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Datasheet for the decision of 9 December 2021

Case Number: T 2521/18 - 3.3.01

Application Number: 10768922.6

Publication Number: 2488158

IPC: A61K31/167, A61K31/56

Language of the proceedings: EN

Title of invention:
IMPROVED MEDICINAL AEROSOL FORMULATIONS

Patent Proprietor:
Jagotec AG

Opponent:
Generics [U.K.] Limited

Headword:
Aerosol formulations/JAGOTEC

Relevant legal provisions:
EPC Art. 54
RPBA 2020 Art. 13(2)

Keyword:
Novelty - (no)

Decisions cited:
G 0002/88

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Case Number: T 2521/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 9 December 2021

Appellant: (Opponent)	Generics [U.K.] Limited Station Close Potters Bar Herfordshire EN6 1TL (GB)
Representative:	FRKelly 27 Clyde Road Dublin D04 F838 (IE)
Respondent: (Patent Proprietor)	Jagotec AG Wildensteinerstrasse 1 4132 Muttenz (CH)
Representative:	Haile, Alison Victoria Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 July 2018 concerning maintenance of the European Patent No. 2488158 in amended form**

Composition of the Board:

Chairman	A. Lindner
Members:	J. Molina de Alba
	L. Bühler

Summary of Facts and Submissions

I. This appeal by the opponent (appellant) is directed against the opposition division's interlocutory decision finding that European patent No. 2 488 158 as amended in the form of auxiliary request 2 and the invention to which it relates met the requirements of the EPC.

II. The following document is referred to in the present decision:

F1: WO 2005/034911

III. The patent had been granted with 20 claims. Claim 13 as granted reads as follows:

"*13. Use of 0.01 to 0.1% by weight sodium cromolyn in the preparation of a pharmaceutical suspension formulation in HFA propellant comprising 0.003 to 0.04% by weight formoterol fumarate dihydrate and 0.01 to 0.6% by weight fluticasone propionate microparticles for forming floccules of formoterol fumarate dihydrate, fluticasone propionate and sodium cromolyn having an average density the same as that of the HFA propellant ±0.2 g/cm^3, preferably ±0.1 g/cm^3; more preferably ±0.05 g/cm^3.*"

The compound sodium cromolyn is also known as disodium cromoglycate or DSCG (see patent, paragraph [0020] and F1, page 14, line 24).

IV. The patent had been opposed on the grounds that the claimed subject-matter lacked novelty and inventive

step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed (Article 100(a), (b) and (c) EPC).

V. In the decision under appeal, the opposition division concluded, among other things, that the subject-matter of the main request and of auxiliary request 1 was not inventive. In relation to auxiliary request 2, the opposition division held that it did not add subject-matter and that its subject-matter was novel and inventive over document F1.

VI. The appellant filed notice of appeal requesting that the opposition division's decision be set aside and the patent be revoked in its entirety. In its statement of grounds of appeal, the appellant raised objections under Articles 123(2), 83, 54 and 56 EPC.

VII. In its reply to the statement of grounds of appeal, the patent proprietor (respondent) requested that the appeal be dismissed (main request), or alternatively that the patent be maintained in amended form on the basis of the claims of any of the first to third auxiliary requests filed therewith.

VIII. The board scheduled oral proceedings in line with the parties' requests. In preparation for the oral proceedings, the board issued a preliminary opinion in which, among other things, it indicated (point 9, last paragraph) that a decisive point in the discussion of novelty in relation to claim 1 of the main request was whether the intended purpose of using sodium cromolyn to form floccules was limiting.

IX. Oral proceedings were held as a videoconference on 9 December 2021. During the oral proceedings, the respondent filed a corrected version of the main request and of the first to third auxiliary requests, and also new fourth to seventh auxiliary requests. At the end of the oral proceedings, the respondent withdrew all the claim requests on file except the fifth auxiliary request.

Claim 1 of the fifth auxiliary request is identical to claim 13 as granted with the exception that it does not indicate that the given percentages are by weight.

X. At the end of the oral proceedings the board announced its decision.

XI. The appellant's arguments, where relevant to the present decision, can be summarised as follows:

The subject-matter of claim 1 of the fifth auxiliary request was not novel. The patent disclosed (paragraph [0074]) the preparation of aerosol suspensions by combining selected amounts of micronised formoterol fumarate dihydrate (FF), fluticasone propionate (FP) and sodium cromolyn (DSCG) with a pre-mix of a hydrofluoroalkane (HFA) propellant and ethanol. This combination produced a suspension in which floccules containing FF, FP and DSCG and having the density of the propellant mixture were spontaneously formed. In this context, claim 1 concerned the use of DSCG in the preparation of a pharmaceutical suspension for forming floccules. The wording of claim 1 conflated a use to achieve an effect with a process of preparation. According to G 2/88, there were two types of use claims: i) the use of an entity to achieve a technical effect, and ii) a process for the production of a

product. Claim 1, despite being formulated as a use claim, defined a process for the production of a product. Therefore its purpose (formation of three-way floccules) was not limiting.

Example 1 of F1 disclosed the preparation of an aerosol suspension by combining micronised FF, FP and DSCG with a mixture of a HFA propellant and ethanol. The suspension was prepared in the same manner and using the same components in the same amounts as defined in claim 1. Although F1 did not explicitly disclose that DSCG formed floccules, it disclosed the use of DSCG for preparing a formulation as defined in claim 1 in which floccules containing FF, FP and DSCG having the density of the propellant mixture were inevitably formed. Hence the preparation of the formulation in Example 1 of F1 anticipated the subject-matter of claim 1.

XII. The respondent's arguments, where relevant to the present decision, can be summarised as follows:

The subject-matter of claim 1 of the fifth auxiliary request was novel. The claim did not relate to a method of preparation, but concerned the use of DSCG for forming floccules of micronised FF, FP and DSCG that had the same density as the HFA propellant. F1 neither explicitly nor implicitly disclosed the formation of floccules as defined in claim 1, let alone the use of DSCG for forming such floccules. The only disclosure in F1 regarding DSCG was that it protects the formulation against moisture. However, protection against moisture was unrelated to the formation of three-way floccules defined in claim 1. Floccule formation required narrower concentration ranges of the components, especially DSCG, and achieved a particular stabilising

effect of the aerosol formulations. Therefore, in accordance with G 2/88, the use of claim 1 was novel.

XIII. The parties' final requests were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the fifth auxiliary request filed during the oral proceedings on 9 December 2021.

Reasons for the Decision

1. The appeal is admissible. It meets the requirements of Articles 106 to 108 and Rule 99(2) EPC.

2. *Admittance of the fifth auxiliary request*

The fifth auxiliary request was filed by the respondent at the oral proceedings before the board. The appellant requested that it not be admitted into the proceedings.

In the board's view, the filing of the fifth auxiliary request was a direct response to submissions made for the first time in the discussion on inventive step at the oral proceedings before the board. In view of the outcome of the assessment of novelty (see point 3.4), the board does not need to give details on the reasons

why Article 13(2) RPBA 2020 does not preclude admission of the fifth auxiliary request.

3. *Novelty - claim 1 of the fifth auxiliary request*

The parties disputed whether document F1, especially its Example 1, disclosed the subject-matter of claim 1 of the fifth auxiliary request. Their opposing views were a direct consequence of their different interpretations of claim 1. Thus the assessment of novelty requires a preliminary step to construe the claim. Before that, with a view to making the analysis more comprehensible, the board will outline the inventions of F1 and the patent and put them into their context.

3.1 *The inventions of F1 and the patent*

3.1.1 F1 is directed (page 1, lines 3-8 and 25-29; page 3, lines 2-7 and page 9, lines 25-26; page 4, lines 4-9 and 30-32) to the preparation of stable aerosol suspensions comprising micronised FF and FP for use in metered dose inhaler devices. The formulation of FF in aerosol suspensions is particularly difficult because its particles agglomerate easily, adhere to the inner surface of the canister and valve, and do not re-disperse readily. This causes irregular dosing of the drug. The inventors of F1 found (page 3, lines 14-16, page 6, lines 7-12 and page 7, lines 12-16) that moisture is at the origin of this instability and that the aerosol suspensions can be stabilised by keeping their total moisture content at low levels, e.g. within the range of 100 to 600 ppm. This is achieved by two measures (page 10, lines 8-20 and page 13, lines 1-5): drying FF before mixing it with the other ingredients, and adding 0.01 to 0.1 wt.% DSCG as water scavenger.

Regarding the aerosol propellant, F1 notes (page 11, line 18 to page 12, line 11) the importance of its density matching that of the suspended solids so that the solids remain in suspension better. In particular, F1 proposes HFA propellants containing small amounts (1.5 wt.% or less) of ethanol, which reduce the density of the propellant, matching it with that of the suspended solids.

The invention of F1 is illustrated in Example 1, which discloses the preparation of an aerosol suspension having the following composition:

FF	0.009 wt.%
FP	0.179 wt.%
DSCG	0.034 wt.%
Abs. ethanol	1.429 wt.%
HFA 227	98.350 wt.%

The suspension was prepared by drying FF and DSCG and putting them into a filling vessel together with FP. A propellant mixture consisting of HFA 227 and absolute ethanol was then fed into the vessel. The suspension thus formed was pressure-filled into aluminium cans and its stability at 40°C and 75% RH was tested at 1, 3 and 6 months. The results, disclosed in Examples 3 and 4, showed that the suspension had a high delivered dose uniformity, both among containers and over the life of each container. It was common ground between the parties that dose uniformity is a measure of the stability of the suspension.

3.1.2 Like F1, the patent concerns (paragraphs [0001], [0051], [0059] and [0061]) the preparation of stable aerosol suspensions for use in metered dose inhalers. Also like F1, the suspensions contain micronised FF, FP

and DSCG as the solid phase. The propellant is also an HFA, preferably HFA 227 with small amounts of ethanol.

The patent also identifies (paragraphs [0016] to [0019]) moisture as the main factor causing instability in aerosol suspensions containing FF. As a solution, it proposes the measures taught in F1. First, reducing the total moisture of the suspension to 600 ppm or less using sub-therapeutic doses (0.1-0.01 wt.%) of DSCG as water scavenger (paragraphs [0043], [0046] and [0047]). Second, matching the average densities of propellant and suspended solids (paragraph [0021]).

The suspensions in the examples of the patent were prepared following the method disclosed in paragraph [0074]. Micronised FF and FP were weighed and transferred into the batching vessel. DSCG was then added and the vessel closed. The propellant mixture was made in a separate vessel and transferred into the batching vessel. The resulting mixture was homogenised to form a suspension. In Example 3, the patent discloses the preparation of an aerosol suspension according to claim 1 of the fifth auxiliary request which has a composition that is almost identical to that in Example 1 of F1, namely:

FF	0.0086 wt.%
FP	0.1785 wt.%
DSCG	0.0343 wt.%
Abs. ethanol	1.43 wt.%
HFA 227	qs to 100.0 wt.%

Like the suspension of Example 1 of F1, the suspension of Example 3 of the patent exhibits high stability when tested at 40°C and 75% RH at 1, 3 and 6 months.

3.1.3 The main difference between the disclosures of F1 and the patent is that the patent teaches (paragraphs [0030] to [0033] and [0045]) that DSCG increases the stability of the aerosol suspensions not only by scavenging water but also by forming three-way floccules with FF and FP which match the average density of the propellant. However, considering that the composition of the formulations in Example 1 of F1 and in Example 3 of the patent (i.e. according to claim 1) are practically the same and that they were prepared in essentially the same manner, the board is persuaded that three-way floccules according to claim 1 are also formed in Example 1 of F1. This assumption is supported by the fact that both formulations showed high stability when tested at 40°C and 75% RH at 1, 3 and 6 months.

3.1.4 Thus Example 1 of F1 discloses the use of DSCG in the preparation of a pharmaceutical suspension as defined in claim 1. The only feature in claim 1 that could potentially render the claimed subject-matter novel over F1 would be the explicit mention of the purpose that DSCG is used for forming three-way floccules which have the average density of the propellant. Therefore claim 1 needs to be construed to determine whether that purpose is limiting (as defended by the respondent) or merely descriptive (as defended by the appellant). In this context, the parties referred to decision G 2/88.

3.2 *Construction of claim 1*

G 2/88 deals with second or further non-medical uses, which is the type of use defined in claim 1. As noted by the appellant (statement of grounds of appeal, page 7), G 2/88 distinguishes between two types of use claims (Reasons, 5.1, paragraphs 2 and 3):

i) the use of a physical entity to achieve an effect, and
ii) the use of a physical entity to produce a product.

In its reply to the third question referred to it, the Enlarged Board in G 2/88 (Order, point (iii)) dealt specifically with the interpretation of use claims of type i). It established that in such claims the purpose, which is based on a technical effect described in the patent, should be interpreted as a functional technical feature. Thus the purpose in type i) use claims is limiting. The decision did not deal with type ii) use claims. It merely suggested (Reasons 5.1, last paragraph) that those uses equate to a process within the meaning of Article 64(2) EPC, i.e. a process for the preparation of a product.

The appellant considered that claim 1 was a type ii) claim, while the respondent maintained that it belonged to type i).

Having regard to the wording of claim 1 and the nature of its invention, the board agrees with the appellant that claim 1 is a type ii) use claim: it relates to a process for the production of a product within the meaning of Article 64(2) EPC. Contrary to the respondent's view, the formation of three-way floccules defined in claim 1 cannot be considered as the achieving of an effect in the sense of G 2/88. The floccules, which were already present in the aerosol suspension of Example 1 of F1 (see point 3.1.3 above), constitute a structural feature of the suspension. They contribute to the actual effect achieved, namely stabilising the formulation, but do not themselves

constitute the achieving of a new effect. According to both the patent and F1, the effect brought about by DSCG is to increase the stability of the aerosol suspensions. This is achieved by scavenging water. The patent's inventors observed that, in addition to scavenging water, DSCG also forms three-way floccules that match the average density of the propellant. However, the formation of floccules, rather than constituting a new effect, is an additional explanation of the mechanism of how DSCG exerts its stabilising effect. Consequently, despite the purpose indicated in its wording, claim 1 is aimed at the preparation of a formulation.

As point (iii) of the order of G 2/88 deals only with type i) use claims, it is not applicable to claim 1 of the fifth auxiliary request.

3.3 It is established case law that the purpose mentioned in a claim to a process for the production of a product is not suitable for distinguishing the claimed process from other preparation processes carried out using identical features but for a different purpose. Therefore the interpretation of claim 1 as being directed to a process for the preparation of a product leads to the conclusion that the purpose of forming three-way floccules having the average density of the propellant is merely descriptive and cannot render the claimed subject-matter novel. As Example 1 of F1 discloses the preparation of a formulation according to the essential features of claim 1, the subject-matter of claim 1 is not novel.

3.4 Therefore claim 1 does not meet the requirements of Article 54 EPC.

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:

M. Schalow A. Lindner

Decision electronically authenticated