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**Datasheet for the decision
of 12 June 2019**

Case Number: T 1704/14 - 3.3.01

Application Number: 08837108.3

Publication Number: 2203068

IPC: A61K31/4439, A61K9/58, A61P1/04

Language of the proceedings: EN

Title of invention:
METHODS OF TREATING GASTROINTESTINAL DISORDERS INDEPENDENT OF
THE INTAKE OF FOOD

Applicant:
Takeda Pharmaceuticals U.S.A., Inc.

Headword:
Dexlansoprazole/TAKEDA

Relevant legal provisions:
EPC Art. 54

Keyword:
Novelty - (no)



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Case Number: T 1704/14 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 12 June 2019

Appellant: Takeda Pharmaceuticals U.S.A., Inc.
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Deerfield, IL 60015 (US)

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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 10 March 2014
refusing European patent application No.
08837108.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairwoman M. Pregetter
Members: J. Molina de Alba
M. Blasi

Summary of Facts and Submissions

I. The present appeal lies from the decision of the examining division refusing European patent application No. 08 837 108.3. The decision was based on the set of 13 claims filed by the applicant on 13 January 2014.

Claim 1 reads as follows (emphasis in the original):

"1. A pharmaceutical composition for use in a method of treating a gastrointestinal disorder in a patient in need of treatment thereof by administering to said patient said pharmaceutical composition independently of the intake or consumption of food or meal;

wherein said pharmaceutical composition comprises a therapeutically effective amount of a dosage form comprising:

(a) a first solid particle, wherein said first solid particle comprises dexlansoprazole and a first enteric coating, wherein the first enteric coating releases the dexlansoprazole from the solid particle at a pH of about 5.0 to about 5.5; and

(b) a second solid particle, wherein said second solid particle comprises dexlansoprazole and a second enteric coating, wherein the second enteric coating releases the dexlansoprazole from the solid particle at a pH of about 6.2 to about 6.8;

and

wherein the first solid particle is present in the pharmaceutical composition in an amount of from about

15% to about 50% by weight of the pharmaceutical composition and the second solid particle is present in the pharmaceutical composition in an amount of from about 50% to about 85% by weight of the pharmaceutical composition; and

wherein the gastrointestinal condition is heartburn, inflammatory bowel disease, Crohn's disease, irritable bowel syndrome, ulcerative colitis, a peptic ulcer, a stress ulcer, a bleeding peptic ulcer, a duodenal ulcer, infectious enteritis, colitis, diverticulitis, gastric hyperacidity, dyspepsia, gastroparesis, Zollinger-Ellison syndrome, gastroesophageal reflux disease, Helicobacter pylori associated disease, short-bowel syndrome, hypersecretory states associated with systemic mastocytosis or basophilic leukemia or hyperhistaminemia or combinations of any of the above disorders."

II. The following documents, cited in the examination proceedings, are referred to in the present decision:

D1: US 2006/0013868
D4: C. Scarpignato et al., Dig. Dis., 2006, 24, 11-46
D6: P.O. Katz et al., Aliment. Pharmacol. Ther.,
2006, 23 (Suppl. 2), 9-22
D9: US 2006/0257467
D11: R.D. Lee et al., Am. J. Gastroenterol., 2007, 102
(Suppl. 2), S145, Abstract No. 78

III. In the decision under appeal, the examining division found, *inter alia*, that the subject-matter of claim 1 was not novel. In particular, the examining division considered that the feature in claim 1 "*independently of the intake or consumption of food or meal*" did not allow the skilled person to distinguish the claimed

subject-matter from the content of document D1. Firstly, D1 did not disclose the administration of dexlansoprazole in connection with food intake; even if, according to documents D4, D6 and D9, proton pump inhibitors were preferably administered some time before a meal, they could also be administered independently of the intake of food, as confirmed by document D11. Secondly, the mentioned feature in claim 1 encompassed the administration of dexlansoprazole at any time, including before a meal.

- IV. The applicant (appellant) filed an appeal against the decision of the examining division. With the statement of grounds of appeal, the appellant requested that the appealed decision be set aside and a patent be granted on the basis of the claims filed on 13 January 2014, which are the claims on which the decision was based. A copy of the claims was also annexed to the statement of grounds of appeal.
- V. In a communication sent as an annex to the summons to oral proceedings, the board gave its preliminary opinion that, *inter alia*, the subject-matter of claim 1 was not novel over the content of document D1.
- VI. With a letter dated 15 May 2019, the appellant withdrew its request for oral proceedings and requested a decision based on the state of the file.
- VII. Oral proceedings were held on 12 June 2019 in the absence of the appellant.
- VIII. The appellant's arguments, where relevant to the present decision, may be summarised as follows:

The feature in claim 1 "*independent of the intake or consumption of food or meal*" excludes the teaching of document D1, which implicitly discloses an administration of dexlansoprazole dependent on food intake. This implicit disclosure derives from the general knowledge at the effective date of the application that proton pump inhibitors had to be administered in connection with food intake. This knowledge was reflected in documents D4, D6 and D9 and also corresponded with the timing of administration prescribed by doctors. As document D1 does not contain any clinical tests deviating from the then established practice, the skilled person would have assumed that the administration times applicable to the formulations in D1 were dependent on the intake of food.

In addition, the uncoupling of the time of administration and the food intake reflects a new clinical situation which renders the claimed subject-matter novel.

- IX. The appellant's main and sole request is that the appealed decision be set aside and a patent be granted on the basis of the claims filed on 13 January 2014.

Reasons for the Decision

1. The appeal is admissible.
2. The appellant withdrew its request for oral proceedings and requested a decision according to the state of the file. The board nevertheless decided not to cancel the oral proceedings and decided instead to abide by the

scheduled date in order to come to a decision and conclude the case.

The oral proceedings before the board took place in the absence of the duly summoned appellant pursuant to Rule 115(2) EPC. In accordance with Article 15(3) RPBA, the appellant was treated as relying on its written case.

3. Novelty of the subject-matter of claim 1

- 3.1 The appellant has not disputed the examining division's finding in the appealed decision (see point 2.1 thereof) that document D1, which is a US patent application filed by the appellant, illustrates dexlansoprazole formulations that are identical to those defined in claim 1.

The board agrees with this finding:

As correctly noted by the examining division, claim 41 of document D1 discloses a capsule comprising a combination of two types of tablets, granules or fine granules, each of which comprises a core particle coated with a pH-dependent controlled-release layer. In one case, the coating is soluble in the pH range of 6.0 to 7.5 (preferably 6.5 to 7.0, see claim 47), while in the other case it is soluble in the pH range of 5.0 to 6.0 (preferably 5.5, see paragraph [0065]). The core particle is preferably the R-isomer of lansoprazole, i.e. dexlansoprazole (see claim 44).

Such capsules, containing an admixture of two types of enteric coated dexlansoprazole particles, are illustrated in examples 5, 6, 11, 12, 15-18, 21, 22, 24, 25, 32-36, 39-43, 47-50, 57-59, 61-65, 67 and 72.

The board notes that not all of those examples clearly fulfill the weight conditions defined in present claim 1; nevertheless, most of them do. This is particularly the case for examples 21, 22, 32-36, 39-43, 47-50, 57-59, 61-65, 67 and 72.

In addition, as also correctly set out by the examining division, document D1 discloses:

- the use of the formulations for the treatment of gastrointestinal disorders as listed in present claim 1 (see paragraph [367]);
- a dosage regime of once, twice or three times a day (see paragraph [0373]), and
- a sustained release of the active ingredient which provides a therapeutic effect for at least 6 hours, preferably 16 hours (see paragraph [0092]).

3.2 The point of dispute between the appellant and the examining division was whether or not the feature in claim 1 "*independent of the intake or consumption of food or meal*" is suitable to render the claimed subject-matter novel over the disclosure of D1.

In this respect, the board observes that document D1 provides only limited information on aspects related to the time of administration of the proton pump inhibitor formulations; it only indicates the dosage regime (once, twice or three times a day) and the duration of the therapeutic effect (at least 6 hours, preferably 16 hours). Thus, considering that D1 is silent on any specific timing of administration and, in particular, on any link with the intake of food, it cannot be inferred from it that the formulations should be administered in co-ordination with the intake of food.

Rather the opposite: the given information on the dosage regime and the duration of the therapeutic effect point towards an administration at regularly scheduled intervals throughout the day (around the clock), i.e. independently of the intake or consumption of food or meal. Hence, contrary to the appellant's opinion, the feature in claim 1 that the pharmaceutical composition is administered "*independently of the intake or consumption of food or meal*" does not render the claimed subject-matter novel over the disclosure of document D1.

- 3.3 In this connection, the appellant submitted that the link between the administration of dexlansoprazole and the food intake was implicit in D1 because it was general knowledge that proton pump inhibitors had to be administered at times dependent on the intake of food. This was supported by the teaching of documents D4, D6 and D9.

The board disagrees. Documents D4 and D6 are review articles that teach the convenience of administering proton pump inhibitors some time before a meal in order to maximise their effect (see D4, page 13, right column, last paragraph and page 14, left column, paragraphs 1-2; and D6, page 10, right column, paragraph 2). This teaching is confirmed in the patent application D9 (see paragraphs [0005] and [0006]). However, none of the documents D4, D6 or D9 states, or even suggests, that a timing of administration linked to food intake is indispensable to the proton pump inhibitor achieving its effect. Therefore, these documents fail to prove that the general knowledge at the effective date of the application in suit was that the administration of proton pump inhibitors some time before a meal was compulsory. Already for this reason,

the board cannot accept that this condition was implicit in D1.

This view is reinforced by the fact that, contrary to document D1, documents D4, D6 and D9 do not deal with formulations providing a controlled release of proton pump inhibitors; the pharmacokinetics in document D1 and its impact on the time administration schedule are fundamentally different from those in documents D4, D6 and D9. In that respect, the teaching of document D11, which is specifically directed to the formulation of a proton pump inhibitor that provides prolonged plasma concentrations with one daily oral dose, appears to be more relevant. Thus, having regard to the conclusion in D11 that the sustained-release formulation of the proton pump inhibitor can be administered without regard to food intake, there is no reason to read in document D1 an implicit link between the administration of dexlansoprazole and the intake of food.

In this context, the appellant's argument that document D1 does not contain any clinical tests showing an administration timing independent from food intake does not change the situation.

- 3.4 An additional argument of the appellant was that the uncoupling of the time of administration and food intake in claim 1 reflected a new clinical situation.

Following the conclusion above that the feature "*independent of the intake or consumption of food or meal*" does not render the claimed subject-matter novel, the feature cannot reflect any new clinical situation either.

3.5 Consequently, the subject-matter of claim 1 is not novel (Article 54 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



M. Schalow

M. Pregetter

Decision electronically authenticated