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Datasheet for the decision of 10 April 2025

Case Number: T 1041/23 - 3.3.07

Application Number: 08732695.5

Publication Number: 2139494

IPC: A61K31/70, A61K9/16, A61K9/20, A61P3/10

Language of the proceedings: EN

Title of invention:
PHARMACEUTICAL FORMULATIONS CONTAINING DAPAGLIFLOZIN PROPYLENE GLYCOL HYDRATE

Patent Proprietor:
AstraZeneca AB

Opponents:
Zentiva, k.s.
Galenicum Health S.L.U.
Generics [UK] Limited
Stada-Arzneimittel Aktiengesellschaft
Gedeon Richter Plc.
Kraus & Lederer PartGmbB

Headword:
Dapagliflozin formulations / ASTRAZENECA

Relevant legal provisions:
EPC Art. 113(1), 104(1)
RPBA 2020 Art. 11
EPC R. 103(1)(a)
RPBA Art. 16(1)

Keyword:
Substantial procedural violation - violation of the right to be heard (yes)
Remittal to the department of first instance - fundamental deficiency in first instance proceedings (yes)
Reimbursement of appeal fee - equitable by reason of a substantial procedural violation (yes)
Apportionment of costs - not equitable

Decisions cited:
G 0001/92

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Beschwerdekammern

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Case Number: T 1041/23 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 April 2025

Appellant: (Patent Proprietor)	AstraZeneca AB 151 85 Södertälje (SE)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Respondent: (Opponent 1)	Zentiva, k.s. U kabelovny 130 102 37 Praha 10 - Dolni Mecholupy (CZ)
Representative:	Aera A/S Niels Hemmingsens Gade 10, 5th Floor 1153 Copenhagen K (DK)
Respondent: (Opponent 2)	Galenicum Health S.L.U. CL Sant Gabriel n°50 08950 Esplugues de Llobregat (ES)
Representative:	Galenicum Health S.L.U. CL Sant Gabriel n°50 08950 Esplugues de Llobregat (ES)
Respondent: (Opponent 3)	Generics [UK] Limited Building 4, Trident Place Mosquito Way Hatfield Hertfordshire AL10 9UL (GB)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)

Respondent: (Opponent 4)	Stada-Arzneimittel Aktiengesellschaft Stadastrasse 2-18 61118 Bad Vilbel (DE)
Representative:	Kernebeck, Thomas Kernebeck Patentanwalts GmbH Stiftstraße 2 60313 Frankfurt am Main (DE)
Respondent: (Opponent 5)	Gedeon Richter Plc. Gyömröi út 19-21 1103 Budapest (HU)
Representative:	Dr. Schön, Neymeyr & Partner Patentanwälte mbB Bavariaring 26 80336 Munich (DE)
Respondent: (Opponent 6)	Kraus & Lederer PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Representative:	Kraus & Lederer PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 16 March 2023 revoking European patent No. 2139494 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	L. Basterreix

Summary of Facts and Submissions

I. Six oppositions were filed against European patent 2 139 494 (hereinafter "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 application as filed.

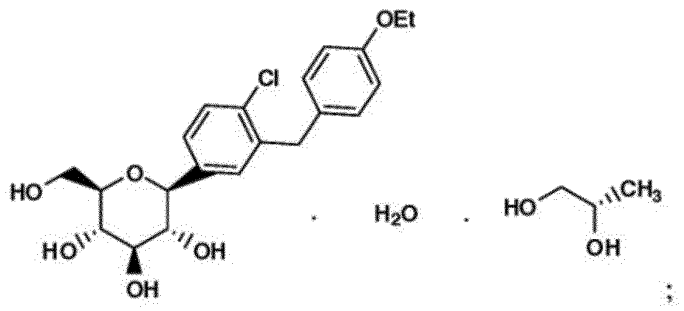
II. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent.

The decision was based on the patent as granted as main request and on auxiliary requests 1-3 filed on 19 May 2022.

Claim 1 was identical in all requests and pertained to:

"An immediate release pharmaceutical formulation in the form of a stock granulation for loading in capsules or forming tablets, or in the form of a capsule or a tablet containing the stock granulation, the stock granulation comprising:

a) dapagliflozin propylene glycol hydrate having the formula



;

b) one or more bulking agents;
c) one or more binders;
d) one or more disintegrants;
e) optionally one or more glidants and/or anti-adherents; and
f) optionally one or more lubricants."

III. The opposition division decided that the subject-matter of the main request and of each of the auxiliary requests lacked novelty over the public prior use in the clinical study NCT00263276 shown in D1. According to the decision, the tablet formulations distributed to the study participants were publicly available, and could be analysed by placing them in an aqueous physiological medium so as to separate the excipients from the insoluble 1:1:1 dapagliflozin propylene glycol hydrate.

IV. With their statement setting out the grounds of appeal, the appellant expressed among others the view that the decision was based on a new reasoning on which they did not have an opportunity to present their comments. This violation of the appellant's right to be heard justified that the appeal fee be reimbursed.

The appellant further filed D53-D56 with their grounds of appeal, and D60 and D61 with their letter dated 30 October 2024:

D53: Qtern EPAR Public Assessment Report
D54: BMS Final Study Report for MB102008
D55: EMEA ICH Topic E6(R1) Guidelines
D56: Declaration of Simon Morton (AZ)

D60: Front pages of FAQ datasheets for MCC, magnesium stearate, titanium dioxide, talc and iron oxide yellow
D61: Section 8.5 on page 89 of the Clinical Protocol for MB102008

V. In a communication under Article 15(1) RPBA, the Board expressed the preliminary view that the first-instance proceedings were affected by a substantial procedural violation which justified a remittal to the opposition division and a reimbursement of the appeal fee.

VI. Oral proceedings were held before the Board in the presence of the appellant as well as opponents 3, 4 and 5 (respectively respondents 3, 4 and 5).

VII. At the end of the oral proceedings, the parties' requests were the following:

(a) The appellant requested that the decision under appeal be set aside, and that the Board:
- remits the case to the opposition division for further prosecution and reimburses the appeal fee for reason of a violation of the right to be heard or, alternatively,
- considers novelty and remits the case to the opposition division for further prosecution,
- admits documents D53-D56 in the appeal proceedings,
- admits document D60 into proceedings if the aqueous (in)solubility of the excipients of the clinical trial tablets is denied to be common general knowledge by any party, and
- admits document D61 into proceedings if D54 and/or D55 are not admitted, or for some reason

are not considered enough to demonstrate confidentiality.

Lastly, the appellant requested a different apportionment of costs, with the preparation, travel and accommodation costs to be divided between respondents 3, 4 and 5.

(b) Opponents 2-5 (respectively respondents 2-5) requested that the appeal be dismissed.

Respondents 3-5 further requested that none of documents D53-D56 be admitted in the appeal proceedings.

Respondent 5 also requested that documents D60 and D61 not be admitted in the appeal proceedings, and that the Board decide on the admission of documents D53-D56, D60 and D61 in the appeal proceedings.

(c) Opponents 1 and 6 (respectively respondents 1 and 6) did not make any submission in writing in the appeal proceedings.

VIII. The appellant's arguments may be summarised as follows:

(a) The decision was based on a new and unexpected reasoning which had never been mentioned before during written or oral proceedings, namely the critical reasoning given at §2.2.2.8 of the decision about how the skilled person would have allegedly been able to isolate and analyse the crystalline 1:1:1 dapagliflozin (S)-PG monohydrate (1:1:1-DSPGM) solvate from the clinical trial tablets. The appellant's right to be heard had thus not been respected. This substantial procedural

violation justified a reimbursement of the appeal fee.

(b) The conduct of respondents 3, 4 and 5, who persisted in their requests for oral proceedings despite knowing of the violation of Article 113(1) EPC, justified a different apportionment of costs, with the appellant's preparation, travel and accommodation costs to be divided between respondents 3, 4 and 5.

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

(a) The opposition division had expressed the preliminary view that the skilled person was in the position to analyse the dosage form and to discover all technical features of claim 1. The appellant had not reacted early enough to this position. The issue of analysability of the tablet had been discussed during the oral proceedings. Furthermore, the presence of the solvate in the tablet could also be ascertained using well-known analysis techniques, even without destroying the tablet. Finally, in light of the pending referral G 1/23, the possibility to analyse the product might not be a requirement for it to be accessible to the public. Hence the appellant's right to be heard had been respected.

(b) The appellant's request for an apportionment of costs was both presented late and not justified, owing to the fact that the Board's opinion in the communication under Article 15(1) RPBA was merely preliminary, and considering that the right to be

heard during oral proceedings had to be respected for the respondents as well.

Reasons for the Decision

1. Procedural violation

1.1 According to the appellant, the proceedings are affected by a violation of the right to be heard because the appealed decision is based on grounds on which they had no opportunity to present their comments, namely the critical reasoning (given at §2.2.2.8 of the decision) about how the skilled person would have been able to isolate and analyse the crystalline 1:1:1 dapagliflozin (S)-PG monohydrate (1:1:1-DSPGM) from the clinical trial tablets.

The Board agrees for the following reasons.

1.2 The relevant parts of the proceedings before the opposition division may be summarised as follows:

The objection of lack of novelty over the clinical trial reported in D1 was initially raised by opponent 1 in their notice of opposition (see §5). Concerning the possibility to analyse the medication administered in this clinical trial, opponent 1 mentioned various analytical techniques, such as HPLC/MS and XRPD, that would allow the determination of the active ingredient as containing propylene glycol and the fact that it was in crystalline form, i.e. in the form of the propylene glycol solvate (see §5.3).

With their reply dated 25 June 2021 (see page 12-13), the patent proprietor countered that this prior use was not public, and in particular that no evidence had been adduced that patent proprietor lost control of the medication during clinical trials.

In the preliminary opinion dated 6 October 2021 (see §4.2), the opposition division briefly expressed the view that the skilled person was in the position to analyse the medication and discover all technical features of claim 1, and that the sole question was whether the prior use was public.

In their further letter dated 19 May 2022 (see §2.2), the patent proprietor emphasised that, even assuming that the study medication became public during the clinical trial, given the presence of the additional excipients, a skilled person attempting to analyse the study medication used in the clinical trial would not have been able to conclusively discover that dapagliflozin was present in the claimed solvate form, namely dapagliflozin . water . S-propylene glycol in a 1:1:1 stoichiometry.

In section §2.2.1.7, the appealed decision addresses the question of whether all technical features of claim 1 could be retrieved by analysing the study medication. The opposition division reasons that the skilled person would be able to separate the excipients from the insoluble dapagliflozin propylene glycol hydrate by placing the tablet of the clinical study in an aqueous physiological medium. The decision then mentions various techniques for the analysis of the crystal, citing D10, D15 and D11, and concludes that these would allow the determination of the active ingredient being

a crystal containing dapagliflozin, propylene glycol and water in the proportions 1:1:1.

Likewise, in section §2.2.2.8, the opposition division reasons that the dapagliflozin propylene glycol hydrate is not soluble in a physiological aqueous medium, whereas the tablet dissolves in aqueous medium, thus leaving the crystal in solid form. Once isolated, the crystal can be fully analysed in order to ascertain its structure, using any of the methods described in D10.

1.3 Thus, the issue of whether the technical features of claim 1 could be determined by analysing the study medication was the topic of debate from the beginning of the opposition proceedings.

However, in reply to the appellant's objection that the analysis of the medication containing excipients would not allow to identify the claimed solvate form therein, the decision proposes for the first time a method for isolating the solvate from the medication by dissolution in a physiological aqueous medium, followed by analysis of the remaining insoluble crystal. This specific part of the reasoning had not been discussed at any point during the preceding opposition proceedings.

In this respect, the respondents emphasised the lack of details in the minutes of the oral proceedings before the opposition division, and submitted that, while they could not remember exactly, both the issues of separating the excipients from the crystalline material and of analysing the crystalline material had been a topic of discussion during these oral proceedings. However, the respondents do not dispute that the specific method of isolating the solvate from the

tablet by dissolution in a physiological medium so as to analyse the crystal was never mentioned during the oral proceedings. There is not indication in the minutes of any discussion on this point either.

1.4 Under Article 113(1) EPC, the decisions of the EPO may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments. The grounds or evidence under Article 113(1) EPC are to be understood as meaning the essential legal and factual reasoning on which the decision is based (see the Case Law of the Boards of Appeal, 10th edition, 2022, hereinafter "Case Law", III.B.2.3.2).

The factual allegations regarding the solubility properties of the solvate according to claim 1, and the specific isolation method based thereon proposed by the opposition division, are an essential part of the decision, in the sense that the decision does not suggest any means of ascertaining by analysis the presence of the claimed solvate in the medication other than by firstly resorting to this isolation method. Contrary to respondent 4's view (see their reply dated 8 December 2023, pages 12-13), the appealed decision does not indicate any means of analysing the whole tablets for the presence of the claimed solvate without separating its components, i.e. neither explicitly nor implicitly by citing D10 (paragraphs [0177]-[0195]), D15 (pages 41-42) or D11 (example 7 on pages 43-44), as these documents pertain to the analysis of e.g. isolated solvates as such but not as part of a complete medication including excipients.

1.5 The Board concludes that the first-instance proceedings are affected by a substantial procedural violation.

1.6 The respondents point out the opposition division's preliminary view that "The skilled person is in the position to analyse a dosage form like the Forxiga product and to discover all technical features of present claim 1 (G 1 /92)" (see the annex to the summons dated 6 October 2021, §4.2). According to the respondents, the appellant did not react early enough to this position, i.e. the burden of proving that the tablet could not be analysed or its components separated rested with the appellant. They further submit that the presence of the solvate in the tablet could otherwise be ascertained using well-known analysis techniques, even without destroying the tablet. They finally take the view that, in light of the pending referral G 1/23, the possibility to analyse the product might not be a requirement for it to be accessible to the public.

However, the question under Article 113(1) EPC is whether the appellant had an opportunity to present their comments on the factual reasoning used in the decision. The appealed decision reasons that, following G 1/92, the features of claim 1 characterising the formulation are available to the public if they could be retrieved by analysing the tablet from the clinical study, and concludes that this was possible by isolating the solvate from the medication by dissolution in a physiological aqueous medium, followed by analysis of the remaining insoluble crystal. Whether the same finding that the composition of the tablet was prior art could alternatively have been justified by reasonings others than the one used in the decision has no bearing on the issue of right to be heard. It is thus not necessary, for that purpose of Article 113(1) EPC, to assess whether the burden of proving that the

tablet could not be analysed rested with the appellant, or whether the tablet could be analysed as such without prior separation, because the decision is not based on such aspects. It is for the same reasons not necessary to speculate on the answers to be given by the Enlarged Board of Appeal in the current referral G 1/23, and whether the possibility to analyse the features of the tablet could become irrelevant to their being state of the art, because the assumption that analysability is a requirement is also an essential part of the reasoning in the appealed decision.

1.7 Accordingly, the appealed decision does not meet the requirements of Article 113(1) EPC and must be set aside for this reason. Respondent 3's unspecific considerations of procedural economy cannot lead to a different conclusion because they cannot take precedence over the fundamental right to be heard enshrined in Article 113(1) EPC.

2. Remittal and reimbursement of the appeal fee

Under Article 11 RPBA, the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. As a rule, fundamental deficiencies which are apparent in the proceedings before that department constitute such special reasons.

In the case at hand, the above substantial procedural violation is a fundamental deficiency in the sense of Article 11 RPBA. The Board therefore decides to remit the case to the opposition division for further prosecution.

As a further consequence of this substantial procedural violation, a reimbursement of the appeal fee is equitable under Rule 103(1)(a) EPC.

3. Admission of documents D53-D56, D60 and D61

Respondent 5 requested at the end of the oral proceedings that the Board decide on the admission of documents D53-D56, D60 and D61 in the appeal proceedings, that is before remittal to the opposition division.

The Board could in theory, under Article 111(1) EPC, exercise the opposition division's discretionary power regarding admittance of these documents. This would however not be appropriate for the following reasons. As explained above, in view of the substantial procedural violation, the Board can decide on the appeal by setting aside the appealed decision and remitting the case. This entails that the opposition division is to further prosecute the case and assess, if need be, whether any late filed evidence is to be admitted. A decision by the Board on the admittance of D53-D56, D60 and D61 is not only unnecessary to decide on the appeal, but would even be inappropriate as it would pre-empt the opposition division's overall examination.

Accordingly, appellant 5's request was rejected.

4. Apportionment of costs

4.1 The appellant's request for an apportionment of costs was made in the following context:

In the communication under Article 15(1) RPBA, the Board had already expressed the preliminary view that the first-instance proceedings were characterised by a substantial procedural violation justifying both a remittal of the case to the opposition division for further prosecution and a reimbursement of the appeal fee. In the same communication, the Board had invited the parties to clarify their requests for oral proceedings before the Board in this event.

In reply, the appellant agreed to the remittal, but respondents 3, 4 and 5 maintained their requests for oral proceedings in case the appeal would not be dismissed.

The appellant questioned the need for oral proceedings in a letter dated 14 March 2025. Then, at the end of the oral proceedings before the Board, the appellant submitted a request for a different apportionment of costs, with their preparation, travel and accommodation costs to be divided between respondents 3, 4 and 5. The appellant justified their request by the conduct of respondents 3, 4 and 5, who had persisted in their request for oral proceedings despite knowing of the violation of Article 113(1) EPC.

4.2 Under Article 104(1) EPC, each party to the opposition proceedings shall bear the costs it has incurred, unless the Opposition Division, for reasons of equity, orders, in accordance with the Implementing Regulations, a different apportionment of costs. In opposition appeal proceedings, the same rule applies: in application of Article 16(1) RPBA, the Board may on request order a party to pay some or all of another party's costs, but this is subject to Article 104(1) EPC. Thus, departing from the general principle that

each party bear its own costs requires special circumstances making such a departure equitable. The equity criteria has generally been interpreted by the Boards such that apportionment of costs is justified if the conduct of one party is not in keeping with the care required, that is if costs arise from culpable actions of an irresponsible or even malicious nature (see Case Law, III.R.2).

No such special circumstances are apparent in the present case. The fact that respondents 3, 4 and 5 upheld their requests for oral proceedings can neither be regarded as abusive nor in breach of their duty of care. Their behaviour does not go beyond a legitimate defence of their position and argumentation that no substantial procedural violation occurred, and a normal exercise of their absolute right to oral proceedings under the circumstances. While the Board expressed an opinion in the Article 15(1) RPBA communication which was contrary to the position of the respondents, this opinion was merely a preliminary one, and there was nothing abusive in the respondents upholding their position and presenting their arguments at the oral proceedings. The appellant's speculation that the respondents knew of the violation of Article 113(1) EPC is in this respect completely irrelevant: the respondents certainly knew of the facts of the case, i.e. attended the oral proceedings and were notified the decision, but they were nonetheless entirely entitled to present legal arguments to the effect that these facts did not amount to a violation of the right to be heard. Lastly, none of the typical situations recited in Article 16(1) RPBA were relied on by the appellant or apply here, namely (a) amendment to a party's appeal case pursuant to Article 13; (b) extension of a period; (c) acts or omissions

prejudicing the timely and efficient conduct of oral proceedings; (d) failure to comply with a direction of the Board; (e) abuse of procedure.

4.3 Accordingly, the Board rejected the appellant's request for a different apportionment of costs.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division for further prosecution.

The appeal fee is to be reimbursed.

The request for a different apportionment of costs is rejected.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated