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Datasheet for the decision of 3 November 2020

Case Number: T 2431/17 - 3.3.07

Application Number: 09722278.0

Publication Number: 2265251

IPC: A61K47/44, A61K31/535, A61K31/5575, A61K31/542, A61K45/06, A61K31/215, A61K31/216

Language of the proceedings: EN

Title of invention:
PHARMACEUTICAL COMPOSITIONS HAVING DESIRABLE BIOAVAILABILITY

Patent Proprietor:
Alcon Research, Ltd.

Opponents:
Pohlman, Sandra M.
Alfred E. Tiefenbacher (GmbH & Co. KG)
Generics [UK] Limited (trading as Mylan)

Headword:
Pharmaceutical Compositions having Desirable Bioavailability / ALCON

Relevant legal provisions:
EPC Art. 123(2), 87(1), 54(3), 83
RPBA 2020 Art. 11
EPC R. 80

Keyword:
Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Priority - transfer of priority right - validity of priority date (no)
Remittal - special reasons for remittal

Decisions cited:
T 0844/18, J 0019/87, T 1008/96, T 0577/11, T 0205/14, T 0517/14

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Case Number: T 2431/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 3 November 2020

Appellant: (Patent Proprietor)	Alcon Research, Ltd. 6201 South Freeway, MS-TB4-8 Fort Worth, TX 76134-2099 (US)
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Appellant: (Opponent 1)	Pohlman, Sandra M. Fünf Höfe Theatinerstraße 16 80333 München (DE)
Representative:	Greiner, Elisabeth df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstraße 16 80333 München (DE)
Appellant: (Opponent 2)	Alfred E. Tiefenbacher (GmbH & Co. KG) Van-der-Smissen-Straße 1 22767 Hamburg (DE)
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Appellant: (Opponent 3)	Generics [UK] Limited (trading as Mylan) Building 4 Trident Place Mosquito Way Hatfield Hertfordshire AL10 9UL (GB)

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 9 October 2017 concerning maintenance of the European Patent No. 2265251 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: E. Duval
A. Jimenez

Summary of Facts and Submissions

I. European Patent 2 265 251 (hereinafter "the patent") was granted on the basis of 13 claims.

Claim 1 as granted related essentially to a aqueous ophthalmic pharmaceutical composition free of benzalkonium chloride (BAC), comprising:
- a pharmaceutical vehicle;
- a therapeutic agent including prostaglandin therapeutic agent, where the amount of prostaglandin therapeutic agent was from 0.00001 w/v % to less than 5 w/v % of the composition;
- an effectively low amount of surfactant, including hydrogenated and/or ethoxylated vegetable oil surfactant in amounts of 0.005 w/v % to less than 0.3 w/v % of the composition; and
- polyquaternium-1 (PQ-1) as a preservative.

II. Three oppositions were filed against 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.

III. The appeals were filed by the patent proprietor (appellant P), opponent 1 (appellant O1), opponent 2 (appellant O2) and opponent 3 (appellant O3) against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 1 filed during the oral proceedings, the patent met the requirements of the EPC.

IV. The decision was based on a main request filed on 11 October 2016, a new main request filed during the

oral proceedings and auxiliary request 1 also filed during the oral proceedings.

Claim 1 of the main request filed on 11 October 2016 differed from granted claim 1 in that the expression "prostaglandin therapeutic agent" had been replaced with "travoprost".

Claim 1 of auxiliary request 1 differed from granted claim 1 by the addition of the feature "wherein the therapeutic agent is travoprost".

V. In the present decision, reference is made to the following documents:

D15: US 61/037117 (1st priority doc)
D16: US 61/111920 (2nd priority doc)
A 045: WO 2008/052031
A 048: decision of the opposition division in the proceedings against the divisional EP 3 042 646 of the present patent
A 049: WO 2009/117242
A 050: 2000 - Employment Contract - Bhagat (Redacted)
A 051: 2000 - Employment Contract - Chowhan (Redacted)
A 052: 2000 - Employment Contract - Dahlin (Redacted)
A 053: 2000 - Employment Contract - Gan (Redacted)
A 054: 2000 - Employment Contract - Jani (Redacted)
A 055: 2000 - Employment Contract - Kabra (Redacted)
A 056: 2002 - Change of name
A 057: 2008-01-01 License Agreement (Redacted)
A 058: 2019 - Witness Statement of David O. Taylor - Executed

VI. The opposition division decided that:

(a) The main request complied with the requirements of Article 123(2) EPC, but infringed Article 123(3) EPC, because contrary to granted claim 1, claim 1 of the main request allowed for unlimited concentrations of protaglandin therapeutic agents other than travoprost.

(b) The new main request filed during the oral proceedings was not admitted into the proceedings under Rule 80 EPC.

(c) Auxiliary request 1 was admitted into the proceedings. This request met the requirements of Articles 123(2), 123(3) and 83 EPC, and was not open to objections under Article 84 EPC.

The priority was validly claimed because the same disclosure provided in the application as filed was found in both priority documents. Hence the claimed subject-matter was novel.

The BAC-free Travatan® Z formulation shown in D26 represented the closest prior art. The differentiating features of claim 1 of auxiliary request 1 were:

(i) the presence of PQ-1 as preservative, and

(ii) the concentration of hydrogenated and/or ethoxylated vegetable oil surfactant.

The technical problem was to provide adequate ocular bioavailability of travoprost and adequate preservation (stability) of the formulation while avoiding the use of BAC as preservative. The prior art did not motivate the skilled person to consider the solution claimed in auxiliary request 1.

VII. With its statement setting out the grounds of appeal filed on 6 February 2018, appellant P submitted an amended main request and auxiliary requests 1-5. Claim 1 of the main request read as follows:

"An aqueous ophthalmic pharmaceutical composition, comprising:
a pharmaceutical vehicle suitable for topical application to an eye;
an amount of therapeutic agent;
an effectively low amount of surfactant; and
polyquaternium-1 as a preservative;
wherein the therapeutic agent includes prostaglandin therapeutic agent and the surfactant includes hydrogenated and/or ethoxylated vegetable oil surfactant;
wherein the amount of prostaglandin therapeutic agent is at least 0.00001 w/v % but is less than 5 w/v % of the composition;
wherein the effectively low amount of hydrogenated and/or ethoxylated vegetable oil surfactant is at least 0.005 w/v % but is less than 0.3 w/v % of the composition;
wherein the composition is free of benzalkonium chloride; and
wherein the prostaglandin therapeutic agent comprises travoprost."

VIII. With its reply dated 4 July 2018, appellant P addressed the grounds of appeal of appellants O1, O2 and O3, and filed auxiliary requests 1-18. Appellant P submitted further arguments with its letter dated 30 November 2018.

Claim 1 of auxiliary request 1 differed from claim 1 of the main request by the additional feature that PQ-1 had a number average molecular weight between 2,000 and 30,000.

IX. By letters filed on 2 May 2019 and 15 August 2019, appellant O2 introduced documents A045-A049. Appellant O2 argued that the right to priority had not been validly transferred to appellant P, and raised objections of lack of novelty and inventive step based on A045 and A049.

X. On 31 December 2019, appellant P filed documents A050-A060 and the amended versions "a", "b", "c" and "d" of the main request and of auxiliary requests 4, 8 and 12.

XI. The Board set out its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

XII. Oral proceedings were held before the Board on 3 November 2020.

XIII. The arguments of appellants O1, O2 and O3, as far as relevant to the present decision, can be summarised as follows:

(a) Neither the main request nor auxiliary request 1 met the criteria of Rule 80 EPC. Appellant P had given no reason for the amendments to claims 6 and the deletion of claims 11 and 13. Furthermore, the deletion of granted dependent claim 11 could not address any ground for opposition.

(b) Neither the main request nor auxiliary request 1 met the criteria of Article 123(2) EPC.

In the main request and auxiliary request 1, the feature "the prostaglandin therapeutic agent comprises travoprost" in claim 1 allowed for the presence of travoprost together with other prostaglandins, and also for the presence of less than 0.00001% travoprost in the composition. This was not disclosed in the application as filed. The basis given by appellant P (page 10, lines 29-32 and page 11, lines 8-14) only disclosed the presence of travoprost as the sole prostaglandin.

Furthermore, starting from page 11, paragraph 2, of the application as filed, claim 1 resulted from multiple selections in respect of the lower and upper amounts of prostaglandin, the lower and upper amounts of surfactant, the selection of "free of BAC" from "substantially free of BAC" (page 14, paragraphs 2 and 3) and the presence of PQ-1. The application as filed contained no pointer to the claimed combination of features.

Claim 1 also lacked several further typical features shown in the description (namely the pH of 4-9 on page 12, paragraph 2, and the amount of more than 0.01 % borate on page 13, paragraph 3) and an essential feature regarding the use of boric acid polyol complex in case of the absence of BAC (see page 22 lines 14-16 and the examples). The absence of these features introduce added subject-matter.

The upper limit of 0.2 w/v % surfactant mentioned in claim 8 was neither disclosed on page 11, paragraph 2, of the application as filed, nor did it derive from claim 9 as filed, which related to a different composition.

Lastly, in the main request, the feature of claim 1 pertaining to the presence of PQ-1 resulted from an intermediate generalisation from its combination with the molecular weights of page 14, paragraph 4.

(c) Sufficiency of disclosure

The claims merely recited that low amounts of hydrogenated and/or ethoxylated vegetable oil surfactant be included into the ophthalmic prostaglandin composition, whereas all of the examples of the patent used only HCO-40 as the surfactant. It had not been sufficiently disclosed whether hydrogenated and/or ethoxylated vegetable oil surfactants other than HCO-40 could be used.

Additionally, the data in the patent regarding the stability of the compositions showed increasing amounts of degradation product with decreasing HCO-40 concentration, suggesting that, for concentrations as low as 0.005 %, the amounts of degradation product would be unacceptable for topical application to an eye. The data in the patent also showed that the exemplified compositions comprised amounts of degradation products above the upper limit of 1% accepted for pharmaceutical compositions. Lastly, the examples did not make plausible that the mere presence of PQ-1, in the absence of boric acid and polyols, could lead to a composition useful in pharmacy. A pharmaceutical composition as claimed could accordingly not be prepared.

(d) Priority

The applicants of the priority applications D15 and D16 were not identical to the applicant of the international application from which the patent derived. There was no evidence of a transfer or succession in title of the right to priority under Article 87(1) EPC from the applicants of D15 or D16 to the present applicant before the original PCT application was filed. Accordingly, the claimed priority was not valid. This was confirmed by the decision A048 of the opposition division in the divisional case EP 3 042 646.

As a consequence, A045 was part of the state of the art under Article 54(2) EPC, and A049 was part of the state of the art under Article 54(3) EPC.

(e) Novelty, inventive step

The compositions exemplified in A049 (see examples E, G, H, I-L, M-P and R-U) were prejudicial to the novelty of the subject-matter of all requests.

Furthermore, the claimed subject-matter did not involve an inventive step over A045.

(f) Remittal to the opposition division

A remittal to the opposition division was not justified. The issues of patentability over A045 and A049 had been sufficiently debated and had also been addressed in other related cases.

XIV. Appellant P's arguments, as far as relevant to the present decision, can be summarised as follows:

(a) The amendments corresponding to the main request and auxiliary request 1 were allowable under Rule 80 EPC. The deletion of granted claims 11 and 13 addressed some objections of added subject-matter of appellants O1 and O3. Claim 6 was amended to overcome appellant O2's objection that the term "the surfactant is entirely or substantially entirely castor oil" was insufficiently disclosed.

(b) Article 123(2) EPC

In the main request and auxiliary request 1, the feature "the prostaglandin therapeutic agent comprises travoprost" of claim 1 found basis in the application as filed on page 10, lines 29 to 32 and page 11, lines 8 to 14. The application as filed clearly considered combinations of prostaglandins (see top of page 6 and page 11, lines 4-6). Additionally, page 11, lines 8 to 18, stated the preferred concentrations of prostaglandin therapeutic agent but did not put any further restrictions on concentrations of individual components of the prostaglandin therapeutic agent. Therefore, the possibility for travoprost to be present at less than 0.00001 w/v% did not add subject-matter.

The lower and upper amounts of prostaglandin and of surfactant found basis, in combination, in page 11, second paragraph, of the application as filed. In this paragraph, the connectives "moreover", "further", "also" directed the skilled person towards the combination of the upper and lower

limits for both the therapeutic agent and the surfactant. Page 11, second paragraph, provided at least a direct and unambiguous disclosure of the outer limits of "at least 0.00001 w/v %" and "less than 5 w/v %" for the amount of therapeutic agent, and "at least 0.005 w/v %" and "less than 0.5 w/v %" for the amount of surfactant. The further combination with the "even more typically less than 0.3 w/v %" upper limit for the surfactant concentration did not involve any selection but defined a preferred subrange of surfactant concentration.

The combination of the presence of PQ-1 and absence of BAC was based on page 14, lines 11-14, stating that a composition substantially free of BAC was particularly preferred, on lines 14-15, stating that the presence of polymeric quaternary ammonium compounds was highly preferred, and on lines 29-30 confirming that PQ-1 was the most preferred of this group.

The fact that features described as typical were not meant as essential features was made clear by the expression "when used" on page 13, paragraph 3 of the application as filed (regarding the presence of borate. Also the disclosure on page 14, lines 9 and 30-31 of the application as filed, which provides basis for the inclusion of PQ-1 as preservative, did not state that a borate/polyol complex must be used together with PQ-1.

Although 0.2 % as a possible upper limit for the amount of surfactant was not disclosed in paragraph 2 of page 11, it was disclosed in claim 9 of the application as filed along with the values of 0.3%

and 0.15% which were disclosed in paragraph 2 of page 11. Therefore, it would be clear to the skilled person that this upper limit could form part of the claimed subject-matter.

Lastly, it was clear from the examples that no particular molecular weight constraints were placed on PQ-1. No intermediate generalisation occurred by not limiting PQ-1 to the specific number average molecular weight range mentioned on page 14, paragraph 4.

(c) Sufficiency of disclosure

The appellants-opponents had provided no rationale or evidence to cast doubt on the possible use of hydrogenated and/or ethoxylated vegetable oil surfactants other than HCO-40.

There was no evidence on file that the claimed compositions would not be stable under normal conditions. The stability tests reported in the patent were performed under stress conditions for 8 weeks at 55 °C. Furthermore, the breakdown product travoprost free acid was not toxic and did not make the compositions unsuitable for use as an ophthalmic pharmaceutical composition.

For the purpose of sufficient disclosure, all that was required was that the skilled person was given enough information to enable him to make compositions falling within the scope of the claims without undue burden. The claims did not require any specific degree of stability or bioavailability.

(d) Priority

Even though no single assignment document from the inventors of D15 to the patentee existed, the subject-matter of the claims of the main request was entitled to the priority date of D15 as a result of the following "chain of title":

- all six inventors of D15 executed in 2000 an employment contract with Alcon Research Ltd (ARL) wherein they assigned to Alcon Universal Ltd. (AUL) their inventor's right (see A050-A055);
- in 2001, AUL changed its name into Alcon Inc. (AI) (see A056);
- on 1 January 2008, ARL entered into a licence agreement (see A057) with Alcon International SA (AISA). This licence agreement acknowledged that AISA had assumed the economic benefits and burdens of AI's intellectual property. A057 further provided in paragraph 2.3 that any future discoveries "shall be the sole and exclusive property of the appropriate R&D Principal(s) funding such Discoveries". According to appellant P, there were no reasons to doubt that ARL was the R&D Principal in this case, because ARL was the employer of the six named inventors.

This was supported by the expert declaration A058.

Although AI was not a party to the agreement A057 between AISA and ARL, there was no reason to doubt the statement in A057 that AISA had acquired AI’s rights. This would include the prospective ownership of any IP rights arising from inventions conceived or developed by the 6 named inventors. It was acknowledged that A057 did not provide any hint

that the rights deriving from D15 and D16 were among these IP rights, for the simple reason that such rights only came into being after A057 was executed. For this reason precisely, the ownership of the priority rights from D15 and D16 fell to be considered under the terms of paragraph 2.3 of A057 and thus was passed from AISA to ARL as the appropriate R&D Principal. Contrary to the position of the opposition division, the appropriate standard was the "balance of probabilities". In the current case, there was no doubt that the priority right was transferred along with the ownership in the employment contracts, or that AUL changed its name to AI, or that ARL acquired the right in A057. The fact that ARL went on to file the PCT application showed, on the balance of probabilities, that they were the rightful applicant.

Thus the priority was validly claimed, and neither A045 nor A049 were part of the prior art.

(e) Novelty

If the priority of D15 was found to be not validly claimed, it was not disputed that A049 deprived the claims of the main request of novelty.

However, with respect to auxiliary request 1, the specific examples in A049 contained PQ-1 but did not clearly and unambiguously disclose a number average molecular weight between 2,000 to 30,000. This feature established novelty.

(f) Remittal to the opposition division

The appealed decision did not cover the issues of priority and patentability over A045 and A049. This constituted special reasons to remit the case. There were not sufficient written submissions from the parties on these issues. The fact that this prior art was assessed in other related cases did not justify that the Board proceed with examining these issues in the present case, because the claims in these related cases were different.

XV. Appellant P requests that the decision under appeal be set aside and that the patent be maintained based on the main request filed with its grounds of appeal dated 6 February 2018, or, alternatively, on the basis of one of the auxiliary requests AR1 to AR18 filed by letter dated 4 July 2018.

Appellant P further requests:

1- that the Board refers the following question to the Enlarged Board of Appeal:

what standard of proof is required to establish the applicant’s right to claim priority as "successor in title" within the meaning of Article 87(1) EPC;

2- that in case the Board disagrees and finds any one of the main request or AR1-AR18 to lack a valid claim to priority, the case be remitted to the opposition division for examination of novelty over A045 and A049;

3- If this request for remittal was denied, that a new series of auxiliary requests suffixed with "a", "b", "c" or "d" (with the letter of 31 December 2019,

appellant (patent proprietor) submitted the "a", "b", "c" and "d" versions of the MR, AR4, AR8 and AR12 only) be admitted and that it had the opportunity to introduce the further limitations of AR1 and/or AR2 and/or AR3 should these be deemed necessary to ensure compliance with Articles 76(1) and 123(2) EPC.

XVI. Each of the appellant O1, appellant O2 and appellant O3 requests that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. Main request (filed on 6 February 2018)

1.1 Rule 80 EPC

The amendments carried out in the main request are occasioned by grounds of opposition raised by the opponents, namely:

- the specification in claim 6 that the castor oil is "ethoxylated and/or hydrogenated" is in reply to appellant O2's objection of insufficiency of disclosure against the term "the surfactant is entirely or substantially entirely castor oil" (see appellant O2's notice of opposition, page 6);

- granted claims 11 and 13 were deleted in reply to objections of added subject-matter raised in their respective notices of opposition by appellant O1 (see page 5, section V.4) and by appellant O3 (page 6, line 33 to page 7, line 2; page 7, lines 6-15).

Thus, the main request meets the requirements of Rule 80 EPC.

1.2 Article 123(2) EPC

1.2.1 The appellants - opponents expressed the view that the feature "the prostaglandin therapeutic agent comprises travoprost" introduces added subject-matter. The Board does not share this view. The application as filed not only discloses that travoprost may be chosen as the prostaglandin therapeutic agent (see page 10, lines 29-32, and page 11, lines 8-9), but also that the prostaglandin therapeutic agent may be a combination of prostaglandins including travoprost (see top of page 6 and page 11, lines 4-6).

Claim 1 of the main request defines the range of 0.00001 w/v % to less than 5 w/v % for the amount of prostaglandin therapeutic agent, and openly defines the prostaglandin therapeutic agent as comprising travoprost. As a result, claim 1 allows for travoprost concentrations of less than 0.00001 w/v %. However, this does not present the skilled person with new technical information, because the application as filed defines the lower amount of 0.00001 w/v % for the prostaglandin therapeutic agent (see page 11, lines 10-11), but does not put any restrictions on concentrations of individual components of the prostaglandin therapeutic agent such as travoprost.

1.2.2 The Board does not consider either that claim 1 of the main request results from multiple selections.

The second paragraph on page 11 discloses lower and upper limits for the amounts of prostaglandin therapeutic agent and of surfactant in the form of four

lists of values going from the most general (i.e. lowest lower limit or highest upper limit) to the most specific. These lower and upper limits cannot be viewed as pertaining to separate embodiments but must be read in combination as pertaining to the same aqueous ophthalmic composition, considering the connectives ("moreover", "further", "also") and the repeated references to "the" composition. The choice of the lowest lower limit for both the therapeutic agent (0.00001 w/v %) and the surfactant (0.005 w/v %), and of the highest upper limit for the therapeutic agent (5 w/v %), which encompass all other values, is not seen as a selection. As to the intermediate value of 0.3 w/v % for the upper limit of surfactant, the Board agrees with appellant P that this choice does not involve any selection either but defines a preferred subrange of surfactant concentration, especially considering the stated purpose of the invention to lower the surfactant concentration (see e.g. bottom of page 2).

1.2.3 The combination of the presence of PQ-1 and absence of BAC is based on page 14, lines 11-14, stating that a composition substantially free of BAC is particularly preferred, on lines 14-15, stating that the presence of polymeric quaternary ammonium compounds is highly preferred, and on lines 29-30 confirming that PQ-1 is the most preferred of this group. The application as filed further states that the amounts of surfactants specified therein can offset losses in bioavailability that may occur when BAC is not present (see page 14, lines 18-19). This also provides a basis for the absence of BAC and establishes a connection with the other features of claim 1.

1.2.4 The appellants opponents pointed out further features of the description, namely the pH of 4-9 (page 12,

paragraph 2), the amount of more than 0.01 % borate (page 13, paragraph 3) and the use of boric acid polyol complex in case of the absence of BAC (see page 22 lines 14-16 and the examples).

The Board does not consider that any of these further features is described as essential in the application as filed. The expression "typically" (page 12, line 13) does not mean that the pH range is essential. The optional nature of the borate is made clear by the expression "when used" on page 13, paragraph 3. Lastly, the disclosure on page 14 of the application as filed, which provides basis for the absence of BAC and the inclusion of PQ-1 as preservative, does not state that a borate/polyol complex must be used in this case. Accordingly, the absence of these features in claim 1 of the main request does not introduce added subject-matter.

1.2.5 Regarding the alleged intermediate generalisation of polyquaternium-1 (PQ-1) from its combination with the molecular weights of page 14, paragraph 4, the Board shares appellant P's position that the examples clarify that no particular molecular weight constraints are placed on PQ-1.

1.2.6 Lastly, dependent claim 8 of the main request specifies an upper limit of 0.2 % by weight for the amount of surfactant. The Board considers that this value finds basis in the claims as filed.

In claim 1 as filed, the amount of surfactant is functionally defined by reference to an area under a concentration/time curve, which is not present in claim 1. However, claim 9 as filed, which is dependent on this claim 1 as filed, defines this amount of

surfactant to be 0.2 %, along with the values of 0.3% and 0.15% which are disclosed in paragraph 2 of page 11. In these circumstances, the Board considers that no added subject-matter is introduced by this upper limit in the context of the claims of the main request.

1.2.7 In conclusion, none of the objections raised by the appellants opponents justify that the opposition division's finding of compliance with Article 123(2) EPC be set aside. The requirements of Article 123(2) EPC are met.

1.3 Article 123(3) EPC

Claim 1 of the main request differs from claim 1 of the patent as granted by the additional feature "wherein the prostaglandin therapeutic agent comprises travoprost". This amendment does not extend the protection conferred by the patent, for the reasons set out in the communication under Article 15(1) RPBA issued on 23 June 2020 (see paragraph 4.3). The requirements of Article 123(3) EPC are thus met.

1.4 Sufficiency of disclosure

The appellants opponents submit that the use hydrogenated and/or ethoxylated vegetable oil surfactants other than HCO-40 is not sufficiently disclosed. In the Board's view, this allegation is not substantiated. No evidence or explanation were provided to show that aqueous ophthalmic pharmaceutical compositions according to claim 1 could not be prepared with surfactants other than HCO-40.

As to the alleged excessive extent of degradation, the Board considers that claim 1 of the main request does

not comprise any feature regarding any specific upper limit in degradation product. The expression "pharmaceutical composition" of claim 1 neither implies a specific upper limit in degradation, such as the upper limit of 1% required for regulatory approval, nor that the standards for microbial stability listed on paragraph [0059] of the patent be fulfilled.

Additionally, the appellant opponents did not provide any evidence that amounts of surfactants at the lower end of the claimed range (namely 0.005 %), or the absence of boric acid and polyols, would lead to compositions which are not suitable for use as ophthalmic pharmaceutical compositions. In this respect, the amounts of degradation products reported in the patent (see e.g. table H) were obtained under stress conditions (55°C). These data neither show that such degradation levels would arise under normal conditions, nor that the claimed composition could not be used topically.

Accordingly, the requirements of sufficiency of disclosure are met.

1.5 Priority

1.5.1 The patent claims priority from the applications D15 (US 61/037117) and D16 (US 61/111920). The validity of this priority claim is relevant to the determination of patentability for the claimed invention over A045 and A049.

1.5.2 Under Article 87(1) EPC, the right of priority belongs to the person who has duly filed D15 and D16 or his successor in title.

The applicants of the priority applications D15 and D16 are not identical to the applicant of the Euro-PCT application from which the patent in suit derives (European patent application number 09722278.0, filed under the PCT as PCT/US2009/037077, hereinafter "the application"):

- Alcon Research, Ltd. (hereinafter ARL) is the applicant of the application (and the patent proprietor, i.e. appellant P), whereas

- the applicants of D15 are Kabra, Jani, Gan, Bhagat, Chowhan and Dahlin, and

- the applicants of D16 are Bhagat, Carreras, Chowhan, Cuchi, Dahlin, Galán, Gan, García, González, Jani, Jiménez, Kabra and Martínez.

The question arises as to whether ARL is in fact the successor in title of the original applicants of D15 and D16. This formal requirement of Article 87(1) EPC must be assessed by the EPO, for the reasons set out in T 844/18 (see points 11-24 of the reasons).

1.5.3 If entitlement to priority is challenged, a successor in title, who desires to take advantage of the priority of a first application and who asserts that priority is rightly claimed from the first application, has to prove its entitlement to that right, which includes a valid transfer of the right of priority (cf. J 19/87, Facts, point VIII; T 1008/96, Reasons, point 3.3; T 577/11, Reasons, point 6.1; T 205/14, Reasons, point 3.5; and T 517/14, Reasons, point 2.6).

Here, appellant P only seeks to rely on a right of priority from D15. Consequently, the burden of proof is on appellant P to establish that:

(a) before the date of filing of the application (i.e. 13 March 2009),
(b) the right of priority derived from the US provisional application D15 had been transferred to it
(c) by the six original applicants and inventors
(d) in accordance with the requirements of the relevant law.

1.5.4 Appellant P did not produce any direct assignment of the right to priority for each of the six inventors of D15 to ARL. Rather, appellant P relies on the following "chain of title" to establish that it is the successor in title of the right to priority from D15:

(a) each of the six inventors of D15 signed in 2000 an employment contract with ARL wherein the inventor (employee) assigns to Alcon Universal Ltd. (hereinafter AUL) the rights to inventions "heretofore or hereinafter conceived" (see A050-A055);

(b) in 2001, AUL changed its name into Alcon Inc (hereinafter AI) (see A056);

(c) on 1 January 2008, i.e. shortly before the filing of the priority application D15, ARL entered into a licence agreement (see A057) with Alcon International SA (hereinafter AISA). This licence agreement states that AISA "has acquired and assumed the economic benefits and burdens with respect to AI's intellectual property

ownership" (see page 1). The licence agreement further provides that any future discoveries (see paragraph 2.3 of A057) "shall be the sole and exclusive property of the appropriate R&D Principal(s) funding such Discoveries". According to appellant P, there were no reasons to doubt that ARL was the R&D Principal in this case.

To further support this alleged "chain of title", appellant P filed Mr Taylor's declaration A058. The declaration states that "if ARL funded the Discoveries disclosed in [D15] and those Discoveries were developed or acquired as a result of activities conducted pursuant to the agreement [i.e. A057], then on the date [D15] was filed, any rights to claim priority therefrom otherwise owned by AISA (for example, by virtue of its acquisition and assumption of the economic benefits and burdens with respect to [AI]'s Intellectual Property ownership (as "Intellectual Property" is defined in the agreement)) were immediately transferred to ARL pursuant to the terms of the agreement."

1.5.5 In the opposition proceedings relating to the divisional case EP 3 042 646, the opposition division found this alleged "chain of title" unconvincing (see the grounds for the decision A048 in this divisional case, point 5.4.4-5.4.6).

The Board shares the opinion of the opposition division set out in A048 that the succession in title has not been credibly established, for the following reasons.

The six inventors of D15 had signed, in 2000, the employment contracts A050-A055, which assign to AUL their rights in respect of invention to be conceived thereafter. AUL then became AI in 2001. As a result,

when the right to priority from D15 came into existence at the time of its filing, namely on 17 March 2008, this right was automatically assigned to AI.

However, as acknowledged by appellant P (see letter of 31 December 2019, paragraph (45)), and as noted in the decision A048 (see paragraph 5.4.4), there is no evidence in A057 that this right to the priority from D15 was then transferred to AISA. The right to priority from D15 only came into existence after A057 was executed. Hence, the statement in A057 that AISA had acquired and assumed the economic benefits and burdens with respect to AI's intellectual property ownership does not cover the priority from D15. There is no support either in A057 for appellant P's assertion that this transfer of ownership would include the prospective ownership of any IP rights arising from inventions (later) conceived or developed by the 6 named inventors.

1.5.6 Accordingly, appellant P's case rest solely on paragraph 2.3 of A057, which provides that any future discoveries "shall be the sole and exclusive property of the appropriate R&D Principal(s) funding such Discoveries", which R&D Principal would in the present case be ARL according to appellant P.

However, even if ARL were considered to be the "R&D Principal(s)" funding the discoveries to which D15 pertains, the later provision of A057 assigning the property of these discoveries to ARL is contradicted by the earlier employment contracts assigning this property to AI.

The Board cannot follow appellant P's argument that the agreement A057 of 2008 between AISA and ARL would

supersede the employment contracts of 2000 or change the position for future rights, because neither the inventors of D15 nor AUL/AI are party to the agreement A057. There is no evidence that the rights deriving from D15 had been acquired directly by ARL or by AISA for it to assign them to ARL.

1.5.7 Finally, the Board does not share the opinion of appellant P that the fact that ARL went on to file the PCT application showed, on the balance of probabilities, that they were the rightful applicant. The fact that ARL filed a PCT application pertaining to the invention of D15 shows that it had knowledge of this invention, but it does not demonstrate that it had formally acquired the right to claim priority from D15 before filing the PCT application.

1.5.8 Accordingly, the Board finds that the transfer of the right of priority from D15 to ARL has not been demonstrated. The Board adds that appellant P's chain of title falls short of a proper demonstration even using the normal standard of proof of the "balance of probabilities". Consequently, the question as to whether a stricter standard of proof is required to establish the applicant’s right to claim priority as "successor in title" within the meaning of Article 87(1) EPC is not relevant to the present case. Accordingly, a referral to the Enlarged Board of Appeal regarding this question needs not be considered.

1.5.9 In conclusion, the priority from D15 is not validly claimed. This finding also applies to the priority from D16, since appellant P did not submit any evidence regarding the transfer of the right of priority deriving from this document.

1.6 Novelty

Since the priority is not validly claimed, A049 is prior art under Article 54(3) EPC. Appellant P does not dispute that A049 deprives claim 1 of the main request of novelty. The Board also regards the compositions shown in A049 (see compositions E, G, H, I-L, M-P and R-U on pages 15-23) as prejudicial to the novelty of the subject-matter of claim 1, since they comprise:

- no BAC,
- 0.002-0.004 % Travoprost,
- 0.1 % HCO40 (a hydrogenated castor oil) and
- PQ-1 as preservative.

Consequently, the main request does not meet the requirements of novelty.

Since appellant P does not contest that the main request lack novelty over A049, a remittal to the opposition division to examine this point is not appropriate.

2. Auxiliary request 1 - remittal

As a result of the finding that the priority is not validly claimed, and the filing, during appeal proceedings, of documents A045 and A049, new issues arise in respect of auxiliary request 1 which are not covered by the appealed decision, namely the question of novelty over A049 and inventive step taking into account A045.

Article 11 RPBA 2020 provides that 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. This provision must be applied taking into account the principle recalled in Article 12(2) RPBA 2020 that the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner.

The Board holds that special reasons in the sense of Article 11 RPBA 2020 are apparent in the present case because no appealable decision exists on the essential outstanding issues pertaining to A045 and A049. This conclusion is not modified by the fact that A045 and A049 may have been considered in proceedings relating to divisional cases, since the claims in these related cases may be different.

Under these circumstances, the Board considers it appropriate to allow appellant P's request for remittal of the case to the opposition division.

Order

For these reasons it is decided that:

1. The decision is set aside.

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

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated