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**Datasheet for the decision  
of 6 October 2010**

**Case Number:** T 0837/07 - 3.3.08  
**Application Number:** 95931109.3  
**Publication Number:** 0804616  
**IPC:** C12Q 1/68  
**Language of the proceedings:** EN

**Title of invention:**

Specific and universal amplification primers to rapidly detect and identify common bacterial pathogens and antibiotic resistance genes from clinical specimens for routine diagnosis in microbiology laboratories

**Patentee:**

Infectio Diagnostic (I.D.I.) Inc.

**Opponents:**

- 1) Innogenetics N.V.
- 2) Roche Diagnostics

**Headword:**

Diagnostic primers/INFECTIO

**Relevant legal provisions:**

EPC Art. 123(2)(3), 84  
RPBA Art. 12(2), 13(1)

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Main request - added subject-matter (yes)"

"First auxiliary request - clarity (no)"

"Second auxiliary request - support by the description (no)"

"Request at oral proceedings to file a new auxiliary request  
(not allowed)"

**Decisions cited:**

T 0371/88, T 0190/99, T 0446/00, T 0579/01, T 1300/06

**Catchword:**

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Case Number: T 0837/07 - 3.3.08

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.08  
of 6 October 2010

**Appellant I:** Infectio Diagnostic (I.D.I.) Inc.  
(Patent Proprietor) 4ème étage  
2050 Boulevard René Lévesque Ouest  
Sainte-Foy  
Québec G1V 2K8 (CA)

**Representative:** Helbing, Jörg  
von Kreisler Selting Werner  
Deichmannhaus am Dom  
Bahnhofsvorplatz 1  
D-50667 Köln (DE)

**Appellant II:** Roche Diagnostics  
(Opponent 02) Sandhoferstr. 116  
D-68305 Mannheim (DE)

**Representative:** Dey, Michael  
Weickmann & Weickmann  
Patentanwälte  
Richard-Strauss-Strasse 80  
D-81679 München (DE)

**Other Party:** Innogenetics N.V.  
(Opponent 01) Technologiepark 6  
BE-9052 Zwijnaarde (BE)

**Representative:** -

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
4 May 2007 concerning maintenance of European  
patent No. 0804616 in amended form.

**Composition of the Board:**

**Chairman:** L. Galligani  
**Members:** P. Julià  
D. S. Rogers

## Summary of Facts and Submissions

- I. The patentee (appellant I) and the opponent 02 (appellant II) each lodged an appeal against the interlocutory decision of the opposition division dated 4 May 2007, whereby the European patent no. 0 804 616 was maintained on the basis of a third auxiliary request filed at the oral proceedings before the opposition division.
- II. The main request and the first auxiliary request both filed on 28 September 2006 were considered to contravene Article 123(3) EPC. A new first auxiliary request filed at the oral proceedings to replace the first auxiliary request was not admitted into the opposition proceedings because the opposition division considered that it did not *prima facie* overcome the objection raised under Article 123(3) EPC. The second auxiliary request also filed at the oral proceedings was considered to contravene Articles 123(2) and 83 EPC.
- III. The patent, which had been opposed by two opponents on the grounds as set forth in Articles 100(a), (b) and (c) EPC, had been granted with 29 claims. Claim 1 as granted read as follows:

"1. A method to detect the presence of a bacterial species in a sample, from amongst a plurality of possible bacterial species and identifying said bacterial species characterized by, contacting the sample with one or a plurality of different amplification primer pair(s),

- (i) said primer pair(s) being specific for said bacterial species and derived from a DNA fragment also being species-specific and ubiquitous to the said bacterial species,
- (ii) wherein when one primer pair is insufficient to identify a species with an ubiquity of at least 80%, more than one pair of primers, derived from a DNA fragment being species-specific and ubiquitous for the bacteria is used,
- (iii) wherein the primers are all chosen to allow multiplex amplification,
- (iv) allowing amplification to proceed under one set of conditions; and

detecting the presence or amount of amplified product(s) as an indication of the presence of the bacterial species present in the sample." (bold and underline added by the board)

- IV. With its grounds of appeal, appellant I filed a new second auxiliary request. The first auxiliary request was the first auxiliary request filed at the oral proceedings before the opposition division on 29 November 2006 and not admitted into the opposition proceedings. The main request was the main request as filed on 28 September 2006.
- V. The board issued a summons to oral proceedings to which a communication was attached. In that communication the parties were informed of the board's preliminary, non-binding views on the issues to be discussed at the upcoming oral proceedings.

- VI. In its reply to the board's communication, appellant I filed a new second auxiliary request and submitted as its first auxiliary request the set of claims upon which the patent was maintained by the opposition division. Its main request was the main request as filed on 28 September 2006.
- VII. Oral proceedings took place on 6 October 2010 in the absence of opponent 01 (party as of right), who had informed the board of its intention not to attend these proceedings.
- VIII. Appellant I's **main request** (filed on 28 September 2006) consisted of 29 claims, wherein claim 1 read as follows:
- "1. A method to simultaneously detect the presence of bacterial species in a sample, from amongst a plurality of possible bacterial species and identifying said bacterial species characterized by, contacting the sample with a plurality of different amplification primer pairs,
- (i) each primer pair being specific for said bacterial species and derived from a DNA fragment also being species-specific and ubiquitous to the said bacterial species,
- (ii) wherein when one primer pair is insufficient to identify at least 80% of the isolates of said species, more than one pair of primers, derived from a DNA fragment being species-specific and ubiquitous for the bacteria is used,
- (iii) wherein the primers are all chosen to allow multiplex amplification,

(iv) allowing multiplex amplification to proceed under one set of conditions; and detecting the presence or amount of amplified product(s) as an indication of the presence of the bacterial species present in the sample."

IX. Appellant I's **first auxiliary request** (claims as maintained by the opposition division) consisted of 9 claims, wherein claim 1 read as follows:

"1. A nucleic acid having at least twelve nucleotides in length and being capable of hybridizing with the nucleotide sequence of any one of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 34, SEQ ID NO: 36, SEQ ID NO: 37, and a complementary sequence thereof, when in single stranded form, and which ubiquitously and specifically hybridizes with its respective target bacterial DNA selected from the following sequences as a probe or primer:

- SEQ ID NO. 3, SEQ ID NO. 4, SEQ ID NO. 5, SEQ ID NO. 6, SEQ ID NO. 7 and a complementary sequence thereof, for determining the presence or amount of *Escherichia coli*;

- SEQ ID NO. 8, SEQ ID NO. 9, SEQ ID NO. 10, SEQ ID NO. 11, and a complementary sequence thereof, for determining the presence or amount of *Klebsiella pneumoniae*;

- SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, SEQ ID NO. 15 and a complementary sequence thereof, for determining the presence or amount of *Proteus mirabilis*;

- SEQ ID NO. 30, SEQ ID NO. 31, SEQ ID NO. 34, SEQ ID NO. 35 and a complementary sequence thereof, for determining the presence or amount of *Streptococcus pneumoniae*;

- SEQ ID NO. 37 and a complementary sequence thereof, for determining the presence or amount of *Staphylococcus aureus*;

- SEQ ID NO. 36 and a complementary sequence thereof, for determining the presence or amount of *Staphylococcus epidermidis*;

- SEQ ID NO. 21, SEQ ID NO. 22, SEQ ID NO. 23, SEQ ID NO. 24, and a complementary sequence thereof, for determining the presence or amount of *Staphylococcus saprophyticus*;

- SEQ ID NO. 25, SEQ ID NO. 26, SEQ ID NO. 27 and a complementary sequence thereof, for determining the presence or amount of *Haemophilus influenzae*; and

- SEQ ID NO. 28, SEQ ID NO. 29 and a complementary sequence thereof, for determining the presence or amount of *Moraxella catarrhalis*."

X. Appellant's **second auxiliary request** (filed on 6 September 2010) consisted of 9 claims, wherein claim 1 read as follows:

"1. A nucleic acid having at least twelve nucleotides in length and being capable of hybridizing under conditions of 0.1X SSC/1% SDS at 25°C, with the nucleotide sequence of any one of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 28, SEQ ID NO: 29, SEQ ID NO: 30, SEQ ID NO: 34, SEQ ID NO: 36, SEQ ID NO: 37, and a



complementary sequence thereof, when in single stranded form, and which ubiquitously and specifically hybridizes with its respective target bacterial DNA selected from the following sequences as a probe or primer:

- SEQ ID NO. 3, SEQ ID NO. 4, and a complementary sequence thereof, for determining the presence or amount of *Escherichia coli*;
- SEQ ID NO. 8, SEQ ID NO. 9, SEQ ID NO. 10, and a complementary sequence thereof, for determining the presence or amount of *Klebsiella pneumoniae*;
- SEQ ID NO. 12, SEQ ID NO. 13, SEQ ID NO. 14, and a complementary sequence thereof, for determining the presence or amount of *Proteus mirabilis*;
- SEQ ID NO. 30, SEQ ID NO. 34, and a complementary sequence thereof, for determining the presence or amount of *Streptococcus pneumoniae*;
- SEQ ID NO. 37 and a complementary sequence thereof, for determining the presence or amount of *Staphylococcus aureus*;
- SEQ ID NO. 36 and a complementary sequence thereof, for determining the presence or amount of *Staphylococcus epidermidis*;
- SEQ ID NO. 21, SEQ ID NO. 22, SEQ ID NO. 23, SEQ ID NO. 24, and a complementary sequence thereof, for determining the presence or amount of *Staphylococcus saprophyticus*;
- SEQ ID NO. 25, and a complementary sequence thereof, for determining the presence or amount of *Haemophilus influenzae*; and
- SEQ ID NO. 28, SEQ ID NO. 29 and a complementary sequence thereof, for determining the presence or amount of *Moraxella catarrhalis*."

XI. The arguments of appellant I, insofar as they are relevant to the present decision, may be summarized as follows:

*Main request*

*Article 123(3) EPC*

Decision T 190/99 of 6 March 2001 provided guidance on how to interpret the claims as granted for the purpose of Article 123(3) EPC. According to this decision, the patent had to be construed by a mind willing to understand so as to arrive at an interpretation of the claim which was technically sensible when account was taken of the whole disclosure of the patent. Illogical interpretations of a claim or interpretations without technical sense should be ruled out. Also in accordance with the case law, such as in decision T 579/01 of 30 June 2004, the legal notion of "protection conferred" in Article 123(3) EPC referred to the totality of the protection established by the granted claims and not to the scope of protection within the wording of each single granted claim.

Claim 1 as granted could be interpreted as being directed to a method to detect the presence of either "only one" bacterial species or else "at least one" bacterial species. When, for clarifying which one of these interpretations was technically meaningful in determining the actual scope of protection of this claim, account was taken of the whole disclosure of the patent and the set of claims as granted, it could only be concluded that the mention of "a" bacterial species in claim 1 did not limit the claim to the detection of "only one" bacterial species but rather permitted the

detection of several bacterial species. The wording "characterized by" used in claim 1 introduced only the minimal requirements of the claimed method but did not exclude the presence of other possible features or steps, such as the detection of further bacterial species. This was also consistent with the whole disclosure of the patent and the granted dependent claims. Indeed, claims 8 and 9 as granted referred, respectively, to "one or more bacterial colonies" and to a "multiplex PCR". The conclusion of the opposition division was based on an inaccurate narrow interpretation of the scope of the granted claims.

Claim 1 of the main request fulfilled the requirements set out in decision T 371/88 (OJ EPO, 1992, page 157) for replacing a restrictive term in a granted claim with a less restrictive one. The simultaneous detection and identification of one or more bacterial species was clearly contemplated in the patent-in-suit and thus, a skilled person immediately understood that a claim directed to the detection of "a" bacterial species did not exclude embodiments in which one or more additional bacterial species were also detected. It was also clear from the prosecution history of the patent-in-suit that the use of several primer pairs to simultaneously detect and identify more than one bacterial species was never intended to be excluded from the granted claims. Thus, the deletion of the term "a" from granted claim 1 clearly met the two requirements set out in decision T 371/88 (*supra*).

*First auxiliary request*

*Article 84 EPC*

The presence of SEQ ID NO in the second part of claim 1 which did not have any counterpart SEQ ID NO in the first part (preamble) of that claim did not render the claim unclear, because the sequences recited in the preamble were not required to specifically and ubiquitously hybridize to every nucleic acid listed in the second part of the claim. Thus, there was no discrepancy or inconsistency in the presence of a different SEQ ID NO in the preamble and in the second part of claim 1. A perfect match between the SEQ ID NO of the preamble and of the second part of claim 1 was not necessarily required, a certain mismatch was possible and allowable.

The claimed subject-matter related to primers and probes to detect the presence of bacterial species. For such a diagnostic purpose, it was known to the skilled person that safe conditions were required in order to avoid false positive results. The skilled person understood from this purpose that at least normal or high stringency hybridization conditions, but certainly not low stringency conditions, had to be used in the hybridization of claim 1. These hybridization conditions were within the common general knowledge of the skilled person and well-known in the art, as shown by the references found in the patent-in-suit.

At this stage of the proceedings, it was highly questionable whether it was possible to raise clarity objections which had not been earlier raised or which had not been considered relevant by the first instance.

The more so in view of the scope of the now claimed subject-matter which was the same as, or similar to, that of the granted claims.

*Second auxiliary request*

*Article 123(2) EPC*

It was known to the skilled person that the final hybridization wash was the decisive step in the hybridization because the conditions used in that wash decided which sequences remained bound to the target sequence. It was not necessary to specify in claim 1 the complete conditions used, i.e. i) pre-hybridization, ii) hybridization and iii) post-hybridization conditions, because the skilled person understood that certain variability - which was well-known in the art - could be present in the conditions of steps i) and ii) and that step iii) was the decisive one, in particular, the conditions used in the final wash.

*Adjournment of the oral proceedings in order to draft and submit a set of claims as a further auxiliary request*

The second auxiliary request was filed in reply to the board's communication and showed that serious efforts had been made to take account of all the issues raised in that communication. The amendments introduced into this request, such as the deletion of several SEQ ID NOs. and the recitation of the hybridization conditions, were prompted by comments and objections raised in that communication. The second auxiliary request replaced the earlier first and second auxiliary requests filed

with the grounds of appeal and, in reply to the board's communication, unconditionally withdrawn.

It was established practice of the Boards of Appeal, and in line with the case law, that the patentee should be allowed a "last chance" to save its patent. Hence, it was unfair to deprive the patentee from that chance and not to allow the filing of a further auxiliary request that intended only to overcome the objections raised at the oral proceedings before the board against its second auxiliary request.

XII. The arguments of appellant II, insofar as they are relevant to the present decision, may be summarized as follows:

*Main request*

*Article 123(3) EPC*

Whereas granted claim 1 was directed to a method to detect the presence of a single bacterial species, claim 1 of the main request was directed to a method to detect the presence of more than one bacterial species. The scope of protection of claim 1 of the main request was different from, and broader than, that of granted claim 1.

The amendments introduced into claim 1 created new subject-matter which was different from that of granted claim 1. Whereas the primer pair used in part i) of granted claim 1 was defined as being specific for "said bacterial species" and thereby, by back-reference to the preamble ("a bacterial species"), specific for a single bacterial species, claim 1 of the main request

contemplated now the use of primer pair(s) specific for different bacterial species. There was no indication in any of the granted dependent claims to use primer pairs specific for different bacterial species in the method of granted claim 1. The references to multiplex PCR or amplification, such as in granted claim 9, related to the use of several primer pairs which were, however, specific for a single bacterial species. This was also exemplified in the patent-in-suit which showed that, when combinations of primers (for a single bacterial species) were used, a higher ubiquity was reached.

*First auxiliary request*

*Article 84 EPC*

It was not clear for a skilled person how to detect nucleic acids that were required to hybridize first with a SEQ ID NO. indicated in the preamble of claim 1 and then, ubiquitously and specifically, with a target SEQ ID NO. indicated in the second part of that claim, and wherein this second part comprised SEQ ID NO. that were not mentioned in the preamble. All the less so, because no hybridization conditions were indicated in claim 1, although they were essential to fulfil the feature required in the second part of that claim, namely an ubiquitous and specific hybridization.

*Second auxiliary request*

*Article 123(2) EPC*

The conditions introduced into claim 1 were not disclosed in the application as filed as hybridization conditions but only as post-hybridization conditions. In fact, the application as filed disclosed complete

post-hybridization conditions which comprised several washes performed under specific conditions and a final wash as recited now in claim 1. In this disclosure, the length or duration of that final wash (15 min) was also indicated. However, none of these additional requirements were present in claim 1.

It was known that the (stringency) conditions used for the hybridization were essential to determine which sequences would hybridize with the target sequences. Higher hybridization temperatures resulted, for instance, in a higher stringency conditions under which only those sequences having a perfect match with the target sequence could hybridize.

*Adjournment of the oral proceedings in order to draft and submit a set of claims as a further auxiliary request*

The introduction of a new claim request required a detailed study and preparation in order to assess whether or not it fulfilled all the requirements of the EPC. Appellant I/patentee had already been given ample opportunity, both during the opposition and the appeal proceedings, to prepare and file claim requests. This opportunity had been availed of by appellant I/patentee, who filed a main request shortly before the oral proceedings at first instance, a third auxiliary request (now first auxiliary request in appeal) at the end of these oral proceedings and a second auxiliary request filed in reply to the board's communication and one month before the present oral proceedings; this second auxiliary request replacing a first and a second auxiliary requests filed with appellant I/patentee's



grounds of appeal. All these requests presented formal deficiencies and did not overcome the formal objections raised under Articles 123(2),(3) and 84 EPC.

It was also noted that, in its last submissions, appellant I/patentee even failed to indicate a basis for the subject-matter introduced into its second auxiliary request. At this stage of the proceedings and taking account of all the above facts, it would be unfair to appellant II to allow appellant I/patentee yet another opportunity to prepare and file a complete new claim request.

- XIII. Appellant I (patentee) requested that the decision under appeal be set aside and the patent be maintained on the basis of:
- 1) The claims of the Main Request filed with a letter dated 28 September 2006; or
  - 2) as Auxiliary Request 1, the claims as maintained by the opposition division; or
  - 3) The claims of Auxiliary Request 2 filed on 6 September 2010; and
  - 4) Further, appellant I requested the adjournment of the oral proceedings in order to draft and submit a set of claims as a further auxiliary request.
- XIV. Appellant II (opponent 02) requested that the decision under appeal be set aside and the patent be revoked.
- XV. Opponent 01 (party as of right) did not file any requests or substantive submissions in appeal proceedings.

## Reasons for the Decision

*Main request*

*Article 123(3) EPC*

1. Claim 1 as granted was directed to "*a method to detect the presence of **a** bacterial species*" (in bold by the board), whereas claim 1 of the main request relates to "*a method to simultaneously detect the presence of bacterial species*" (cf. points III and VIII *supra*). In the board's judgment, it is clear from this initial wording that both methods are concerned with different subject-matter. Indeed, when reading the description of the patent-in-suit, these two methods correspond to two different preferred embodiments, namely a first embodiment directed to detection of a single bacterial species and a second embodiment directed to the simultaneous detection of several bacterial species (cf. *inter alia*, page 13, paragraphs [0063] to [0065] of the patent-in-suit). The subject-matter of claim 1 as granted has thus now been changed to a different embodiment and thereby, the scope of protection of the claim has been extended.
2. Contrary to appellant I's argumentation (cf. point XI *supra*), the board does not see any indication in granted claim 1 or in any of its dependent claims that could cast serious doubts on the meaning indicated above of granted claim 1. The board fails to see any ambiguity in the initial wording of granted claim 1 nor is this ambiguity introduced by any of the other granted claims. As stated in the description of the patent-in-suit (cf. *inter alia*, page 13, paragraphs [0063] and [0064] and page 19, Table 7, footnote b),

the use of several primers specific for a single bacterial species in a multiplex amplification or multiplex PCR may well be performed to increase the ubiquity of the assay (granted claim 9), as rightly pointed out by appellant II (cf. point XII *supra*). Granted claim 8 may also be understood as referring to a sample consisting of one or more bacterial colonies (isolates or strains) of a single bacterial species (target species or species of interest) which might be used to check both the ubiquity and the specificity of the primer or probe used, as also explained in the patent-in-suit (cf. page 11, paragraphs [0046] and [0051] and page 12, paragraph [0052] of the patent-in-suit).

3. Appellant I referred to three decisions of the Boards of Appeal, namely decisions T 190/99, T 579/01 and T 371/88 (*supra*), which, in its opinion, support its case (cf. point XI *supra*). The board cannot however follow appellant I's arguments for the following reasons:
  - 3.1 As stated in point 1 *supra*, the initial wording of granted claim 1 has a clear and unambiguous technical meaning and no ambiguity is introduced by any of the dependent claims or by claim 1 itself. For a mind willing to understand, as defined in decision T 190/99 (*supra*), the meaning of, or the interpretation given to, granted claim 1 is clear and technically meaningful. Indeed, it corresponds to one of the preferred embodiments explicitly disclosed as such in the patent-in-suit. Thus, there is no need to seek for alternative or different interpretations of granted claim 1.

- 3.2 Indeed, as indicated in decision T 597/01 (*supra*), the "scope of protection" refers to the total protection conferred by the granted claims and not by the individual granted claims. However, the subject-matter of claim 1 of the main request cannot be seen as being comprised within the "total scope of protection" conferred by, or associated with, the claims as granted because none of the granted claims, explicitly or implicitly, covers a method to simultaneously detect the presence of several bacterial species, i.e. the subject-matter of claim 1 of the main request.
- 3.3 According to decision T 371/88 (*supra*), the first condition for deleting or replacing a restrictive feature from a granted claim by a less restrictive feature is that the restrictive feature is so unclear in its technical meaning in the context of the claim that the extent of protection can only be determined by interpreting the claim by reference to the description of the patent (cf. T 371/88, *supra*, part (a) of the Headnote). In the present case, this first condition is certainly not given, since, as discussed in point 1 *supra*, the technical meaning of the feature "a bacterial species" in granted claim 1 is completely clear, unambiguous and not open to interpretation. Thus, the first criterion set out in decision T 371/88 (*supra*) does not apply to the present case.
4. Therefore, the main request is considered to contravene the requirements of Article 123(3) EPC.

*First auxiliary request*

*Article 84 EPC*

5. Claim 1 of the first auxiliary request is based on a combination of granted claims 21 and 6. However, whereas the first part (preamble) of granted claim 21 is identical to that of claim 1, the second part of granted claim 21 only refers back to granted claim 6 but, in contrast to claim 1 of the first auxiliary request, without listing any of the SEQ ID NO. cited in granted claim 6. Thus, the wording of claim 1 as such is not present in the set of granted claims nor is it, as such, made explicit by that set of claims. Therefore, the board is entitled to examine and to decide on whether or not the subject-matter of claim 1 of the first auxiliary request fulfils the formal requirements of the EPC and, in particular, those of Article 84 EPC. This has not been formally contested in appeal proceedings, even though reservations were expressed by appellant I (cf. point XI *supra*). It is worth pointing out here that the fact that objections raised under Article 84 EPC might also be of relevance for the granted claims, cannot prevent the board from considering them in the context of a new amended request, since each request has to be considered individually (cf. *inter alia*, T 1300/06 of 8 April 2008, points 1 and 2 of the Reasons).
  
6. Article 84 EPC requires the claims to be clear and concise. It is not contested that the second part of claim 1 recites several SEQ ID NOs. for which there is no counterpart SEQ ID NO. in the preamble of that claim (cf. point IX *supra*). It may well be, as argued by appellant I, that nucleic acids hybridizing to one of

the SEQ ID NO. in the preamble always hybridize with the corresponding counterpart SEQ ID NO. of the second part of the claim, since there is no SEQ ID NO. from the preamble without a counterpart in the second part of the claim (cf. point XI *supra*). In that case, the presence of other SEQ ID NO. without counterpart in the second part of the claim would be completely irrelevant and superfluous and, for this reason alone, the claim must be considered not to be concise.

7. The board further considers that the presence of SEQ ID NO. with no counterpart SEQ ID NO. renders claim 1 unclear or ambiguous. Should a nucleic acid be found to hybridize, ubiquitously and specifically, with one of the SEQ ID NO. having no counterpart in the preamble of claim 1 and not to hybridize with any of the SEQ ID NO. recited in that preamble, the question may arise whether the particular hybridization conditions used can yet be modified, changed or tinkered so as to be sure that said nucleic acid does, or does not, hybridize with any of the SEQ ID NO. recited in the preamble. Moreover, whereas the hybridization of the nucleic acid with the SEQ ID NO. of the second part of claim 1 is required to be ubiquitous and specific, there is no requirement for the hybridization with the SEQ ID NO. of the preamble. It is, however, well-known that, at lower stringency conditions, the chances to detect (non-specific) hybridization are much higher.
  
8. Indeed, claim 1 fails to define any conditions of hybridization at all. However, these conditions may well affect the results obtained both in the ubiquitous and the specificity tests which are necessary to be performed in order to assess whether a nucleic acid

fulfils the requirements set out in the second part of claim 1 (cf. *inter alia*, page 11, paragraph [0046], in particular lines 24 to 29 of the patent-in-suit). The hybridization conditions are thus considered to be an essential feature of claim 1 which, according to the established case law of the Boards of Appeal (cf. "Case Law", *supra*, II.B.1.1.4, page 257), should be clearly indicated in that claim.

9. It follows from the above that the subject-matter of claim 1 of the first auxiliary request does not fulfil the requirements of Article 84 EPC.

*Second auxiliary request*

*Article 123(2) EPC*

10. The preamble of claim 1 of the second auxiliary request differs from that of claim 1 of the first auxiliary request by the introduction of the wording "... capable of hybridizing under conditions of 0.1X SSC/1% SDS at 25°C, ..." (cf. points IX and X *supra*). It is not disputed that there is a verbatim support for these conditions on page 12, line 24 of the application as filed (in its version published as WO 96/08582). However, these conditions are described therein as characterizing "a final wash" of a 15 min duration performed after several (twice and twice) previous post-hybridization washes for which the specific conditions are also described in the same paragraph (cf. page 12, lines 20 to 25 of the application as filed). In fact, this paragraph refers to an "earlier" description of both the pre-hybridization and hybridization conditions (cf. page 12, lines 19 to 20 of the application as filed), which is actually found

on page 10, lines 7 to 16 of the application as filed, and which includes also a complete disclosure of the post-hybridization conditions.

11. In view of these disclosures, the specific conditions introduced into claim 1 cannot be seen as "hybridization conditions" and, since there is no formal support in the application as filed for requiring a nucleic acid to be "*capable of hybridizing under*" the specific conditions indicated now in claim 1, the subject-matter of that claim is considered, for this reason alone, to contravene Article 123(2) EPC. There is thus no further need to enter into a detailed discussion on the technical relevance of a final post-hybridization wash for the hybridization results.

*Adjournment of the oral proceedings in order to draft and submit a set of claims as a further auxiliary request*

12. Article 12(2) of the Rules of Procedure of the Boards of Appeal (RPBA) requires the statement of grounds of appeal to contain a party's complete case. Article 13 RPBA, which deals with the amendments to a party's case, states in paragraph (1) that "*any amendment to a party's case after it has filed its grounds of appeal ... may be admitted and considered at the Board's discretion*" and that this discretion "*shall be exercised in view of inter alia the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy.*"
13. The objections of lack of clarity of the subject-matter of claim 1 of the first auxiliary request were already raised and discussed in detail at the oral proceedings



before the first instance (cf. page 5 to page 6 of "Minutes of the oral proceedings before the opposition division"). Although, in contrast to the board (cf. point 5 *supra*), these objections were considered not to arise from the amendments made during the opposition proceedings and they were not decided upon by the opposition division (cf. page 5, point 1 to page 6, point 1 of the decision under appeal), they were nevertheless on file and part of the proceedings - as shown by their presence in appellant II's statement of grounds of appeal, even though admittedly under other EPC articles (cf. page 7, point II.1 and pages 8 to 11, points III.1 to III.4 of appellant II's grounds of appeal). However, none of the claim requests filed by appellant I - in its grounds of appeal or in its reply to those of appellant II - took into account these objections.

14. It was only after the board's communication issued under Article 15(1) RPBA in which the parties' attention was drawn again to these objections (cf. pages 9 to 11, points 21 to 24 of the board's communication dated 20 May 2010, point V *supra*), that appellant I filed - one month before the date scheduled for the oral appeal proceedings - a second auxiliary request specifically addressing them and maintaining a first auxiliary request that clearly did not address any of these objections (cf. points IX and X *supra*).
  
15. It derives directly from the review nature and the judicial character of the appeal proceedings (cf. "Case Law", *supra*, VII.E.1, page 821), that claim requests filed at the oral proceedings in appeal before the board are to be considered in principle as late-filed

requests and, as a result thereof, their admissibility into the appeal proceedings is to be fully justified before the board can examine them and decide thereupon. In the present case and in view of the facts mentioned in points 13 and 14 above, the board considers that, at this stage of the proceedings and in the light of the amendments introduced into appellant I's second auxiliary request (cf. points 10 and 11 *supra*), the introduction of a new auxiliary request into the appeal proceedings with the sole purpose to overcome the very same formal objections which allegedly were already addressed by that second auxiliary request, cannot be justified.

16. According to appellant I, it is established case law of the Boards of Appeal that the patentee should always be given a "last chance" to save its patent (cf. point XI *supra*). It has been thoroughly discussed and clearly established by the Boards of Appeal that there is no absolute right for a patentee to such a "last chance" request. On the contrary, the admissibility of a late filed request is always a matter of the board's discretion. Moreover, as stated *inter alia* in decision T 446/00 of 3 July 2003 (cf. point 3.3 of the Reasons for the Decision), the concept of a "last chance" suggests one last chance at the end of the proceedings and not multiple "last chances" on numerous occasions during the course of the appeal. In the present case, the possible admission into appeal proceedings of a new auxiliary request could hardly be seen as the patentee's "last chance" since that new request would only be filed to overcome formal issues discussed at length and in detail during both opposition and appeal proceedings but it would still leave completely open to

discussion substantive issues on novelty and inventive step raised during these proceedings (cf. points 26 to 30 of the board's communication, point V *supra*).

17. Thus, the board comes to the conclusion that appellant I's request for an adjournment of the oral proceedings in order to draft and submit a set of claims as a further auxiliary request is, at this stage of the proceedings and after consideration of all the above facts, not allowable and cannot be granted.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani