Candidate's answer

Note to the client

Regarding the use of Annex 6, this annex will be used in the opposition. This is further explained in the notice of opposition. We will propose Mr. Blackmore as a witness.

Question 2:
It is possible to offer Mr. Blackmore as a witness
(under Art. 117(1) EPC / Rule 117 EPC).
According to case law, (see T474/04) if assertions made in an unsworn witness declaration remain contested (the affidavit of Mr. Blackmore can be considered an unsworn witness declaration), as a rule a request from a party to hear the witness (thus here the proprietor) must be granted before these assertions are made the basis of a decision against the contesting party. Thus, if case law is followed, if the proprietor request the witness to be heard, the opposition division cannot give a decision without having heard this witness.
(see also Guidelines for examination, E, IV, 1.2)
We will propose Mr. Blackmore as witness.

Question 3:
Yes, this is possible; see Rule 120(1) EPC.
If summoned by the EPO, the witness Mr. Blackmore may request to be heard by a competent court in his country of residence. It is possible that in such case the EPO request that competent authority to hear the witness, Mr. Blackmore under oath
(Rule 120(3) EPC)
We will request this in the notice.

Question 4:
The proprietor may file amendments to the claims, provided that these amendments are occasioned by grounds for opposition (see Art 100 EPC), i.e. they are admissible only if they are required to meet a ground for opposition, even if this ground has not been raised by the opponent (you). This is in accordance with Rule 80 EPC (Guidelines D, IV, 5.3). But the addition of new claims (here further dependent claims) to the claims as granted is inadmissible because such amendments cannot be said to meet a ground of opposition. (see Guidelines, E, IV, 5.3)

Question 5 regarding claim 3 will be addressed in the notice of opposition. Note that part of the claim, relating to the aqueous ink is not presentation of information as such as it provides technical effects. The indications of instructions does not provide technical effects to the invention and this subject matter has therefore been attacked in the notice based on a lack of inventive step (Art. 56 EPC).

Notice of opposition

For formal data, see enclosed form 2300

A. Effective dates of the claims

All claims 1 to 7 have as effective date the filing date of 13-02-2003, of A1, because A1 does not claim priority.

B. Documents used

- A1 (EN): patent opposed

- A2 (EN): is an A. 54(2)EPC prior art document as it was published before the filing date of A1.

- A3 (EN) is a A54(2)EPC prior art, as it was published on 22-08-1985, which is prior to the filing date (13-02-'03) of A1

- A4 (EN) is a US patent that was published on 22-08-67, i.e. before the filing date of A1, and is prior art under Art. 54(2)EPC

- A5 (FR) is a French patent application, published on 28-02-'01, i.e. before the filing date of A1, and is prior art under art. 54(2)EPC.

A2, A3, A4 and A5 are prior art under A 54(2) EPC against all claims 1 to 7.

- A6(EN) is an affidavit of Mr. Blackmore dated 22-01-08.
This document is presented as evidence of public prior disclosure, and constitutes Art. 54(2)EPC prior art against all claims 1 to 7.

WHAT: A6 discloses a text entitled "guidelines for sterilisation" and this text constitutes a chapter of a book.

WHEN: The chapter of the book (text disclosed in A6) was distributed at a public conference, held before 13-02-2003, thus public before the filing date of A1.

Under which circumstances: The text was handed out without request for keeping it confidential. The text was available to the public at the conference without any restrictions with regard to confidentiality. The text was handed over by Mr. Blackmore R.
It is proposed that Mr. Blackmore R. would be heard as a witness to testify the circumstances of disclosure and provide explanations on the contents of the text.
It is also requested that Mr. Blackmore would be heard by a competent court in his country of residence (UK)
Further evidence of the date and type of public conference will be provided as soon as possible.

C. Grounds of opposition

1. CLAIM 1

1.1 A 54(2) in view of A5

A5 discloses an apparatus for sterilising (page 21, lines 6-8, “un four” is an apparatus that is suitable for sterilising as the apparatus can be operated at 120°C as indicated, which is a temperature at which sterilisation can be obtained => see A1, page 4, lines 19 which indicates that at least 100°C is required, and enough to kill most germs) comprising a sterilising chamber with a door (see p. 21, line 7 “porte” and figure 2 which respresents a chamber wherein a recipient is contained) and an electrical source of heat (see page 21, line 7, “four electrique” implying that the oven operates with electrical heat) capable of raising the temperature in the chamber, and a means for setting the desired temperature (see elements indicated with reference 5 on figure 2, and page 21, line 7 “réglé”, implying regulating means) wherein a tray for accepting an object (see page 21, line 6 “plateau (7)” = tray which is suitable for accepting an object, in A5 a “une preparation de restauration”, thus a meal = an object) to be sterilised (by heating the meal of A5 is sterilised) is situated within the chamber (page 21, line 6-7; plateau is in the chamber as shown on figure 2) and wherein the apparatus is provided with a window for viewing the object (see page 21, line 6-7: “porte de verre” => which is suitable for viewing the meal and constitutes a window) on the tray while being sterilised.

A5 discloses all features of claim 1.

Claim 1 lacks novelty in view of A5, according to A52(1)EPC, A54(2)EPC and A100(a)EPC.

1.2 Claim 1: A 56 EPC in view of A4 and A2

A4 can be considered as the closest prior art because it relates to a same technical field of sterilisation apparatuses (see [0001] of p. 16 of A4), and has most common features with the apparatus of claim 1.

A4 discloses an apparatus for sterilising (see p. 16, line 16 “apparatus for sterilisation”, and claim 1) of A4) comprising a sterilising chamber with a door (see p. 16, line 20 “thermally insulated” (thus this implies that it can be used for “sterilising”) “chamber with a door (2)”) and an electrical source of heat (see page 16, line 21) capable of raising the temperature in the chamber (see page 16, line 21) and a means for setting the desired temperature (see page 16, line 22 “temperature control knob” and reference “4”) wherein a tray for accepting an object to be sterilised (see “detachable tray” on page 16, line 23) within the chamber (see page 16, l. 23).

Claim 1 differs from A4 in that the apparatus is provided with a window for viewing the object on the tray while being sterilised. A4 discloses a small window (see page 17, line 4-5) but due to its size – exactly matching the size of the temperature scale, this window is not suitable for viewing anything else than the scale. It is not suitable for viewing the tray in the chamber. Modification of the small window (enlargement) would be required for enabling it to be used for the indicated purpose (see Guidelines C, III, 4.13).

This distinguishing feature has the effect that any object placed on the tray in the apparatus can be viewed during the entire sterilisation process, and that an operator can continuously monitor if anything goes wrong within the apparatus (see A1, page 4, lines 7-10).

This solves the problem of allowing an operator to see if anything goes wrong within the apparatus during the sterilisation process.

A2 from a neighbouring field provides a solution to this problem (see page 27, lines 17-21). A2 discloses indicator agents that can be used during sterilisation and refers to an sterilisation apparatus provided with a transparent panel (this corresponds to a "window") and indicates that through such panels sterilisation process can be monitored (see page 27, line 20-21).
A skilled person would see the advantage of such teaching and would have no practical difficulty in implementing it in the apparatus of A4, since this apparatus already has a – albeit small- window. The skilled person would only have to enlarge the size of this small window to arrive at the apparatus of claim 1.

Accordingly, the subject matter of claim 1 does not involve an inventive step in view of A4 and A2 (Art. 52(1) EPC, Art 56 EPC and A 100(a)EPC)

2. CLAIM 2 - dependent on claim 1

2.1 A56 in view of A4 and A2
A4 is the closest prior art for claim 2+1 for the same reasons as for claim 1.

In addition to the features of claim 1 given above, A4 further discloses an apparatus being hermetically sealable (see page 16, line 17) and comprises a source of a chemical sterilising agent (see page 16, line 18) and control means for controlling the supply of the agent into the chamber (these control means are indicated with reference 7 = valve in figure 2 and on page 17, line 11; a valve is also used in A1 – see page 4, line 28-29; the valve 7 in A4 is thus such a control means)

Thus claim 2+1 differs from A4 by the same features as claim 1 (as described above under point 1.2), so that claim 2+1 is not inventive for the same reasons as given for claim 1.
Accordingly, the subject matter of claim 2+1 does not involve an inventive step
(A. 52(1) EPC, Art 56 EPC, A 100(a)EPC) in view of A4 and A2.

3. CLAIM 3

3.1 A56 EPC in view of A2

A2 is the closest prior art for claim 3 because it relates to a same technical field, i.e. it relates to indicator systems that are capable of changing colors under sterilisation conditions. In addition, A2 has most features in common with claim 3. In particular, A2 discloses : a product (an “indicator material” see page 26, line 16 or p. 27 line 5 “indicator”) comprising an aqueous ink (see p. 27, line 12, “inks”; which can be diluted with water and thus are “aqueous”, page 27, lines 12-13) capable of changing colour when subjecting to an sterilising agent (see page 27, line 4 and 6: Alu-W can change color when subjected to oxidising sterilising agents such as H_2O_2).

Claim 3 differs from A2 in that the product comprises instructions for use of the ink, defining 3 steps: i) making an object to be sterilised by the ink, ii) exposing the object to a sterilising agent and iii) inspecting the ink-mark to determine whether sterilisation was successful.

This difference, and none of the said steps, provides any contribution on its own or in combination with other features to the technical character of the invention. The difference thus has no technical character and is thus not relevant for assessing inventiveness (T641/00 and Guidelines C IV 11.7.2). There is no technical effect of this distinguishing feature, and so there is no technical problem solved and thus lack of inventive step.

Hence, the subject matter of claim 3 does not involve an inventive step
(A. 52(1) EPC, Art 56 EPC, A 100 a) EPC) in view of A2.

4. CLAIM 4

4.1 A 56 in view of A3 and A2

A3 is the closest prior art document for claim 4 because it relates to a same technical field, it is the only document disclosing self-adhesive labels with a machine readable code capable of changing colour under specific conditions. A3 has most features in common with claim 4 since A3 discloses a self-adhesive label (see p. 28, line 27 and claim 1 on page 30: “with glue on one surface” => which indicate that it is adhesive on one side) comprising at least one machine readable code (see page 29, line 16 and claim 1 barcodes are used and these codes are machine readable as indicated on
page 29, line 5-6), capable of changing color (see page 29, lines 25-26; and claim 1) when subjected to a chemical sterilising agent (see claim 1 “oxidation treatment” is a treatment with an oxidising (thus chemical) sterilising agent(see also A2, line 4, page 27 and A1 page 5, line 20)

Claim 4 differs from A3 in that the code is capable of changing color from white to black. Although A3 mentions this possibility (see page 29, lines 27-29); it also discloses that at that time no substances enabling such change were known (see page 29, line 29). This indicates that A3 is not enabled for this disclosure and the disclosure cannot be considered as destroying novelty (see Guidelines C, IV 6.2) for this feature. However,

A3 provides for substances which change color from black to white (e.g. Alu-B page 30, line 10-11).

The distinguishing feature has the effect of giving a particular strong contrast which is favorable for machine reading (see A1, page 6, line 13-14).

This solves the problem of providing a strong contrast which favour machine reading.

At the time of publication of A3, agents capable of changing color from white to black were not known. However A3 already provides a clear hint to a skilled person of the possibility of using such substances enabling such color change.

A2, from a neighbouring field of substances which are able to change color under specific conditions, e.g. of sterilisation, discloses substances that can change colors from white to black, such as e.g. Alu-W (see page 27, line 7 or lead thiosulphate see p. 26, line 25).

A2 also discloses the substance Alu-B ((see page 27, line 8) which is also disclosed in A3 (see page 30, line 10)
A skilled person upon reading A3, would leaded by the hint in A3 for using substances which allow color change from white to black, see the possibility of using substances such as e.g. Alu-W, disclosed in A2.
Such skilled person would have no practical difficulties in using a substance provided in A2, which changes from white to black when treated with an oxidising agent, instead of using alu-B, and hence to arrive at the subject matter of claim 4, without exercising inventive skill.
The subject matter of claim 4 does not involve an inventive step in view of A3 and A2 (A 52(1)EPC, A56EPC and A 100 a) EPC.

5. CLAIM 5 (+4)

5.1 <u>A56 in view of A3, A2 and A6</u>

A3 is the closest prior art document for claim 5+4 for the same reasons as given for claim 4 above.

Claim 5+4 differs from A3, in addition to the features already discussed for claim 4, by the additional feature that the machine readable code is a smartcode instead of a lineair barcode used in A3 (see p. 29, line 1 and claim 1).

This has the effect of providing the possibility to encode more data per unit area and to be more resistant to data degradation (see A1, page 6, line 4-7).

This effect has no synergy with the effect achieved with the substance able to change color from white to black distinguishing claim 4 from A3, because the color effect and the effect of the smartcode do not mutually influence each other and have no synergy. They solve two separate partial problems and can therefore be treated separately.

The present further effect solves the problem of providing a higher data density and more resistance to data degradation.

A6, from a neighbouring field of sterilistaion by means of chemical sterilising ag indicated that such agents should be safely used and that smartcodes can be used provide indication on the use of such agents.
A6 mentions that smartcodes have technical advantages over conventional linear codes, especially with regard to data density and decodation in case of damage to the image code.
A skilled person would immediately see the advantages of using smartcodes and would not have practically difficulties to change the lineair codes used in A3 into smartcodes, as provided in A6. Small modifications of the code would be required and this could be done without exercising inventive skill.

As the distinguishing feature of claim 4 is also obvious to the skilled person
(see above under point 4.1) the subject matter of claim 5+4 does not involve an inventive step (A52(1)EPC, A56EPC, A100(a)EPC in view of A3, A2 and A6.

6. CLAIM 6

6.1 A56 in view of A5 and A2

A5 can be considered the closest prior art, because it also provides a method for sterilising object such as test-tubes (see p. 21, line 3 “eprouvettes”) A5 also has most features in common with claim 6.
A5 discloses a process for sterilising a test-tube (see page. 21, line 3 “éprouvettes” and claim 2 of A5) comprising the following steps:

b) simultaneously exposing the test-tube (see claim 1: “récipient” and claim 2 “éprouvette”) (simultaneously : see “simultanément” in claim 1) to a temperature of at least 105°C (A5 discloses a temperature range of 100 to 120°C: at least 105°C implies a range of 105°C or higher. The specific value of 120°C provided in A5 destroys the novelty of this range of at least 105°C) to a chemical sterilising agent in the gas phase (see “agent sterilisant chimique gaseux” in claim 1 of A5 and page 20, line 8-10 and page 20, line 16) and to irradiation with UV-light (see claim 1: “la lumière UV” + page 20, line 14 “il passe sous lampes UV”)

Claim 6 differs from A5 in that it discloses a step a) comprising placing a sterilising indicator on the test tube, wherein said indicator is capable of changing visual appearance when subjected to either chemical sterilising agent or to UV light.

This has the effect of providing a means to control whether the test-tube has been sterilised even after it has left the apparatus (see A1, page 5, line 15-16).

This solves the problem of providing a means for controlling on the object, the test-tube itself, whether it has been sterilised even after it left the apparatus.

A2 from a neighbouring field disclosing various indicator systems that can be used during various sterilisation methods, provides various examples of indicators that can be used during sterilisation and that provide a change in visual appearance (see A2, page 26, line 7) when subject to either chemical sterilising agent (see under point 3 on page 27 of A2) or to the UV-light (see under topic 2. on page 26 of A2).

A skilled person would see the advantage of using this kind of substances on a test-tube for solving the above indicated problem, and would easily apply this kind of indicator agents on a test tube: A2 for instance indicates that such indicators could be printed or written onto the item to be sterilised; thus here a test-tube. A skilled person would have no practical difficulties for applying such indicators on a test tube and this would not require any inventive skill.

Hence, the subject matter of claim 6 does not involve an inventive step in view of A5 and A2 (A. 52(1)EPC, A56 EPC and Art 100(a) EPC).

7. CLAIM 7 (+6)

7.1 A 56 in view of A5 and A6 and A2

A5 is considered the closest prior art for claim 7 for the same reasons as given for claim 6.

Claim 7 differs from A5, apart from the features already discussed for claim 6, by the additional feature that the chemical sterilising agent is hydrogen peroxide, instead of diluted hypohalogenite used in A5 (see page 20, line 2-3).

This has the effect of being a substance that decomposes in non-hazardous components during the sterilisation process (see A1, page 6, line 23-25).

This effect has no synergy with the effect of the use of an indicator on the test tube as distinguishing feature for claim 6 in view of A5, because the effect of the indicator (visuability) and the effect of the chemical sterilising agent (no toxic degradation products) do not mututally influence each other, nor do they provide any synergetic effects. The effects solve two different problems (partial problems) and can therefore be treated separately.

The present further effect solves the problem of avoiding the production or release of hazardous compounds due to decomposition of the chemical sterilising agent.

A6, which discloses the use of environmental friendly chemical agents refers to hydrogen peroxide as a particular example of such compound which decomposes to components that are not harmful to human beings (see page 23, line 14-15) and that provides similar effects, and is as efficient as gaseous hypohalogenite for sterilisation (see page 23, line 26-27).

A skilled person, confronted with such information, would be incited to replace hypohalogenite used in the process of A5 by hydrogen peroxide, especially since he is told by A5 that such agent (H_2O_2) provides similar (as efficient) effects without the disadvantages of hypohalogenite to leave toxic residues.

As the distinguishing feature of claim 6 is also obvious over to the skilled person (see under point 6.1 above), the subject matter of claim 7+6 does not involve an inventive step in view of A5 and A6 and A2 (A. 52(1)EPC, A 56EPC and A 100(a)EPC)

Based on these facts and arguments, it is requested that A1 is revoked in its entirety.

Europäisches Patentamt
European Patent Office
Office européen des brevets

Notice of opposition to a European patent

I. Patent opposed

Patent No.	EP 1702008
Application No.	03030303.3
Date of mention of the grant in the European Patent Bulletin (Art. 97(3), Art. 99(1) EPC)	13-06-2007
Title of the invention	Concept for monitoring a sterilisation process

II. Proprietor of the patent

first named in the patent specification	Dean Parker and Hamer Associated Marshall, Tampa
Opponent's or representative's reference (max. 15 keystrokes)	

III. Opponent

Name	MORSE STEPHEN
Address	Silhouette Gatan 3 S-92137 Hagström Sweden
State of residence or of principal place of business	SE
Nationality	SE
Telephone/Fax	
Multiple opponents (see additional sheet)	☐

IV. Authorisation

1. Representative (name only one representative or name of association of representatives to whom notification is to be made)	MAC ALLPAIN
Address of place of business	Saitenstrasse 6 D-81335 Munich GERMANY
Telephone/Fax	
Additional representative(s) on additional sheet/see authorisation	☐

2. Name(s) of employee(s) of the opponent authorised to act in these opposition proceedings under Art. 133(3) EPC

Authorisation(s) to 1./2.

not considered necessary ☒

has/have been registered under No. ☐

is/are enclosed ☐

V. Opposition is filed against

• the patent as a whole ☒

• claim(s) No(s). ☐

VI. Grounds for opposition:

Opposition is based on the following grounds:

(a) the subject-matter of the European patent opposed is not patentable (Art. 100(a) EPC) because:

• it is not new (Art. 52(1); Art. 54 EPC) ☒

• it does not involve an inventive step (Art. 52(1); Art. 56 EPC) ☒

• patentability is excluded on other grounds, i.e. Article ☐ Art.

(b) the patent opposed does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 100(b) EPC; see Art. 83 EPC). ☐

(c) the subject-matter of the patent opposed extends beyond the content of the application/of the earlier application as filed (Art. 100(c) EPC, see Art. 123(2) EPC). ☐

VII. Facts (Rule 76(2)(c) EPC) presented in support of the opposition are submitted herewith on a separate sheet (annex 1) ☒

VIII. Other requests:

ORAL proceedings are requested according to ART. 116 EPC in the event that the patent opposed is not to be revoked by the opposition division as requested.

300.2 04.08

IX. Evidence presented

Evidence is enclosed ☐

will be filed at a later date ☐

A. Publications:

1

Particular relevance (page, column, line, fig.):

2

Particular relevance (page, column, line, fig.):

3

Particular relevance (page, column, line, fig.):

4

Particular relevance (page, column, line, fig.):

5

Particular relevance (page, column, line, fig.):

6

Particular relevance (page, column, line, fig.):

Continued on additional sheet ☐

B. Other evidence

Continued on additional sheet ☐

X. Payment of the opposition fee is made

- as indicated in the enclosed voucher for payment of fees and costs (EPO Form 1010) [X]
- via EPO Online Services [ ]

XI. List of documents

Enclosure No.

0 Form for notice of opposition [X]

1 Facts (see VII.) [X]

2 Copies of documents presented as evidence (see IX.)

a Publications [2]

b Other documents [ ]

3 Signed authorisation(s) (see IV.) [ ]

4 Voucher for payment of fees and costs (see X.) [1]

5 Additional sheet(s) [ ] Number of sheets [ ]

6 Other [X]

Please specify here:

form for acknowledgement of receipt

XII. Signature of opponent or representative

Place: Munich

Date: 01-03-2008

Signature: Mr Mac ALL Pain.

Name (block capitals): MAC ALL PAIN

In case of legal persons, signatory's position within company:

300.4 04.08