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Datasheet for the decision of 20 March 2025

Case Number: T 0226/23 - 3.3.07

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Language of the proceedings: EN

Title of invention:
MUCO-ADHESIVE, CONTROLLED RELEASE FORMULATIONS OF LEVODOPA AND/OR ESTERS OF LEVODOPA AND USES THEREOF

Patent Proprietor:
Impax Laboratories, LLC

Opponent:
Luigi, Rumi

Headword:
MUCO-ADHESIVE, CONTROLLED RELEASE FORMULATIONS OF LEVODOPA AND/OR ESTERS OF LEVODOPA AND USES THEREOF/Impax Laboratories, LLC

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA 2020 Art. 12(4), 12(6), 11

Keyword:

Admission of new documents (Yes)
All requests - Inventive step (No)
Remittal to the opposition division (No)

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Case Number: T 0226/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 March 2025

Appellant: (Opponent)	Luigi, Rumi Ter Meer Steinmeister & Partner Nymphenburger Strasse 4 80335 Munich (DE)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Respondent: (Patent Proprietor)	Impax Laboratories, LLC 30831 Huntwood Avenue Hayward, CA 94544 (US)
Representative:	Forresters IP LLP Skygarden Erika-Mann-Straße 11 80636 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 18 November 2022 concerning maintenance of the European Patent No. 3054929 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	Y. Podbielski

Summary of Facts and Submissions

I. The European Patent 3 054 929 B1 had been opposed under Article 100 (a) and (c) EPC on the grounds that its subject-matter lacked inventive step and extended beyond the content of the application as filed.

II. The appeal lies from the decision of the opposition division finding that the patent in amended form according to auxiliary request 12 met the requirements of the EPC. The decision was based on the claims as granted as the main request, on auxiliary requests 1-10 filed on 29 July 2022 and auxiliary requests 11 and 12 filed during the oral proceedings on 29 September 2022.

Claim 1 of auxiliary request 12 read:

"1. A controlled release oral solid formulation comprising
(a) a controlled release component comprising a core comprising levodopa and/or an ester of levodopa or salts thereof, wherein the core is free of a decarboxylase inhibitor and is coated with a layer of a muco-adhesive polymer comprising an amino methacrylate copolymer, and externally coated with a layer of an enteric coating polymer; and
(b) an immediate release component comprising levodopa and/or an ester of levodopa or salts thereof."

III. The documents cited during the opposition proceedings included the following:

D1: WO 2015/054302 Al (application as filed)
D2: US 61/887,762 (priority document)

D3: Prescribing information of Sinemet® CR, dated January/2011
D4: Prescribing information of Stalevo®, February, 2009
D5: US 2010/0298268 A1
D6: US 2006/0045865 A1
D7: US 2013/0195973 A1
D8: US 2007/0003621 A1
D9: Modi et al., "Single-Dose Pharmacokinetics and Pharmacodynamics of IPX203 in Patients With Advanced Parkinson Disease: A Comparison With Immediate-Release Carbidopa-Levodopa and With Extended-Release Carbidopa-Levodopa Capsules" Clin Neuropharm, Vol. 42, No. 1, pages 4-8, 2019
D10: Mittur et al., "Pharmacokinetics of Rytary(R), An Extended-Release Capsule Formulation of Carbidopa-Levodopa" Clin Pharmacokinet, Vol. 56, pages 999-1014, 2017
D11: Declaration of Richard D'Souza, signed 27 June 2022
D12: CV of Richard D'Souza

IV. According to the decision under appeal:
- Claim 4 of the main request did not meet the requirements of Article 123(2) EPC;
- Auxiliary requests 1-9 contravened Article 53(c) EPC and did not meet the requirements of Article 56 EPC over D5, in particular example 8; auxiliary requests 4, 6, and 9 did furthermore not meet the requirements of Article 123(2) EPC.
- Auxiliary request 10 did not meet the requirements of Article 53(c) and 123(2) EPC;
- Auxiliary request 11 was not admitted into the opposition proceedings;
- Auxiliary request 12 met the requirements of Articles 123(2) and 84 EPC. D5 was considered to be the closest prior art and the problem was the provision of an

alternative controlled release oral solid formulation comprising levodopa. The claimed solution was considered to be inventive.

V. The opponent (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 15 March 2023, the appellant submitted the following items of evidence:

D13: WO 2007/056570 A2
D14: US 2007/0275060 A1

VI. With its reply received on 31 July 2023, the patent proprietor (hereinafter the respondent) filed auxiliary request 12 which according to the opposition division met the requirements of the EPC, and auxiliary requests 13 to 18. The respondent requested that documents D13 and D14 not be admitted into the appeal proceedings.

Independent claim 1 of the auxiliary requests relevant for the present decision read as follows, the differences, unless otherwise indicated, relating to a comparison with claim 1 of auxiliary request 12.

Auxiliary request 13

The subject-matter of claim 1 of auxiliary request 13 was identical to claim 1 of auxiliary request 12.

Auxiliary requests 14 and 15

The subject-matter of claim 1 of auxiliary requests 14 and 15 was identical and has been amended as follows:

"...(b) an immediate release component comprising levodopa and/or an ester of levodopa or salts thereof **and a decarboxylase inhibitor**.".

Auxiliary request 16

Claim 1 of auxiliary request 16 had been amended as follows:

"...(a) a controlled release component comprising a core comprising levodopa and/or an ester of levodopa or salts thereof, wherein the core is free of a decarboxylase inhibitor and is coated with a layer of a muco-adhesive polymer comprising **poly(butyl methacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate) 1:2:1**, and externally coated with a layer of an enteric coating polymer; and...":

Auxiliary request 17

Claim 1 of auxiliary request 17 had been amended as follows:

"...(a) a controlled release component comprising a core comprising levodopa and/or an ester of levodopa or salts thereof, wherein the core is free of a decarboxylase inhibitor and is coated with a layer of a muco-adhesive polymer comprising **poly(butyl methacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate) 1:2:1**, and externally coated with a layer of an enteric coating polymer; and
(b) an immediate release component comprising levodopa and/or an ester of levodopa or salts thereof **and a decarboxylase inhibitor**.".

VII. A communication from the Board, dated 6 November 2024, was sent to the parties.

VIII. Oral proceedings took place on 20 March 2025. During the oral proceedings the respondent requested that the case be remitted to the opposition for further prosecution on the basis of of auxiliary requests 13 to 17 filed on 31 July 2023. The respondent withdrew furthermore auxiliary request 18.

IX. The arguments of the appellant may be summarised as follows:

Admittance of D13 and D14 into the appeal proceedings

The feature of a core which is free of a decarboxylase inhibitor introduced in claim 1 of auxiliary request 12, was not included in the claims as originally granted, but was taken from the description of the patent in suit during the opposition proceedings. Sets of claims having the aforementioned feature included in claim 1 were presented by the patentee as auxiliary requests 10 to 19 for the first time on the final date for making written submissions before the oral proceedings and were clearly not allowable under Article 53(c) EPC in view of claim 17.

The appellant was not in the position to foresee that the opposition division would finally acknowledge an inventive step of a controlled release oral solid formulation requiring the controlled release component to comprise a core which is free of a decarboxylase inhibitor over the originally filed prior art. Moreover, it was considered that the feature "which is free of a decarboxylase inhibitor" was known from

common general knowledge, a point that the opposition division did not acknowledge in its decision.

Auxiliary request 12 - Inventive step

Starting from document D5 as the closest prior art, the objective technical problem to be solved could merely be seen in the provision of an alternative controlled release oral solid formulation comprising levodopa. Neither example 5 of the patent, nor D9 could be considered in support of a technical effect, since no comparison was provided therein with the composition of example 8 of D5. The claimed solution was obvious in view of D6, D13 and D14.

Remittal to the opposition division

The auxiliary request 13-17 did not present any particular complexity; they furthermore did not comprise any feature that could be inventive.

Auxiliary request 13-17 - Inventive step

There were no further comments.

X. The arguments of the respondent may be summarised as follows:

Admittance of D13 and D14 into the appeal proceedings

Auxiliary request 12 comprising the feature of the core being free of decarboxylase had been filed two months before the oral proceedings, and the appellant had ample opportunity before the oral proceedings and during the oral proceedings to consider these amended claims and to present documents D13 and D14 but failed

to do so. The appellant had ample knowledge that the limitations of auxiliary requests 12-19 were proposed to be discussed under inventive step; the appellant could and should have reacted to the new auxiliary requests before the oral proceedings before the opposition division.

Moreover, D13 are D14 were not documents belonging to common general knowledge as argued by the appellant and were not relevant for this reason.

Auxiliary request 12 - Inventive step

The problem over D5 was the provision of an improved levodopa controlled release formulation.

The formulation in Example 5 was an example of an embodiment within the scope of the claims and the *in vivo* evaluation demonstrated the more extended effect compared to Sinemet® CR and Stalevo®, which showed comparably flat plasma profiles.

The declaration D11 discussed the various formulations disclosed in the patent, D5 and D9, and confirmed which formulations were disclosed in each document. In particular, the declaration confirmed that D5 disclosed the IPX066 formulation, which was commercially known as Rytary®.

There was no pointer in D5 to change the disclosed compositions. D5 and D6 could not be combined in the absence of any pointer, and multiple selections in D6 were needed to arrive at the claimed subject-matter. D13 and D14 could not be taken into account since they were specific disclosures and did not belong to the common general knowledge.

Remittal to the opposition division

The further auxiliary requests comprised additional features which were not discussed during the opposition proceedings. A first discussion during the appeal proceedings would violate the respondent's right to be heard before two instances.

Auxiliary request 13-17 - Inventive step

No inventive step arguments specific to the auxiliary requests were provided.

XI. Requests

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked. They also requested that D13 and D14 be admitted into the appeal proceedings.

The respondent (patent proprietor) requested that the appeal be dismissed and the patent thus be maintained on the basis of auxiliary request 12 which was held by the opposition division to comply with the requirements of the Convention ("main request"). As an auxiliary measure the respondent requested, in the event that the decision under appeal was set aside, that the patent be maintained on the basis of one of auxiliary requests 13 to 17 filed on 31 July 2023.

During oral proceedings, the respondent requested that the case be remitted to the opposition for further prosecution on the basis of of auxiliary requests 13 to 17 filed on 31 July 2023.

The respondent also requested that documents D13 and D14 not be admitted into the appeal proceedings.

Reasons for the Decision

1. Admittance of D13 and D14 into the appeal proceedings

1.1 D13 and D14 were filed by the appellant with its statement of grounds of appeal and are cited in the assessment of inventive step in combination with the closest state of the art D5 or D7.

D13 discloses compositions comprising a controlled release component of levodopa **free of carbidopa** and a immediate release component of levodopa and carbidopa (see example 3).

D14 discloses oral dosage forms providing an extended release of levodopa and carbidopa, in particular in the form of a tablet with a delayed release core comprising levodopa **free of carbidopa** coated with an enteric polymer and an external immediate release component comprising levodopa and carbidopa (see for instance example 2).

1.2 The submission of documents D13 and D14 in the appeal proceedings constitutes an amendment of the case of the appellant. The admittance of such an amendment is left to the discretion of the Board. The Board exercises its discretion by taking into account in particular the complexity and relevance of the amendment as well as the principle of procedural economy (Article 12(4) RPBA).

Moreover, the Board shall not admit evidence which should have been submitted in the proceedings leading to the decision under appeal (Article 12(6) RPBA).

1.2.1 The Board notes that the opposition division gave a negative preliminary opinion in particular with regard to inventive step (cf. communication of 16 December 2021).

In response to the preliminary opinion of the opposition division, the respondent filed auxiliary requests 1-19 with its letter of 29 July 2022 which was the last day for the written submissions before the oral proceedings. Auxiliary requests 10 to 19 were in particular based on the main request with a new limiting feature that in the controlled release component (a) the core is **"free of a decarboxylase inhibitor"**. Said feature "wherein the core is free of a decarboxylase inhibitor" originated from the description (see page 5, lines 1-6, or page 5, line 30-page 6, line 2 of the application), where it was the preferred option, even if the possible presence of a decarboxylase inhibitor within the core is explicitly also envisaged (see the same passages).

In its decision, the opposition division reversed its preliminary opinion on inventive step with regard to auxiliary request 12, which was the first request assessed for inventive step including the new feature **"free of a decarboxylase inhibitor"**. The opposition division considered that the skilled person had no incentive to remove the decarboxylase inhibitor in example 8 of D5 to prepare an alternative composition. The opposition division did not follow the appellant's argument that it was common general knowledge that carbidopa was not always needed. In its decision on

inventive step of auxiliary request 12, the opposition division's main argument was that the appellant did not submit any document showing levodopa formulations without carbidopa or suggesting that it was possible to have part of the composition without carbidopa (see point 34.6 of the decision).

1.2.2 In the Board's view, the submission of D13 and D14 is a direct response to the decision of the opposition division with regard to the obviousness of the claimed solution, since the absence of any document showing controlled release components without any decarboxylase inhibitor, in particular levodopa, was mentioned for the first time at a very late stage of the opposition proceedings, and was furthermore an essential point in the decision (see point 34.6 of the decision).

In view of the file history, it appears furthermore clear that there was no reason to file D13 or D14 earlier. The restriction to the option originating from the description, i.e."wherein the core is free of a decarboxylase inhibitor" was done at the last possible day for filing submissions before the oral proceedings and, given the large number of auxiliary requests, the appellant had little time to react to this restriction. Inventive step of a claim including the feature of a core free of a decarboxylase inhibitor was furthermore never discussed in the written proceedings, and this issue was first addressed during the oral proceedings.

Moreover, the disclosure of D13 and D14 relates to the same technical field as the contested patent and as D5 or D7; their combination with the known closest prior art documents D5 or D7 does not present any complexity. They also tend to confirm the argument of the appellant that dosage forms comprising a controlled release

component without levodopa were commonly known and their teaching appears to be relevant for the decision for this reason.

1.3 Consequently D13 and D14 are admitted into the appeal proceedings (Article 12(4) and 12(6) RPBA).

2. Main request - Inventive step

2.1 The claimed invention relates to a controlled release oral solid composition for treating neurological diseases associated with reduced or impaired dopamine levels.

2.2 D5 was considered to represent the closest prior art by the opposition division in its decision, in particular example 8 of D5. During the opposition proceedings, D7 was also considered as possible closest prior art, since it has a very similar disclosure to that of D5 but it was agreed by the parties to use D5 as closest state of the art.

Document D5 discloses a multiparticulate, controlled release solid oral dosage form intending to provide steadier plasma concentrations of levodopa over a prolonged period of time (see paragraph [0008]) and comprising:
i) a controlled release component comprising a mixture of levodopa, a decarboxylase inhibitor and a rate controlling excipient;
ii) a carboxylic acid component, and
iii) an immediate release component comprising a mixture of levodopa and a decarboxylase inhibitor (see paragraph [0009]).

Example 8 of D5 discloses a capsule formulation comprising "ultra fast release" beads comprising levodopa and carbidopa (component I), "fast release" beads comprising carbidopa and levodopa enterically coated with Eudragit® L100 and S100 (component II), "slow release" beads which comprise levodopa and carbidopa enterically coated with Eudragit® L100 and S100 (components III), and finally "slow release beads" comprising enterically coated tartaric acid (component IV) (see Tables 26 and 27).

D5 does in particular not disclose a controlled release component with levodopa and/or an ester of levodopa or salts thereof **free of a decarboxylase inhibitor** and **coated with a layer of a muco-adhesive polymer comprising an amino methacrylate copolymer**.

2.3 The opposition division defined the problem over D5 as the provision of an alternative controlled release oral solid formulation comprising levodopa. The appellant provided the same problem in its statement of grounds of appeal.

The respondent is of the opinion that the technical problem should be the provision of an improved levodopa controlled release formulation.

2.4 The respondent relies on the technical effect shown by the claimed formulation as a whole over the closest prior art and over prior art commercial formulations in support of a technical effect. In this regard, example 5 of the patent, D9 and D11 were cited by the respondent.

2.4.1 Example 5 of the patent discloses compositions IPX203-C0023, IPX203-C0024 and IPX203-C0025 comprising an

immediate release component I comprising levodopa and carbidopa, combined with a controlled release component II which is a controlled release core comprising levodopa coated respectively with a muco- adhesive layer comprising Eudragit® E100 and a further enteric layer comprising Eudragit® L100 (prototype I in IPX203-C0023) or comprising a further rate-controlling CA-copovidone layer in addition to the muco-adhesive and enteric layers (prototype II and III in IPX203-C0024 and IPX203-C0025). Test formulation IPX203-C0026 comprises a further controlled release core with entacapone (see the specification, par. [0112] and Tables 10-13).

Example 5 of the patent provides also the *in vivo* release profiles of the formulations IPX203-C0023, -C0024, -C0025 and -C0026, as well an *in vivo* evaluation and a comparison of the formulations IPX203-C0023, -C0024, -C0025 and -C0026 with the reference products Stalevo® and Sinemet®.

The comparisons made in example 5 of the patent, i.e. between formulations IPX203-C0023, -C0024, -C0025, -C0026 and the commercial products Sinemet CR and Stalevo®, are however not suitable to demonstrate any technical effect of the distinguishing features, in particular linked with the presence of a muco-adhesive layer, as the commercial products Sinemet® CR and Stalevo® differ from the claimed formulation and from the formulation of D5 in many more aspects than just the muco-adhesive polymer layer; Sinemet® CR is indeed a sustained release tablet comprising carbidopa, levodopa, hydroxypropyl cellulose, magnesium stearate and hypromellose as disclosed in D3 (see pages 1-2, "Description"), while Stalevo® is a tablet formulation of carbidopa-levodopa combined with entacapone, which

does not seem to provide sustained release, as disclosed in D4 (see pages 1-2, "Description").

Example 5 does neither provide any direct comparison with a formulation corresponding to the disclosure of example 8 of D5, namely with a decarboxylase inhibitor in the core of the controlled release component and without being coated with a layer of a muco-adhesive polymer comprising an amino methacrylate copolymer.

Accordingly, example 5 does not provide any evidence of a technical effect linked to the distinguishing features. It is in particular not shown that the claimed muco-adhesive polymer layer indeed facilitates adhesion to the intestinal mucosa and delays the release, in view of the absence of a concrete comparison to a formulation which does not comprise such a muco-adhesive polymer layer, as e.g. disclosed in example 8 of D5. The opposition division came to the same conclusion in its decision (cf. points 18.5 and 34.3 of the decision).

2.4.2 D9 is a study comparing the pharmacokinetics and pharmacodynamics of two extended-release formulations of carbidopa-levodopa, namely IPX203 and Rytary®. The authors of this study conclude that, compared to Rytary®, IPX203 had a longer effect (see D9: e.g. the abstract). The respective compositions of IPX203 and Rytary® are not given in D9, which simply mentions that IPX203 is a new investigational extended release formulation of carbidopa-levodopa without further indication.

The expert declaration D11 confirms that the IPX203 formulation in D9 contains a controlled release part having a core containing levodopa, coated with a

mucoadhesive amino methacrylate, then coated with a layer of enteric coating polymer, as was shown in the examples of the patent, in particular Example 5. In the declaration it is further explained that the product sold as Rytary® corresponds to the IPX066 formulation disclosed in example 8 of D5 (see D11: paragraphs 4-6). D11 confirms also that the main differences between the IPX203 formulation and the IPX066 formulation is the absence of a decarboxylase inhibitor in the core of the controlled release component and the presence of a muco-adhesive layer in said controlled release component.

The Board has however the same concern as the opposition division with regard to the comparison provided in D9. Even if it is acknowledged that the compositions IPX203 provide an effect over the compositions IPX066 (Rytary®) corresponding to the formulation of example 8 of D5, there are however at the same time uncertainties with regard to the exact composition of the formulation IPX203 used in D9 and whether the observed effect has its origin in one of the distinguishing features of the claimed invention, compared to the closest prior art D5.

The Board notes indeed that the formulations IPX203 disclosed in example 5 of the patent comprise **four different options**, namely IPX203-C0023, IPX203-C0024, IPX203-C0025 and IPX203-C0026, all differing in the nature and amounts of coatings as shown in Table 11 for the prototypes I-III. However, **declaration D11 does not specify which one of these formulations would correspond to IPX203 as shown in D9.**

Importantly, the formulations IPX203-C0024 and IPX203-C0025 comprise furthermore a rate-controlling membrane

of cellulose acetate-copovidone which has necessarily an impact on the release of the active agents and which is not claimed in claim 1 of auxiliary request 12. It cannot be excluded that the effect on the pharmacokinetics and pharmacodynamics observed in D9 is principally linked to the presence of the rate-controlling membrane. Moreover, the nature and amounts of enteric coating are different in the compositions of example 8 of D5 and in example 5 of the patent, while it would have been necessary to make a comparison based exclusively on the distinguishing features.

It is therefore impossible to draw a conclusion as to the existence of a technical effect linked with the distinguishing features on the basis of the experiments of D9.

2.4.3 In the absence of any experimental evidence or plausible technical argumentation, it is not possible to conclude that the claimed subject-matter relates to an improved levodopa controlled release formulation and the problem is as defined by the opposition division in its decision, namely the provision of an alternative controlled release oral solid formulation comprising levodopa.

2.4.4 The respondent argued that the technical effect should be assessed in relation to the formulation as a whole, rather than focusing only or mainly on the muco-adhesive polymer layer. According to the respondent, this led the opposition division to incorrectly conclude that the objective technical problem was the provision of an alternative rather than improved levodopa controlled release formulation.

In the Board's view, any alleged advantage or technical effect must be supported by sufficient evidence over the closest prior art, whether said advantage or effect is provided by one feature or by a combination of features. In the present case, although it can be acknowledged that the examples of the patent and the data in D9 demonstrate that the claimed formulations achieve controlled release of levodopa, there is no evidence that any of the distinguishing features, individually or in combination, result in an unexpectedly prolonged effect compared to the formulation disclosed in document D5.

Moreover, there is no teaching in the application as filed or any credible technical argument on file that the combination of features provides an unexpected or synergistic effect. It is in particular not possible to associate the absence of a decarboxylase inhibitor, which was originally one option out of two in the granted patent, to any particular effect, in the absence of any teaching or plausible technical argumentation with this regard in the contested patent.

2.4.5 In view of the information found in the examples of the contested patent the Board is convinced that the problem of providing an alternative controlled release oral solid formulation comprising levodopa has been plausibly solved.

2.5 It remains to determine whether the claimed solution, i.e the provision of a formulation free of a decarboxylase inhibitor and coated with a layer of a muco-adhesive polymer comprising an amino methacrylate copolymer is obvious. With regard to obviousness, documents D6, D13 and D14 were cited.

2.5.1 D13 and D14 belong to the same technical field as the contested patent, and disclose several examples of solid formulations in which the core comprises levodopa and is free of a decarboxylase inhibitor, with a further enteric coating and and external immediate release mantle or coating layer of levodopa/carbidopa (see for instance example 3 of D13 or D14).

D14 furthermore guides the skilled person to the use of a controlled release component in which the core comprises preferably only levodopa (see par. [0106]).

D13 and D14 show therefore that a core comprising levodopa without decarboxylase inhibitor was a known alternative or option.

2.5.2 D6 relates to enteric-coated, bioadhesive drug delivery systems for the administration of *inter alia* levodopa (see par. [0042]). Enteric-coated, bioadhesive tablets or multiparticulates may be formulated wherein the enteric coating is "triggered" to dissipate, revealing the underlying bioadhesive coating (see D6, par. [0068]-[0070], [0076], [0082]). The bioadhesive element improves the gastrointestinal retention via adherence of the formulation to the walls of the gastrointestinal tract. In this context, D6 teaches the use of bioadhesive polymers, wherein the Spheromer® polymers are preferred, but also alternative bioadhesive polymers such as Eudragit® E100 in formulations comprising for instance levodopa (see par. [0086] and claim 1).

Figure 1B shows a solid oral dosage form comprising a multiparticulate formulation (31), containing drug(s), excipients, a bioadhesive polymer composition, and optionally permeation and or dissolution enhancers,

composed in a single hard gelatin or cellulose-based capsule (30), or monolithic matrix. The particulates are optionally coated with one or more layers of release rate controlling polymers or enteric polymers (32), as disclosed in paragraph [0141].

Example 7 of D6 discloses a specific composition with levodopa/carbidopa with one or more bioadhesive coating layer(s) (see par. [0205]-[0213]). The results show that the controlled release bioadhesive formulations had better bioavailability parameters compared to the control Sinemet® (see Figures 7A-7D).

Accordingly, the use of a bioadhesive coating for the preparation of controlled release components is known, as well as its combination with an enteric layer. This particular coating or combination of coatings is furthermore known for dosage forms comprising levodopa.

2.5.3 Accordingly, the skilled person looking for an alternative to the dosage form disclosed in D5 would have modified the teaching in the closest prior art document in the light of the teaching known from D6, D13 and/or D14 to arrive at the claimed invention. The claimed subject-matter is therefore not inventive over D5 combined with D6 and D13/D14.

Considering that the problem to be solved has been defined as the provision of an alternative, the alleged lack of a pointer to the particular arrangement of coating layers of claim 1, as argued by the respondent, cannot affect this conclusion. It is established case law that the simple act of arbitrarily choosing known technical alternatives is devoid of any inventive character.

3. Remittal to the opposition division

3.1 The respondent requested that the case be remitted to the opposition division for consideration of the auxiliary requests.

3.2 The Board, using its discretion under Article 111(1) EPC, decides not to remit the case to the opposition division for further prosecution.

The primary object of appeal proceedings is the review of the decision under appeal in a judicial manner. This is reflected in the wording of Article 12(2) RPBA. However, according to established case law, parties have "no absolute right to have each and every matter examined at two instances" (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2020, V.A.9.2.1 and 9.6.1). Article 111(1), second sentence, EPC, leaves it to the Board's discretion to decide on an appeal either by exercising any power conferred on the department of first instance or by remitting the case to that department. Further considerations for exercising its discretion under Article 111(1) EPC not to remit the case for further prosecution are reasons of procedural economy.

Moreover, Article 11 RPBA provides that "the Board shall not remit the case to the department whose decision was appealed unless special reasons present themselves for doing so." The Board holds that such special reasons are not apparent in the present case for the following reasons.

In deciding not to remit the present case, the Board has taken into account that the legal and factual framework established by the decision under appeal, in

which the opposition division held that the subject-matter of auxiliary requests 1-9 and 11 lacked inventive step over the closest prior art D5 in combination with D6, would not significantly be altered by dealing with inventive step of claim 1 of auxiliary requests 13-17. The facts and arguments for the assessment of inventive step of auxiliary requests 13-17 are furthermore also essentially the same as for the assessment of inventive step of auxiliary request 12 in the present decision. In other words, there is no new situation or fresh case.

Moreover, in view of the facts and arguments on file, the effort for the Board and the parties, needed to deal with the topic of inventive step, does clearly not amount to an undue burden. Remitting the case to the opposition division would go against procedural economy.

Under these circumstances, the Board considers it inappropriate to allow the appellant's request for remittal of the case to the examining division (Article 111(1) EPC and 11 RPBA).

4. Auxiliary requests - Inventive step

4.1 None of auxiliary request 13-17 meet the requirements of Article 56 EPC for the following reasons.

4.2 Claim 1 of auxiliary request 13 is identical to claim 1 of the main request, so that the subject-matter of claim 1 of auxiliary request 13 is not inventive for the same reasons as for the main request.

4.3 With regard to claim 1 of auxiliary requests 14 and 15, feature (b) was amended as follows: "...(b) an

immediate release component comprising levodopa and/or an ester of levodopa or salts thereof **and a decarboxylase inhibitor.**".

This additional feature in claim 1 is also present in D5, so that no further distinguishing features is present. Said amendment can therefore not be the basis for acknowledging an inventive step.

4.4 Claim 1 of auxiliary request 16 specifies the type of muco-adhesive polymer, namely "a layer of a muco-adhesive polymer comprising **poly(butyl methacrylate-co-(2-dimethylaminoethyl)methacrylate-co-methyl methacrylate) 1:2:1".**

This additional feature is also disclosed in D6, i.e the alternative bioadhesive polymer Eudragit® E100 (see paragraph [0086] of D6 and paragraph [0030] of the patent). Accordingly, the selection of this specific muco-adhesive polymer does not result in any inventive contributuion over the prior art. The subject-matter of claim 1 of auxiliary request 16 does therefore also not involve an inventive step.

4.5 Claim 1 of auxiliary request 17 has been amended by combining the same features introduced in claim 1 of auxiliary requests 14 and 16, namely by the specification of the presence of a decarboxylase inhibitor in component (b) and the specification of the type of muco-adhesive polymer in feature (a).

The additional features in claim 1 merely combine obvious amendments made in previous auxiliary requests. In the absence of any specific argument explaining the relevance of this combination of features the amendments introduced in this request cannot be the

basis for acknowledging an inventive step. Accordingly, the subject-matter of claim 1 of auxiliary request 17 does not involve an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated