of the main request involves an inventive step.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated