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Datasheet for the decision of 28 October 2021

Case Number: T 0099/20 - 3.3.04

Application Number: 10178590.5

Publication Number: 2278002

IPC: A61K38/54

Language of the proceedings: EN

Title of invention:
Pancreatin with reduced viral content

Patent Proprietor:
Abbott Laboratories GmbH

Opponent:
Nordmark Pharma GmbH

Headword:
Pancreatin/ABBOTT

Relevant legal provisions:
EPC Art. 54(2)

Keyword:
Novelty - (no)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0099/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 28 October 2021

Appellant: (Patent Proprietor)	Abbott Laboratories GmbH Freundallee 9A 30173 Hannover (DE)
Representative:	Miller, David James Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Respondent: (Opponent)	Nordmark Pharma GmbH Pinnauallee 4 25436 Uetersen (DE)
Representative:	RGTH Patentanwälte PartGmbB Neuer Wall 10 20354 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 October 2019 revoking European patent No. 2278002 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	G. Alt
Members:	B. Rutz
	L. Bühler

Summary of Facts and Submissions

I. An appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division to revoke European patent No. 2 278 002 ("the patent") entitled "*Pancreatin with reduced viral content*".

II. The patent was opposed on the grounds of Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and of Article 100(b) EPC, in relation to disclosure of the invention.

III. In its decision, the opposition division held, *inter alia*, that the subject-matter of claim 1 of the main request (as amended) lacked novelty over the disclosure of documents D2/D9, D6, D18, D20, D26 and D28a (Article 54 EPC).

With regard to auxiliary requests 1 to 23, the opposition division held that the subject-matter of claim 1 thereof lacked novelty for the same reasons as the main request.

Moreover, auxiliary requests 4 to 7 and 16 to 19 did not meet the requirements of Article 123(2) EPC.

Furthermore, auxiliary requests 12 to 23 did not meet the requirements of Articles 84 EPC or 123(3) EPC.

IV. With the statement of grounds of appeal, the appellant filed sets of claims of a main request and of auxiliary requests 1 to 7 (which are identical to the main request and auxiliary requests 1 to 3 and 8 to 11,

respectively, that were considered in the decision under appeal).

V. The opponent (respondent) replied to the statement of grounds of appeal.

VI. The board summoned the parties to oral proceedings by video-conference, as requested by both parties, and informed them of its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

VII. Oral proceedings were held by video-conference.

At the end of the oral proceedings, the Chair announced the board's decision.

VIII. Claim 1 of the main request reads:

"1. A pharmaceutical composition comprising a pharmacologically effective quantity of a pancreatin and one or more pharmaceutically acceptable excipients, wherein the pancreatin is decreased in viral contaminants, and is obtainable by a process comprising the steps of
(a) pre-heating a dispersed form of pancreatin containing one or more solvents to a temperature of from 85 °C to 100 °C, and
(b) continuing heating of the dispersed form of pancreatin at a temperature of from 85 °C to 100 °C for a period of from 18 hours to 30 hours, and obtaining a total solvents content in the dispersed form of pancreatin of equal to or less than 3.5% by weight at any point during process step (b),
wherein the dispersed form of pancreatin is selected from powders, pellets, micropellets, microspheres, granules and granulates,

wherein the titer level of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less, than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating, and
wherein the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating."

Claim 1 of auxiliary request 1 reads as follows (difference over the main request is underlined):

"1. ... viral contaminant present in the dispersed pancreatin after heating is at least 10000 times less,... "

Claim 1 of auxiliary request 2 reads as follows (differences over the main request are underlined):

"1. ...
(a) ... from 85 °C to 95 °C ...
(b) ... from 85 °C to 95 °C ..."

Claim 1 of auxiliary request 3 reads as follows (differences over the main request are underlined):

"1. ...
(a) ... from 85 °C to 95 °C ...
(b) ... from 85 °C to 95 °C ...
... viral contaminant present in the dispersed pancreatin after heating is at least 10000 times less,..."

Claim 1 of auxiliary request 4 reads as follows (differences over the main request are underlined):

"1. A pharmaceutical composition comprising a pharmacologically effective quantity of a pancreatin and one or more pharmaceutically acceptable excipients, wherein the pancreatin is decreased in viral contaminants, and is obtainable by a process comprising the steps of
(a) pre-heating a dispersed form of pancreatin containing one or more solvents to a temperature of from 85 °C to 95 °C, wherein the solvents content at the end of step (a) is from 0.1% to 1.6% by weight, and
(b) continuing heating of the dispersed form of pancreatin at a temperature of from 85 °C to 95 °C for a period of from 18 hours to 30 hours, and obtaining a total solvents content in the dispersed form of pancreatin of equal to or less than 1.6% by weight at any point during process step (b),
wherein the dispersed form of pancreatin is selected from powders, pellets, micropellets, microspheres, granules and granulates,
wherein the titer level of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less, than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating, and
wherein the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating."

Claim 1 of auxiliary request 5 reads as follows (difference over auxiliary request 4 is underlined):

"1. ... viral contaminant present in the dispersed pancreatin after heating is at least 10000 times less,... "

Claim 1 of auxiliary request 6 reads as follows (difference over auxiliary request 4 is underlined):

"1. ... for a period of from 18 hours to 24 hours ..."

Claim 1 of auxiliary request 7 reads as follows (differences over auxiliary request 4 are underlined):

"1. ... for a period of from 18 hours to 24 hours ... ... viral contaminant present in the dispersed pancreatin after heating is at least 10000 times less,..."

IX. The following documents are cited in the present decision:

D2 JP 49-36886 A

D9 English translation of document D2

D24 European Medicines Agency (EMEA): CHMP/BWP report to the CMDh on pancreatin-containing products

X. The appellant's arguments are summarised as follows.

Main request - claim 1
Claim construction and novelty (Article 54 EPC)

The claim recited process steps that reduced viral activity, i.e. a sterilisation procedure. Although the process features as such were not to be considered when assessing novelty, the properties conferred by these process features did have to be taken into account when assessing novelty. As explained and exemplified in the patent, the process steps sterilised the product,

thereby reducing the concentration of viral contaminants. A product that had been through a sterilisation process could be readily distinguished from a product that had not, regardless of the initial viral content.

The skilled person would appreciate that a "titer level ... at least 1000 times less" corresponded to a 3-log reduction, which was a standard term used to describe products that had been exposed to a sterilisation procedure that reduced viral load. In this regard, biomanufacturing processes often included steps that aimed to reduce virus load. These steps were evaluated in order to determine their viral clearance capacity. Viral clearance was defined as the difference between the total virus amount in the input sample and in the output sample, i.e. the product-containing fraction after purification. The viral reduction capability was then referred to as the log reduction value (LRV) of a process step.

In the absence of any explicit disclosure in the state of the art regarding the level of viral contaminants within the pancreatin fraction after purification, it could not be simply assumed that a pancreatin fraction disclosed in the prior art fell within the scope of the claims. This was evident from document D24, a report generated by the EMEA assessing the viral risk of pancreatin products. This document stated that: "[f]*rom the above analysis, the assessment of the risk with HEV leads to the conclusion that its presence in the drug substance batches cannot be excluded*" and "[s]*cientific studies using infectivity assays have proven that non-enveloped viruses (PPV) are indeed present in batches of pancreatin*".

Thus, in order for a disclosure to prejudice novelty, it had to be demonstrated that the output pancreatin sample had been exposed to a sterilisation process that (i) decreased the concentration of viral contaminants by at least 3-log titers so that the the output sample had low levels of virus and thus could be safely administered to a patient; and that (ii) maintained the activity of the pancreatin such that it was suitable for achieving the therapeutic effect.

In the absence of any evidence to show that the pancreatin provided according to documents D1, D2/D9, D6, D18, D20, D26 and D28 had the low levels of viral content demanded by the claim, the disclosure within these documents did not anticipate the claimed pancreatin.

Auxiliary requests 1 to 7
Novelty (Article 54 EPC)

The same arguments as for the main request applied.

XI. The respondent's arguments are summarised as follows.

Main request - claim 1
Claim construction and novelty (Article 54 EPC)

The claim contained only three direct product features, namely "pharmaceutical composition", "comprising a pharmacologically effective quantity of a pancreatin" and "one or more pharmaceutically acceptable excipients".

The feature "the dispersed form of pancreatin is selected from powders, pellets, micropellets, microspheres, granules and granulates" did not have a

limiting effect on the product because it only related to the starting material. The form of the pancreatin could, however, change during the process, either through the heating process and/or the solvent or through other process steps which were not mentioned in the claim, but were not excluded ("comprising the steps of ...").

In the absence of a precise definition of the starting material in terms of lipase activity and viral load, the respective functional definitions in the claim resulted in relative values and thus did not have a limiting effect on the product. Document D24, which was cited by the appellant, only showed that different batches of pancreatin could contain certain viruses (e.g. HEV) or not.

The required "total solvent content" did not have a limiting effect either, as it could be reached at "any point during process step (b)" and could also increase again towards the end of the process.

In conclusion, claim 1 was directed to a pharmaceutical composition comprising pancreatin and at least one excipient.

Consequently, the subject-matter of claim 1 lacked novelty over the disclosure of documents D1, D2/D9, D6, D18, D20, D26 and D28.

Auxiliary requests 1 to 7
Novelty (Article 54 EPC)

The same arguments as for the main request applied.

XII. The appellant requested that the decision under appeal be set aside and that the patent be maintained based on the main request filed by letter dated 19 July 2019 or, alternatively, on one of auxiliary requests 1 to 7 filed by letter dated 19 July 2019 as auxiliary requests 1 to 3 and 8 to 11, respectively.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Main request - claim 1
Claim construction and novelty (Article 54 EPC)

2. The pancreatin comprised in the claimed pharmaceutical composition is, *inter alia*, defined by a process ("obtainable by") comprising the two steps (a) and (b) (see section VIII. above).

3. As rightly pointed out by the appellant - and in accordance with established case law of the Boards of Appeal - process features defining a product are not taken into account when determining the characteristics of this product, i.e. a product is not considered distinguished from a product of the state of the art only because it is obtained by a different process. However, properties conferred by the process to the product are taken into account (see Case Law of the Boards of Appeal, 9th edition, 2019, I.C.5.2.7 and II.A.7.1 and 7.2).

4. According to the appellant, the process steps describe a sterilisation process by heating. The direct result

of the process is recited in the claim, i.e. the titer level of any viral contaminant after heating is at least 1000 times less than the level prior to heating. According to the appellant, this reduction is referred to as a "3-log" reduction. In view of the appellant's submission, the board considers the property of the process imparted on the pancreatin to be an at least 3-log reduction of any viral contaminant (see, however, points 6. to 10. below).

5. Pancreatin as a constituent of the claimed pharmaceutical composition is further defined by two functional features: the "titer level of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less, than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating" and "the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating".

6. It is common general knowledge that pancreatin is derived from animals and that, depending on the source, its levels of lipase activity and viral contaminants vary (see e.g. document D24). Thus, the product-by-process feature (see points 3. and 4. above) and the corresponding functional feature (see point 5. above) do not define the titer level of the viral contaminants in the output pancreatin product after heating in absolute terms, but relative to the values in the input product. The same applies to the residual lipase activity.

7. Hence, since the starting material for the process defined in the claim can be pancreatin from any source, the titer level of viral contaminants prior to and

after heating and the lipase activity prior to and after heating may take any value (see point 6. above).

8. The appellant argues that for a disclosure to prejudice the novelty of the subject-matter of claim 1, absent any disclosure in the prior art of the features at issue, it had to be demonstrated that an output pancreatin product had been exposed to a sterilisation process that decreased the viral load by at least 3-log titers and that the lipase activity was maintained such that the product was suitable for therapeutic purposes.

9. Document D2/D9 discloses in Example 1 (page 2) the sterilisation of pancreatin under vacuum for 5 hours at 125 to 130 °C. This heat sterilisation process falls within the process definition in claim 1, thus imparting to the pancreatin the same properties as to the claimed one (see point 4. above).

10. The animal source of pancreatin is not disclosed in document D2/D9, but the claim is not limited to pancreatin from a particular source in any case (see point 7. above).

11. In view of the claim construction in points 2. to 7. above, document D2/D9 discloses a pancreatin product which is the same as the one defined in claim 1, without the need for the actual demonstration of the properties of the disclosed product.

12. The subject-matter of claim 1 lacks novelty over the disclosure of document D2/D9.

Auxiliary requests 1 to 7 - claim 1

13. In the absence of further arguments from the appellant with regard to the novelty of the subject-matter of claim 1 of these requests, the same reasons as for claim 1 of the main request apply.

14. The subject-matter of claim 1 of auxiliary requests 1 to 7 lacks novelty.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: On behalf of the Chair (according to Art. 8(3) RPBA):

A. Chavinier-Tomsic L. Bühler

Decision electronically authenticated