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Datasheet for the decision of 28 April 2015

Case Number: T 1278/12 - 3.3.09

Application Number: 06806443.5

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Language of the proceedings: EN

Title of invention:
METHOD FOR STIMULATING THE INTESTINAL FLORA

Patent Proprietor:
N.V. Nutricia

Opponents:
NESTEC S.A.
United Pharmaceuticals S.A.
Fresenius Kabi Deutschland GmbH

Headword:

Relevant legal provisions:
RPBA Art. 12(4), 13(1)
EPC Art. 84, 54, 56

Keyword:
Admissibility of claim requests
Admissibility of late-filed evidence
Claim amendments - clarity
Novelty - further medical use claim
Inventive step - further medical use claim
Request for referral - further medical use claim

Decisions cited:
G 0005/83, G 0003/14, T 1020/03

Catchword:

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Case Number: T 1278/12 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 28 April 2015

Appellant: (Patent Proprietor)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
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Representative:	Starck-Loudes, Anne-Caroline Cabinet Becker & Associés 25, rue Louis le Grand 75002 Paris (FR)
Respondent: (Opponent 3)	Fresenius Kabi Deutschland GmbH Else-Krömer-Strasse 1 61352 Bad Homburg (DE)
Representative:	Fresenius Kabi Deutschland GmbH Patent Department Else-Kröner-Straße 1 61352 Bad Homburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 March 2012 revoking European patent No. 1940250 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	W. Sieber
Members:	M. O. Müller
	K. Garnett

Summary of Facts and Submissions

I. This decision concerns the appeal filed by the proprietor (N.V. Nutricia) of European patent No. 1 940 250 against the decision of the opposition division to revoke it.

II. Oppositions were filed by opponent I (Nestec SA), opponent II (United Pharmaceuticals) and opponent III (Fresenius Kabi Deutschland GmbH) requesting revocation of the patent in its entirety on the grounds that the claimed subject-matter was neither novel nor inventive (Article 100(a) EPC), that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC) and that the patent contained subject-matter which extended beyond the content of the application as filed (Article 100(c) EPC).

The documents submitted during the opposition proceedings included:

D6: WO 2004/112509 A2;

D7: R. Bennet et al, Acta Paediatr., volume 81, 1992, pages 784 to 787;

D26: WO 2005/039319 A2;

D32: E. Bezirtzoglou et al, J. Perinat. Med., volume 17, 1989, pages 139 to 143;

D36: EP 1 714 660 A1;

D38: B. Laubereau et al, Arch. Dis. Child, volume 89,

2004, pages 993 to 997;

D46: Product information on Lactospectrum® of Laboratories Le Stum;

D47: Declaration of Mr Denis, signed 6 January 2012;

D48: "Nutri-Thema Ecosystème digestif 1ère partie", La Lettre d'information des Laboratoires Le Stum, Numéro 4, September 2005, pages 1 to 6;

D49: J. Knol et al, J. Ped. Gastroenterol. Nutr., volume 40, 2004, pages 36 to 42;

D50: Y. Morishita et al, Nutrition Research, volume 22, 2002, pages 1333 to 1341; and

D51: M.-M. Grölund et al, J. Ped. Gastroenterol. & Nutr., volume 28, 1999, pages 19 to 25.

III. The opposition division's decision, announced orally on 29 February 2012 and issued in writing on 23 March 2012, was based on a main request (patent as granted) as well as auxiliary requests 1 to 3. According to the decision, the invention as defined in claim 1 of the main request was insufficiently disclosed, claim 1 of auxiliary request 1 did not meet the requirements of Article 123(2) EPC, claim 1 of auxiliary request 2 lacked inventive step in view of any of D7, D38 or D48 taken as the closest prior art and claim 1 of auxiliary request 3 lacked inventive step in view of D7 taken as the closest prior art.

The only claim request relevant to the present decision is auxiliary request 3, claim 1 of which reads as follows:

"1. Use of at least one microorganism and at least one indigestible oligosaccharide for the manufacture of a composition for enteral administration to an infant delivered via caesarean section, wherein the composition contains at least one species of Bifidobacteria selected from the group consisting of Bifodobacterium breve, Bifodobacterium infantis, Bifodobacterium bifidum, Bifodobacterium catenulatum, Bifodobacterium adolescentis and Bifodobacterium longum and wherein the composition comprises an indigestible oligosaccharide selected from the group consisting of transgalactooligosaccharides, indigestible dextrins, xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligo-saccharides, isomalto-oligosaccharide and fructopolysaccharides."

IV. On 31 May 2012, the proprietor (hereinafter: "the appellant") filed an appeal and, on the same day, paid the prescribed fee. The statement setting out the grounds of appeal was filed on 2 August 2012 together with auxiliary requests 1 to 10, the main request being that the patent be maintained as granted.

V. A response was filed by opponent II (hereinafter: "respondent II") with its letter of 5 December 2012, by opponent I (hereinafter: "respondent I") with its letter of 11 December 2012, and by opponent III (hereinafter "respondent III") with its letter of 17 December 2012 together with:

D54: E. F. Werner et al., Obstetrics & Gynecology,

volume 120(3), 2012, pages 560 to 564 including a copy of the form used for ordering the document.

VI. With its letter of 4 February 2013, the appellant filed a reply including new auxiliary requests 6 to 9, as well as:

D55: M. Hällstrom et al., Eur. J. Clin. Microbiol. Infect. Dis., volume 23, 2004, pages 463 to 470; and

D56: New experimental evidence.

Claim 1 of new auxiliary request 6, which later became the main request, reads as follows:

"1. Use of at least one microorganism and at least one indigestible oligosaccharide for the manufacture of a composition for enteral administration to an infant delivered via caesarean section, wherein the composition contains at least one species of Bifidobacteria selected from the group consisting of Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium bifidum, Bifidobacterium catenulatum, Bifidobacterium adolescentis and Bifidobacterium longum, and wherein the composition comprises an indigestible oligosaccharide selected from the group consisting of transgalactooligosaccharides, indigestible dextrins, xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligo-saccharides, isomalto-oligosaccharide and fructopolysaccharides."

VII. By its communication dated 8 September 2014, the Board communicated its preliminary opinion to the parties.

The Board observed that novelty of the subject matter of claim 1 of the then auxiliary request 1 over D6, D26 and D36 was questionable. In this context it was pointed out that the indication "composition for enteral administration to an infant delivered via caesarean section" appeared not to constitute a therapeutic indication as required for a further medical use claim. Such an indication was limiting only in so far as the composition had to be suitable for enteral administration to an infant delivered via caesarean section. The board furthermore observed that D48 alone was of particular relevance for inventive step. The board finally stated that in its preliminary view D56 could have been filed during the opposition proceedings so that it might not be admitted into the proceedings.

VIII. By its letter dated 26 September 2014, respondent I provided arguments relating to the board's preliminary opinion as regards D36.

IX. By its communication dated 10 October 2014, the Board issued a second communication clarifying that D36 appeared to be prior art under Article 54(3) EPC and therefore not relevant to inventive step.

X. By its letter dated 9 March 2015, the appellant submitted a main request and auxiliary requests 1 to 3 and withdrew all previous claim requests. The relevant requests for the current decision are the main request and auxiliary request 1.

Claim 1 of the main request is identical to claim 1 of auxiliary request 6 filed with letter dated 4 February 2013 (see point VI above). Claim 1 of auxiliary

request 1 reads as follows (differences from claim 1 of the main request in bold type):

"1. Use of at least one microorganism and at least one indigestible oligosaccharide for the manufacture of a composition for enteral administration to an infant delivered via caesarean section, **for increasing the biodiversity of microorganisms in the intestinal flora of said infant**, wherein the composition contains at least one species of Bifidobacteria selected from the group consisting of Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium bifidum, Bifidobacterium catenulatum, Bifidobacterium adolescentis and Bifidobacterium longum, and wherein the composition comprises an indigestible oligosaccharide selected from the group consisting of transgalactooligosaccharides, indigestible dextrins, xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligo-saccharides, isomalto-oligosaccharide and fructopolysaccharides."

XI. On 28 April 2015, oral proceedings were held before the Board. Initially the appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of its main request or alternatively one of its auxiliary requests 1 to 3, all as filed with its letter dated 9 March 2015. After the Board had announced its opinion on the main request and auxiliary request 1, the appellant withdrew its auxiliary requests 2 and 3.

The appellant furthermore requested that the following questions be referred to the Enlarged Board of Appeal:

"1. Does *specified use* according to G 5/83 mean that a second medical use claim, either Swiss type

or EPC2000 format, should explicitly define the therapeutic treatment in the claim, for instance complying with specific requirement such as (i), (ii), and (iii) in T 4/98, in order to fall within the ambit of A54(5) EPC, or does *specified use* merely distinguish from *unspecified* first medical use claims according to T 1020/03?

2. In the latter case, does it suffice that the claim is in the appropriate second medical use format and that the method encompassed by applying the features in the claim implicitly or inherently falls, as derivable from the application as a whole, within the scope of A53 EPC?

3. In case specified use should be explicit in the claims, to what extent is specificity required?"

The appellant finally requested that D46 to D51 be not, or no longer, admitted into the proceedings.

The respondents requested that:

- The appeal be dismissed;

- None of the appellant's claim requests be admitted into the proceedings;

- D46 to D51 be admitted into the proceedings; and

- D55 and D56 be not admitted into the proceedings.

XII. The appellant's arguments, in as far as relevant to the present decision, can be summarised as follows:

- The main request should be admitted into the proceedings. This request in substance corresponded to auxiliary request 3 discussed during the oral proceedings before the opposition division such that the respondents could not be surprised by such a request being filed during the appeal proceedings. Furthermore, the arguments made in the grounds of appeal with regard to the then auxiliary request 1 applied by way of analogy to the then auxiliary request 4, which in substance corresponded to the present main request. It was thus not true that, as argued by the respondents, the grounds of appeal were not substantiated with regard to the then auxiliary request 4.

  The subject-matter of claim 1 of the main request was novel. The therapeutic effect of claim 1 was implicit and inevitable due to fact that the group of caesarean-section delivered infants was specifically targeted. Furthermore, the description of the opposed patent disclosed various therapeutic effects which were covered by claim 1. According to T 1020/03, claim 1 thus constituted a further medical use claim. It was in particular set out in this decision that for a claim to qualify as a further medical use claim, it did not need to specify any therapeutic effects. If the board thought that T 1020/03 was wrong, then it should refer several appropriate questions to the Enlarged Board of Appeal (see point XI above).

- Auxiliary request 1 should be admitted into the proceedings. The inclusion of the feature of increased biodiversity into all the independent

claims represented a reaction to the respondents' objection that claim 1 did not constitute a second medical use claim. This objection had been raised for the first time during the oral proceedings before the opposition division. Therefore, the filing of auxiliary request 5 with the grounds of appeal, to which auxiliary request 1 in substance corresponded, constituted a direct reaction to the respondents' objection.

The feature of increased biodiversity was clear. The skilled person would know from the opposed patent and the prior art that the increase of biodiversity referred to in claim 1 meant that, as a consequence of the claimed administration of certain Bifidobacteria species, the intestinal flora was enriched by one or more of these species, which were originally not present in the infant's intestine. As regards the respondents' objection that different measurement methods would lead to different results for the biodiversity, this objection was a mere allegation and was not backed up by any experimental evidence.

As regards inventive step, D56 should be admitted into the proceedings. It was *prima facie* relevant, because it proved that the claimed use led to an increased biodiversity in infants born via caesarean section. More specifically, the experiment of D56 carried out on infants' faeces showed that the administration of galactooligosaccharide and Bifidobacteria breve (hereinafter the acronym "B." will be used in the context of Bifidobacteria species) led to an increase in the number of total Bifidobacterium, the number of B. longum and the number of

B. breve. The administration of galactooligosaccharide and B. breve created a favourable environment in the infants' intestines not only for B. longum and B. breve but also for other species. D56 should be admitted for the further reason that the experiments in D56 took a long time, since in most European countries approval by a medical-ethical committee was needed to get faecal samples from infants and, in the end, a country had to be chosen for the experiments where no such approval was needed.

The subject-matter of claim 1 was inventive. D48 did not constitute the closest prior art since the passage referred to by the respondents about the adjustment of the intestinal flora to a more natural one did not relate to infants born via caesarean section. D48 also did not mention the problem referred to in the opposed patent, namely that the guts of infants born via caesarean section were devoid of Bifidobacteria. Even if D48 was considered to represent the closest prior art, the subject-matter of claim 1 was inventive. The problem solved over D48 was the provision of a composition that led to a higher biodiversity in the guts of infants delivered via caesarean section. Since the passage about the adjustments of the intestinal flora to a more natural one did not relate to infants born via caesarean section, the skilled person would not have had any incentive to apply a composition as disclosed in this passage to this type of infants, let alone the product Lactospectrum® disclosed on the last page of D48.

XIII. The respondent's arguments, in as far as relevant to the present decision, can be summarised as follows:

- Although the main request in substance corresponded to auxiliary request 3 before the opposition division, and was filed as auxiliary request 4 with the statement of grounds of appeal, it should not be admitted into the proceedings since (i) the statement of grounds of appeal was not substantiated with regard to the then auxiliary request 4 and (ii) the main request could have been filed during the opposition proceedings (Article 12(4) RPBA).

  The amendments in the main request did not meet the requirements of Article 123(2) EPC.

  The subject-matter of claim 1 lacked novelty. This claim did not constitute a claim relating to a further medical use since it did not specify any therapeutic effect. This view was in conformity with T 1020/03, which clearly stated that for a claim to qualify as a further medical use claim, the therapeutic effects had to be in the claim to some level of specificity. Therefore the enteral administration to an infant delivered via caesarean section in claim 1 limited the composition defined in this claim only in so far as it had to be suitable for this enteral administration. Since each of D6, D26 and D36 disclosed such compositions, the subject-matter of claim 1 lacked novelty over each of these documents.

- Auxiliary request 1 should not be admitted into the proceedings since it could have been filed

during the first instance proceedings. Indeed, the opposition division had indicated during the oral proceedings that none of the appellant's claim requests was allowable and, thereafter, had given the appellant another chance to file additional requests, but yet it had not filed a claim set including the feature of increased biodiversity as now present in auxiliary request 1. In fact, this feature had never been an issue during the opposition proceedings. Furthermore, auxiliary request 1 should not be admitted for the additional reason that it introduced new deficiencies into the proceedings.

The feature of increasing biodiversity in claim 1 lacked clarity under Article 84 EPC. It was in particular not clear whether the term "increased biodiversity" in claim 1 referred to an increased number of any bacterial species including species different from Bifidobacteria or only to an increased number of Bifidobacteria species. Furthermore, the measurement method by which the biodiversity had to be determined was not specified. In particular two different methods DGGE and TGGE were given in the opposed patent and these had a different resolution so that the application of one method could lead to the finding that biodiversity had been increased while the application of the other method could give the opposite result. Moreover, it was not clear by how many species the intestinal flora had to be enriched for the biodiversity of the flora to qualify as being increased. Finally, it was not clear whether it would qualify as increased biodiversity if B. longum was administered to an infant already containing this species and if as a

consequence thereof the number of only B. longum increased.

As regards inventive step, D56 should not be admitted into the proceedings. It was filed extremely late and not *prima facie* relevant. The appellant's argument that the feeding with B. breve in D56 created a favourable environment in the intestine for the growth of further bacteria species already present in low amounts raised the question whether such a favourable environment could also be created by the administration of other Bifidobacteria different from the specific one administered in D56.

The subject-matter of claim 1 of auxiliary request 1 was not inventive in view of D48 as the closest prior art. This document disclosed that the intestines of infants born via caesarean section did not contain any Bifidobacteria. This document furthermore suggested on page 3 feeding these infants with a composition containing prebiotic oligosaccharides and probiotics in order to get a more natural and thus a more diversified intestinal flora. The wording "all these infants" in this passage clearly referred to the infants discussed in the previous three subsections, which discussion included infants born via caesarean section. The problem to be solved over D48 was merely to choose a specific composition of prebiotics and probiotics. The solution to this problem was disclosed in D48 itself, which referred on page 6 to Lactospectrum®, which, as proven by D46 and D47, contained B. infantis and longum as well as fructooligosaccharides.

The auxiliary request furthermore did not meet the requirements of Articles 83 and 123(2) EPC.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. Admissibility

2.1 The respondents requested that the main request be not admitted into the proceedings.

2.2 For the admissibility of the main request, the timeline in which this request and its corresponding preceding requests were filed is important. This timeline is as follows:

During the oral proceedings before the opposition division, the appellant filed an auxiliary request 3 that was found not to be allowable by the opposition division (for the wording of claim 1 of this request, see point III above). With the statement of grounds of appeal (letter dated 2 August 2012), the appellant re-filed this request as auxiliary request 4. With its letter of 4 February 2013, the appellant filed an auxiliary request 6 which in substance corresponded to this auxiliary request 4 (for the wording of claim 1 of auxiliary request 6, see point VI above). Then, with its letter of 9 March 2015, the appellant made its previous auxiliary request 6 to its main request. Consequently, the main request, the admissibility of which has been contested, is identical to auxiliary request 6 filed with letter of 4 February 2013, which in substance corresponds to auxiliary request 4 filed

with the statement of grounds of appeal, which is identical to auxiliary request 3 discussed during the oral proceedings before the opposition division.

2.3 The respondents' first argument against the admittance of the main request was that the statement of grounds of appeal was entirely unsubstantiated as regards auxiliary request 4 then filed, and by the same token the present main request. The present main request should therefore not be admitted into the proceedings.

2.4 The statement of grounds of appeal indeed focused on inventive step of the then auxiliary request 1 rather than the then auxiliary request 4, to which the present main request in substance corresponds. More specifically, the key argument in the statement of grounds of appeal was that auxiliary request 1 was inventive since the problem solved was to provide Bifidobacteria biodiversity in caesarean section delivered infants and none of the closest prior art documents used by the opposition division addressed the issue of increased biodiversity. However, this argument applied by way of analogy also to the then auxiliary request 4. More specifically, in the same way as for the then auxiliary request 1, the problem to be solved by auxiliary request 4 is to provide Bifidobacteria biodiversity in caesarean section delivered infants. Consequently, contrary to the respondents' assertion, the statement of grounds of appeal was sufficiently substantiated as regards the then auxiliary request 4.

2.5 The respondents' second argument was that the main request could have been filed during the opposition proceedings and thus should not be admitted under Article 12(4) RPBA. This article indeed gives the Board a discretion not to admit a claim request if it could

have been filed during the first instance proceedings. However, as set out above, the main request in substance corresponds to auxiliary request 3 filed during the opposition proceedings. So, the main request was in substance actually filed during opposition proceedings. Consequently, it is not appropriate to apply Article 12(4) RPBA with respect to the admissibility of the main request.

2.6 The Board therefore decided to admit the main request into the proceedings.

3. Novelty

3.1 Claim 1 refers to the use of at least one microorganism and at least one indigestible oligosaccharide for the manufacture of a composition for enteral administration to **an infant delivered via caesarean section**, wherein the composition contains at least one species of Bifidobacteria selected from the group consisting of B. breve, B. infantis, B. bifidum, B. catenulatum, B. adolescentis and B. longum, and wherein the composition comprises an indigestible oligosaccharide selected from the group consisting of transgalactooligosaccharides, indigestible dextrins, xylooligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligo-saccharides, isomalto-oligosaccharide and fructopolysaccharides.

3.2 As not disputed by the appellant, a composition containing the components required by claim 1 is disclosed in each of D6, D26 and D36. More specifically,

- example 3 of D6 discloses the use of B. longum (corresponding to the Bifidobacteria of claim 1)

and fructooligosaccharides ("FOS") (corresponding to the indigestible oligosaccharide of claim 1) for the manufacture of a starter formula for infants;

- example 4 of D26 discloses the use of B. breve (corresponding to the Bifidobacteria of claim 1) and galactooligosaccharides and polyfructose (corresponding to the indigestible oligosaccharide of claim 1) to prepare an infant formula; and

- example 1 (the only example) of D36 discloses the use of B. breve (corresponding to the Bifidobacteria of claim 1) and transgalactooligosaccharide (corresponding to the indigestible oligosaccharide of claim 1) to prepare an infant nutrition.

Since the compositions disclosed in the above examples of D6, D26 and D36 are infant formulae, they must be suitable for enteral administration to infants delivered via caesarean section.

3.3 However, the appellant argued that claim 1 constituted a further medical use claim (also denoted as "Swiss type claim"), where the reference to the patient group of caesarean section infants implicitly indicated a therapeutic effect. Since the use of the claimed composition for this patient group was not disclosed in any of D6, D26 or D36, the implicit therapeutic effect rendered the subject-matter of claim 1 novel over these documents.

It has thus to be decided whether the reference to "an infant delivered via caesarean section" qualifies claim 1 as a further medical use claim.

3.3.1 According to G 5/83, a further medical use claim is a claim directed to the use of a substance or composition for the manufacture of a medicament **for a specified therapeutic application** (headnote II and points 19 to 21). Such a claim is novel according to G 5/83 if the therapeutic application, i.e. the therapeutic effect obtained by the claimed use, is novel.

3.3.2 In the present case, claim 1 relates to the use of a composition for enteral administration to an infant delivered via caesarean section. An enteral administration to an infant delivered via caesarean section only specifies the mode of delivery to the patient, but does not relate to any therapeutic effect obtained thereby. Therefore, the format of claim 1 is not the one prescribed by G 5/83 for further medical use claims.

3.3.3 While this was not disputed by the appellant, it argued that according to T 1020/03, the therapeutic effect did not need to be specified in a claim to qualify it as a further medical use claim.

3.3.4 The Board does not share the appellant's view.

Firstly, T 1020/03 refers to a case where the relevant claims (claim 1 and 13) read as follows:

"1. Use of insulin-like growth factor-I (IGF-I) in the preparation of a medicament for administering to a mammal **so as to sustain its biological response in the treatment of a chronic disorder in the mammal** wherein ..." (emphasis added by the board);

"13. Use of insulin-like growth factor—I (IGF-I) in the preparation of a medicament **for treating chronic renal failure in a mammal** wherein ..." (emphasis added by the board).

Consequently, the claims underlying the case in T 1020/03 specify therapeutic effects, namely the sustainment of a biological response in the treatment of a chronic disorder in a mammal (claim 1) and the treatment of chronic renal failure in a mammal (claim 13). The case underlying T 1020/03 thus is not comparable to the present one where no therapeutic effect at all is specified in claim 1.

Secondly, contrary to the appellant's assertion, the board in T 1020/03 did not hold that no therapeutic effect is needed in a claim to qualify it as a second medical use claim. More specifically:

- In point 7 of that decision, the board held that a claim to the preparation of a composition for a further medical use was allowable, irrespective of the detail in which that use was specified, subject to the use being novel and inventive.

  The Board then went on to discuss three specific cases, in all of which the claims specified a therapeutic effect.

- In subsequent passages of T 1020/03, the Board referred numerous times to the claim format approved by G 5/83. For instance, in point 12, the board stated that "it considers that a claim formulated in the way approved by the Enlarged Board of Appeal in decision G 0005/83 prima facie cannot be considered as producing any results

contravening Article 52(4) EPC [1973], ...". The way approved by the Enlarged Board of Appeal in G 5/83 can only be the one defined in headnote II of this decision, namely of the use of a substance or composition for the manufacture of a medicament **for a specified new and inventive therapeutic application**.

- In point 18, the board held that claims "which take the form of the use of a composition for the preparation of a medicament **for a specified therapeutic use**, will thereby avoid being in conflict with Article 52(4) EPC [1973], irrespective of the degree of detail with which the therapeutic use is stated" (emphasis and insertion in square brackets added by the present board).

Consequently, there can be no doubt that the claims which the board in T 1020/03 had in mind and on which its decision was based were claims in which the therapeutic use was specified to some extent. In fact, the board even explicitly stated in point 34 of its decision that in a further use claim "... the further medical indication **must be specified in the claim with some degree of specificity**" (emphasis added by the board).

3.3.5 Since claim 1 of the main request does not specify any therapeutic effect at all, it represents a non-medical use claim. Therefore the wording "for enteral administration to an infant delivered via caesarean section" limits claim 1 only in so far as the composition has to be suitable for the enteral administration to caesarean section infants. Since this suitability is given in the above examples of D6, D26

and D36 (see point 3.2 above), these are novelty-destroying for the subject-matter of claim 1.

4. In view of the fact that the main request is thus not allowable, there is no need to discuss the respondents' further objections under Article 123(2) EPC.

5. Request for referral

5.1 The appellant requested that certain questions (see point XI above) be referred to the Enlarged Board of Appeal should the board think that T 1020/03 was wrong since the Board would then be diverging from T 1020/03.

5.2 The present Board does however not consider decision T 1020/03 to be incorrect and in fact follows rather than diverges from this decision (see point 3.3.4 above). There was therefore no need to refer the appellant's questions to the Enlarged Board of Appeal, which is why the board refused the appellant's request for referral.

Auxiliary request 1

6. Admissibility

6.1 The respondents requested that this request be not admitted into the proceedings since it could have been filed during the first instance proceedings. More specifically, all independent claims of auxiliary request 1 contained the feature of increased biodiversity and such a feature had never been on file during the opposition proceedings despite the fact that the opposition division had indicated during the oral proceedings that none of the appellant's claim requests was allowable and, thereafter, had given the appellant

another chance to file additional requests. So the appellant had had every opportunity to submit claim requests restricted by the feature of increased biodiversity but did not do so during the entire opposition proceedings. Auxiliary request 1 should therefore not be admitted, under Article 12(4) RPPA.

Auxiliary request 1 in substance corresponds to auxiliary request 5 filed with the grounds of appeal which already contained the feature of increased biodiversity in all independent claims. As set out by the appellant, such a request was filed with the statement of grounds of appeal simply as a measure of precaution, because the respondents had raised the objection during the oral proceedings before the opposition division that a claim without the indication of a specific therapeutic effect did not constitute a second medical use claim. There was no need to file this request during the oral proceedings since the opposition division did not follow the respondents' objection but acknowledged in the appellant's favour that claim 1 then on file (without any specification of a further therapeutic effect) constituted a second medical use claim.

Therefore, it is not appropriate to apply Article 12(4) RPBA so as not to admit auxiliary request 1.

6.2 Respondent II also argued that the filing of auxiliary request 1 introduced new deficiencies into the proceedings such that this request should not be admitted. This objection relates to the criterion of complexity as referred to in Article 13(1) RPBA. However, this article is only relevant for claim requests filed by an appellant after the statement of grounds of appeal and thus does not apply to auxiliary

request 1, which in substance was filed with the statement of grounds of appeal as auxiliary request 5.

6.3 The Board therefore decided to admit auxiliary request 1 into the proceedings.

7. Amendments - Article 84 EPC

7.1 The respondents attacked the feature of increased biodiversity in claim 1 under Article 84 EPC. This feature was not present in any of the granted claims and hence is open to an objection under Article 84 EPC in opposition appeal proceedings (G 3/14).

The respondents' main arguments were that it was not clear whether (i) the term "increased biodiversity" in claim 1 referred to an increased number of any bacterial species including species different from Bifidobacteria or only to an increased number of Bifidobacteria species, (ii) by how many species the intestinal flora had to be enriched for the biodiversity of said flora to qualify as being increased, and (iii) whether it would qualify as an increased biodiversity if B. longum was administered to an infant already containing this species, and if as a consequence thereof the number of only B. longum increased.

7.1.1 The Board does not find the respondents' arguments convincing. Claim 1 pertains to the administration of an indigestible oligosaccharide and one or more species of Bifidobacteria to infants born via caesarean section in order to increase biodiversity of their intestinal flora. The skilled person reading the opposed patent would know that the intestinal flora of infants born by caesarean section is essentially devoid of any

Bifidobacteria (see table 1 of the opposed patent). In fact this had been known to the skilled person long before the priority date of the opposed patent (see, e.g., the table on page 140 of D32, which was published in 1989). The increase of biodiversity referred to in claim 1 can thus only mean that as a consequence of the claimed administration of certain Bifidobacteria species, the intestinal flora gets enriched by **one or more** of these **Bifidobacteria** species, **which were not present in the infant's intestine before**. There is thus no ambiguity as regards points (i) to (iii) referred to by the respondents.

7.1.2 The respondents also argued that the measurement method by which the biodiversity had to be determined was not specified. In particular two different methods, DGGE and TGGE, were given in the opposed patent (paragraph [0058]), and these had a different resolution such that the application of one method could lead to the finding that biodiversity had been increased while the application of the other method could give the opposite result.

However, no proof has been provided that the administration of the same composition leads to different conclusions on the questions of increased biodiversity, depending on which of the two methods is applied. Therefore, the respondents' objection is a mere assertion without any proper substantiation, which is why this objection must fail.

7.1.3 The feature of increased biodiversity in claim 1 is thus clear. Therefore, the claims of auxiliary request 1 are not objectionable under Article 84 EPC.

8. Novelty

Unlike the claims of the main request, all independent claims of auxiliary request 1 refer with some degree of specificity to a therapeutic effect, namely to the increase of the biodiversity of microorganisms in the intestinal flora of infants born via caesarean section. Hence these claims constitute second medical use claims, so that the novelty objection made with regard to the main request no longer applies, and novelty over the cited prior art is to be acknowledged. Indeed, the respondents did not raise any novelty objection.

9. Admissibility of documents D46 to D49 and D56

9.1 In particular D46 to D48 and D56 were cited in the context of inventive step and their admissibility was a point of dispute. Therefore this issue will be discussed before assessing inventive step.

9.2 Admissibility of D46 to D49

D46 to D49 were filed by respondent II during the opposition proceedings (letter dated 10 January 2012) and admitted into the proceedings by the opposition division. The appellant requested that D46 to D49 be no longer admitted into the proceedings as these documents were filed late and were not *prima facie* relevant. Except for D48, no reasons were given for this allegation.

As will be set out below in points 9.3 to 9.5, the board considers D48 to be *prima facie* relevant. In view of this, and in the absence of any arguments from the appellant as regards D46, D47 and D49, the board did not see any reason to set aside the decision of the

opposition division to admit these documents. The Board therefore refused the appellant's request that D46 to D49 be no longer admitted into the proceedings.

9.3 Admissibility of D56

9.3.1 The respondents requested that D56 be not admitted into the proceedings.

9.3.2 D56 is an experimental report filed by the appellant after its statement of grounds of appeal (letter dated 4 February 2013) to show that the compositions as defined in claim 1 solve the problem of increasing biodiversity such that the claimed use is inventive. In D56, faecal samples were collected from infants born via caesarean section and fermented after the addition of

- a prebiotic mixture comprising galacto-oligosaccharide (GOS), or

- a prebiotic mixture comprising GOS and B. breve (according to claim 1).

The different levels of B. breve (added) and the number of B. longum (present at the beginning to some extent) as well the number of total Bifidobacteria was determined throughout the fermentation. It is stated in D56 that for the samples with the prebiotic mixture and B. breve, i. e. the composition according to claim 1, an increase in the number of total Bifidobacteria, the number of B. longum and the number of B. breve was observed. According to the appellant, these results proved that the claimed use led to an increased biodiversity in infants born via caesarean section.

9.3.3 It was already stated during opposition proceedings by respondent III in its letter of 1 July 2011 (page 5), i.e. more than half a year before the oral proceedings before the opposition division, that there was no proof in the opposed patent for an increased biodiversity ("Ferner wäre einer der Vorteil [sic] der Erfindung, dass die erfindungsgemäßen Zusammensetzungen die Biodiversität der intestinalen Flora erhöhen würden (Replik, S. 7, letzter Satz des ersten vollständigen Absatzes und zweiter vollständiger Absatz komplett). Bezüglich des letzten Punktes soll zunächst daraufhin gewiesen werden, dass eine Erhöhung der Biodiversität im Streitpatent an **keiner Stelle nachgewiesen** wird. Dazu liegt weder ein *in vitro* noch ein *in vivo* Nachweis vor:...")

In fact, this lack of proof had already been objected to by respondent II in its notice of opposition, where it stated that example 3 of the patent (the only example related to the feeding of infants born via caesarean section) did not contain any comparison of the effect obtained with the composition according to example 3 and a composition devoid of pre- and probiotics ("Cet exemple ne fournit aucun résultat, en particulier aucune comparaison des flores intestinales respectives d'enfants mis au monde par césarienne auxquels auraient été administrés pour les uns la composition décrite dans l'exemple 3, pour les autres une composition similaire dépourvue de pré- et probiotiques.")

The appellant thus could, and in fact should, have filed D56 in the opposition proceedings.

9.3.4 During the oral proceedings, the appellant referred in particular to the finding in D56 that the total number

of bacteria in the experiment with GOS and B. breve was higher than the sum of the B. longum and breve. According to the appellant, this implied that the administration of galactooligosaccharide and B. breve had not only increased the number of B. longum and breve, i.e. those specifically referred to in D56, but also of further Bifidobacteria, which were already present in the infants' faeces in low amounts. The appellant explained that by the administration of the B. breve, the amount of these bacteria in the intestines grew, such that these bacteria created a favourable environment in the intestine for the growth of further Bifidobacteria species already present in low amounts.

As set out by the respondents during the oral proceedings, this argument raises the question whether such a favourable environment can also be created by the administration of other Bifidobacteria species different from the specific one administered in D56. Consequently, the submission of D56, and in particular the explanations given by the appellant during the oral proceedings, raised a complex new issue.

9.3.5 During the oral proceedings, the appellant argued that the experiments in D56 took a long time since in most European countries, approval by a medical-ethical committee was needed to get faecal samples from infants and in the end a country had to be chosen for the experiments where no such approval was needed.

Accepting this, it would be extremely unfair to the respondents, on the one hand to allow the appellant to take years for the tests in D56 but on the other to give the respondents just the time during the oral

proceedings to react to the appellant's new submissions as regards D56.

9.3.6 In view of the above, the Board decided not to admit D56 into the proceedings (Article 13(1) RPBA).

10. Inventive step

10.1 The closest prior art

10.1.1 The opposed patent refers to methods for feeding and to compositions to be administered to infants delivered via caesarean section (paragraph [0001]) and aims at stimulating a healthy development of the intestinal flora of these infants (paragraph [0015]).

10.1.2 D48 discloses that the intestines of newborn infants are sterile and that the initial colonisation takes place by coming into contact with the vaginal and faecal flora of the mother while passing the vaginal route during birth (left-hand column on page 2). 85% of the infants born via the vaginal route have a strictly anaerobic intestinal flora composed of Bifidobacteria already at the fifth day after birth (second column from the left on page 2). The first bacteria with which infants born via caesarean section come into contact are those of the air and the hospital's personnel, such that the first bacteria that are installed in these infants are Enterobacteria, Enterococci and Staphylococci, while the implementation of Bifidobacteria is retarded (first column from the left on page 3).

D48 is concerned to find ways to adjust the intestinal flora of these infants to a more natural (and thus a more healthy) one:

"Il est possible d'aider à l'implantation d'une flore plus proche de la norme naturelle chez tous ces enfants par la modification de la composition des laits maternisés, ...") (paragraph bridging the second and third column from the left of page 3).

Therefore, in the same way as the opposed patent, D48 is in the technical field of feeding infants born via caesarean section and addresses the problem of adjusting their intestinal flora to a more healthy one. D48 can thus be considered to represent the closest prior art.

10.1.3 The appellant argued that D48 did not constitute the closest prior art since the above-quoted passage on page 3 of D48 about the adjustment of the intestinal flora to a more natural one did not relate to infants born via caesarean section.

This argument is not correct: in the right-hand column on page 2 of D48, a new chapter starts with the heading "Facteurs de modification de la cinétique d'implantation". This chapter contains three sub-sections, starting with the section headings "le terme de naissance" (last paragraph on page 2), "Le mode d'accouchement" (middle of the left-hand column on page 3) and "Le mode d'allaitement" (twelfth line of the second column from the left on page 3). After these three sub-sections, the passage on page 3 of D48 quoted above follows and makes reference to "all these infants" ("tous ces enfants"). This wording can only refer to all the infants discussed in the previous three sub-sections and thus clearly includes the infants born via caesarean section.

10.1.4 The appellant furthermore argued that D48 did not mention the problem referred to in the opposed patent, namely that infants born via caesarean section were devoid of Bifidobacteria.

This argument is not correct either. As set out above (point 10.1.2), D48 discloses that the first bacteria with which infants born via caesarean section come into contact are those of the air and the hospital's personnel, such that the first bacteria that are installed in these infants are enterobacteria, enterococci and staphylococci, and the implementation of Bifidobacteria is retarded (first column from the left on page 3). There can thus be no doubt that the starting point in D48 and the patent is the same, namely that infants born via caesarean section are devoid of of Bifidobacteria.

10.1.5 Consequently, also in view of the appellant's arguments, D48 can be considered to represent the closest prior art.

10.1.6 According to D48, it is possible to assist in the implantation of an intestinal flora of infants born via caesarean section closer to the natural one by modifying the composition of the mother's milk by adding bifidogenic factors (fatty acids and prebiotic oligosaccharides) and probiotics. In particular, the passage on page 3 of D48 quoted above continues as follows:

> "... par la modification de la composition des laits maternisés, en particulier l'apport de facteurs bifidogènes (acides gras, prébiotiques-

oligosaccharides) et par l'apport de probiotiques ...").

10.1.7 The only feature of claim 1 not disclosed in D48 is the specific type of prebiotic oligosaccharide and probiotic as required by claim 1.

10.2 According to the appellant, the problem solved over D48 is the provision of a composition that leads to a higher biodiversity in the guts of infants delivered via caesarean section.

This problem is however already solved in D48 since the composition disclosed on page 3 of this document (prebiotic oligosaccharides and probiotics) is stated to lead to a more natural and thus more diversified intestinal flora of infants born via caesarean section (see the passage of page 3 quoted above).

The appellant argued that this statement in D48 did not relate to infants born via caesarean section. However, as set out above in point 10.1.3, this argument is not correct.

The objective technical problem thus has to be formulated less ambitiously, namely as the selection of a specific composition out of the general classes of prebiotic oligosaccharides and probiotics disclosed on page 3 of D48.

10.3 The claimed solution is already disclosed in D48 itself. More specifically, the only specific composition disclosed in D48 is Lactospectrum® (last column on page 6), which, as proven by D46 and D47, contains fructooligosaccharides, corresponding to the indigestible oligosaccharide of claim 1 and B. infantis

and longum, both corresponding to the species of bificobacteria of claim 1.

Therefore, the claimed solution is obvious in view of D48 alone, such that the subject-matter of claim 1 lacks inventive step.

11. In view of this, there is no need to discuss the respondent's objections under Articles 83 and 123(2) EPC.

12. Admissibility of further documents

The appellant requested that D50 and D51 be not admitted into the proceedings. The respondents requested that D55 be not admitted into the proceedings.

Since none of these documents is relevant to the present decision, there was no need to decide on the admissibility of these documents.

Order

For these reasons it is decided that:

1. The appellant's request to refer certain questions to the Enlarged Board of Appeal is refused.

2. The appeal is dismissed.

The Registrar: The Chairman:

M. Cañueto Carbajo W. Sieber

Decision electronically authenticated