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**Datasheet for the decision
of 15 January 2008**

Case Number: T 1033/05 - 3.3.10

Application Number: 98202100.8

Publication Number: 0884057

IPC: A01N 1/02

Language of the proceedings: EN

Title of invention:

Apparatus and method for inactivating viral contaminants in body fluids

Patentee:

Baxter International Inc.

Opponent:

MACO PHARMA

Headword:

Apparatus for inactivating viral contaminants/BAXTER

Relevant legal provisions:

EPC Art. 56, 123(2)

Keyword:

"Main and auxiliary request 1: inventive step (no) - obvious solution"

"Auxiliary request 2: added subject-matter (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 1033/05 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 15 January 2008

Appellant:
(Opponent)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 7 June 2005
rejecting the opposition filed against European
patent No. 0884057 pursuant to Article 102(2)
EPC 1973.

Composition of the Board:

Chairman: R. Freimuth
Members: J.-C. Schmid
P. Schmitz

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal on 9 August 2005 against the decision of the Opposition Division, posted on 7 June 2005, which rejected the opposition against European patent No. 0 884 057 pursuant to Article 102(2) EPC 1973, independent claim 1 thereof reading as follows:

"1. An apparatus for inactivating viruses in a body fluid with methylene blue comprising:

light generation means (202, 204), which generates a light field of wavelength and intensity sufficient to activate methylene blue comprising a pair of light sources (202, 204) disposed so as to face each other with a gap (208) therebetween,

a support surface (222, 232) located in the gap for supporting a container (10) of body fluid mixed with methylene blue for a time sufficient for viruses to be inactivated on irradiation from the light sources, and

a sensor disposed to sense the amount of light delivered to a container on the support surface (222, 232)."

II. Notice of opposition had been filed by the Appellant requesting revocation of the patent in suit in its entirety on the grounds of lack of inventive step (Article 100(a) EPC) and insufficient disclosure (Article 100(b) EPC. *Inter alia* the following documents were submitted in opposition proceedings:

- (1) WO-A-90/13334,
- (6) B. Lambrecht et al: "Photoinactivation of Viruses in human fresh plasma by Phenothiazine Dyes in Combination with Visible light", Vox Sanguinis, (1991), vol. 60, pages 207 to 213 and
- (7) WO-A-91/03933.

III. The Opposition Division held that the claims in the form as granted satisfied the requirements of the EPC.

As regards inventive step, the Opposition Division considered that document (6) was the closest prior art. The object of the patent-in-suit was to provide a method for the photoinactivation of viruses using methylene blue and an apparatus for use therein. The solution proposed was an apparatus characterized by the presence of a sensor detecting the amount of light passing through the blood product. The skilled person reading document (6) wherein the blood product was disclosed to be not, or only marginally, affected by the irradiation passing through it, would come to the conclusion that a sophisticated apparatus including a sensor was superfluous and, hence, the apparatus as defined by claim 1 of the patent-in-suit was considered to meet the requirement of inventive step.

IV. At the oral proceedings before the Board held on 15 January 2008 the Respondent (Proprietor of the patent) defended the maintenance of the patent in suit on the basis of the claims as granted and subsidiarily on the basis of the claims of the auxiliary requests 1 and 2, identical to former auxiliary requests 5 and 1, filed on 28 February 2006, respectively.

Independent claim 1 of auxiliary request 1 differed from claim 1 as granted in that the apparatus was "further comprising a processor coupled to said light sources (202,204) and sensor and operable to monitor the cumulative amount of light delivered to a container on the support surface (222,232)".

Independent claim 1 of auxiliary request 2 differed from claim 1 of the main request in that the feature "sensor disposed to sense the amount of light delivered to a container on the support surface (222, 232)" was amended to read "sensors disposed to sense the amount of light delivered to a container and the amount of light transmitted through said container on the support surface (222, 232)".

- V. The submissions of the Appellant can be summarized as follows:
- As regards inventive step, the Appellant concurred with the Opposition Division that document (6) represented the closest prior art. However, the apparatus used in document (6) for inactivating viruses from a biological fluid with methylene blue already comprised a sensor. Therefore, the difference between the subject-matter of claim 1 of the patent-in-suit and document (6) could not be the presence of a sensor, but was the position of the light sources disposed so as to face each other. Document (1), which belonged to the same technical field as it related also to the field of inactivation of viruses in blood products by irradiation, disclosed an apparatus for inactivating viruses in blood products having light sources positioned both above and below the layer of blood product and comprising an electronic

exposure control system coupled to a sensor and the light sources. Furthermore, document (7) concerning a process of inactivation of viruses in blood products with methylene blue by irradiation with light reported that light underexposure led to an incomplete inactivation of the viruses while overexposure caused damages of the blood products.

The Appellant therefore concluded that the combination of document (6) with document (1) was obvious and resulted in the claimed invention.

VI. As regards inventive step, the Respondent also agreed that document (6) was the closest prior art. Document (6) disclosed an apparatus wherein the blood product was illuminated from one side only. The selenium-illumination meter was used in the apparatus described in document (6) to measure the intensities of the two types of light sources used and not to monitor the dosage of light during the experiment.

The technical problem starting from document (6) was the provision of an improved apparatus capable of monitoring the amount of light during operation, thereby avoiding over and under exposure of the body fluid.

Document (1) belonged to a different technical field, since the inactivation of viruses with UV light was totally different of that with visible light. UV radiations were known to damage body fluids, water penetration was very poor, so that UV dosages were very important. Visible light was known to not damage body fluids. The sensor of the apparatus described in

document (6) was present only to control the intensity of the light, not to integrate the total intensity delivered. Even if a problem with overexposure did arise, document (7) taught the skilled person to solve it in reducing the concentration of methylene blue, since the damage would have been caused rather by the photosensible agent. As document (6) did not highlight any problems with the disclosed process, it was difficult to see why the skilled person would have included a sensor of the type disclosed in document (1) to monitor the cumulative amount of light that was delivered to the container during the treatment.

The Respondent therefore concluded that the skilled person would clearly be deterred from considering document (1) and would never have combined the teachings of documents (6) and (1).

VII. The Appellant requested that the decision under appeal be set aside and that the patent be revoked.

The Respondent requested that the appeal be dismissed and that the patent be maintained as granted or subsidiarily on the basis of auxiliary request 1 or 2 (former auxiliary requests 5 and 1 respectively) submitted with the letter dated 28 February 2006.

VIII. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible

Main and auxiliary request 1: inventive step

2. Independent claim 1 of auxiliary request 1 is directed to a preferred embodiment of the main request, namely to the subject-matter of dependent claim 9 as granted. Thus, the subject-matter claimed in that auxiliary request is covered by that of claim 1 of the main request. In case the embodiment according to that auxiliary request lacked inventive step, such a line of requests would mandatory result in the conclusion that the preceding main request, which encompasses that obvious embodiment, at least to that extent, cannot involve an inventive step either. For this reason, it is appropriate that the auxiliary request 1, in particular the subject-matter of claim 1 thereof, is examined first as to its inventive ingenuity.

2.1 In accordance with the "problem-solution approach" applied by the Boards of Appeal to assess inventive step on an objective basis, it is in particular necessary to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art.

2.2 Document (6) relates to a process for inactivating viruses in a body fluid with methylene blue. It is carried out by using an apparatus comprising a transparent glass plate (support surface) on which

plastic bags (container) containing methylene blue and plasma (body fluid) are placed and illuminated from beneath by fluorescent tubes (light generation means). The intensity of light is determined by an eye-corrected selene illumination meter (sensor). The Board considers, in agreement with the Opposition Division and the Parties, that this document represents the closest state of the art, and, hence, the starting point in the assessment of inventive step.

2.3 In view of this state of the art, the Respondent submitted during the oral proceedings that the technical problem underlying the patent in suit, consisted in providing an improved apparatus capable of monitoring the amount of light during operation, thereby avoiding over and under exposure of the body fluid.

2.4 As a solution to this problem the patent in suit proposes an apparatus according to claim 1 which is characterized by the position of the light generation means which are disposed so as to face other and by the presence of a processor coupled to the light sources and a sensor and operable to monitor the cumulative amount of light delivered to a container on the support surface.

2.5 The Appellant never disputed that the claimed apparatus successfully achieves to monitor the amount of light during operation and the Board is not aware of any reason for challenging this finding. For these reasons, the Board is satisfied that the problem underlying the patent in suit has been successfully solved.

2.6 Finally, it remains to be decided whether or not the proposed solution to the problem underlying the patent in suit is obvious in view of the cited state of the art.

When starting from the apparatus known from document (6), it is a matter of course that the person skilled in the art seeking to provide an improved apparatus capable of monitoring the amount of light during operation would turn his attention to that prior art in the field of inactivation of viruses just dealing with this need. As a skilled person he would thus be struck by document (1) which relates to an apparatus for inactivation of viruses in body fluids which comprises pairs of light sources disposed so as to face each other with a gap therebetween, a support surface located in the gap, a sensor and an electronic circuitry, i.e. processor, coupling the sensor and the light sources, designed for monitoring the cumulative amount of light by shutting off the light sources (see figure 1; page 8, lines 10 to 24; page 11, lines 13 to 20).

The Board concludes from the above that the state of the art represented by document (1) gives the person skilled in the art a concrete hint as to how to solve the problem underlying the patent in suit as defined in point 2.3 above, namely by taking the apparatus known to monitoring the cumulative amount of light from document (1) while keeping the essential characteristic required by the process described in document (6), namely light sources capable of activating methylene blue, thereby arriving at the claimed apparatus, i.e. the solution proposed by the patent in suit.

2.7 For the following reasons the Board cannot accept the Respondent's arguments designed to support inventive step.

2.7.1 The Respondent argued that the skilled man would have considered the control of light exposure in the apparatus of document (6) as superfluous because that document did not highlight any problems in respect of the apparatus described, so that there was no need to improve that described apparatus. However to derive from the silence on drawbacks in a document describing an apparatus that the skilled man would not contemplate improving that apparatus, cannot convince the Board. The Respondent's argument amounts to raise a (pre)condition which is meaningless where, according to the problem solution approach, the objective problem underlying the invention is to be formulated vis-à-vis the closest document (6) (see point 2.1 above). Thus, in order to avoid any hindsight, it is necessary in the objective assessment of inventive step to start from the closest prior art and to determine in the light thereof the problem which the invention address (see point 2.2 above).

Furthermore, just for the sake of completeness, it is noted that no contribution to inventive step can be seen in the identification of the above-defined objective problem since drawbacks linked to light under- or overexposure are known anyhow in processes of inactivation of viruses in blood product with methylene blue under visible light (see document (7), and page 9, line 8, page 15, lines 6 to 9).

2.7.2 According to the Respondent document (1) belongs to a different technical field since inactivations of viruses with UV light and visible light could be totally different, the technical requirements and precautions needed being not the same for UV and visible light. Hence, the skilled person would be deterred from considering document (1) when striving for a solution to the problem underlying the invention.

However, in the present case the skilled person is concerned with the problem of monitoring the amount of light. He would thus look for any apparatuses generating a light field with an electronic light control. Electronic light control devices being not limited to be operated with only one particular wavelength, the skilled person has no reason to confine himself to those apparatuses describing to inactivate viruses with visible light, but would also consider an apparatus operated with other wavelengths, e.g. in the UV range. Moreover, documents (1) and (6) do belong to the same technical field, which is that of inactivation of viruses by radiation, all the more because document (6) directly refers to processes of inactivation of viruses in body fluid with UV light (see page 207, left-hand column, first paragraph).

Thus, the Respondent's submission that the skilled person was deterred from considering the teaching of document (1) is not supported by the fact with the consequence that it cannot convince the Board.

2.8 Under these circumstances, the Board concludes that the person skilled in the art would combine the teaching of the apparatus described in document (1) with that from

the closest prior document (6) in order to solve the problem underlying the patent in suit, thereby arriving to the apparatus of claim 1 without the exercise of inventive skill.

For these reasons, the solution proposed in claim 1 is obvious in the light of the prior art.

2.9 The main request covers the subject-matter of claim 1 of the auxiliary request in the form of the preferred embodiment of claim 9 as granted. Therefore the considerations having regard to inventive step given in points 2.2 to 2.7 supra and the conclusion drawn in point 2.8 supra with respect to the auxiliary request applies also to the main request, i.e. the subject-matter claimed is obvious and does not involve an inventive step.

3. As a result, the Respondent's main and auxiliary requests are not allowable for lack of inventive step pursuant to Article 56 EPC.

4. *Auxiliary request 2: amendments*

4.1 The fresh amendment in claim 1 of this request concerns the presence of sensors (plural) disposed to sense the amount of light delivered to a container and the amount of light transmitted through said container on the support surface. According to the Respondent this amendment is based on the passage of page 11, lines 15 to 20 of the original application which depicts the apparatus of figure 2.

- 4.2 In order to determine whether or not an amendment offends against Article 123(2) EPC it has to be examined whether technical information has been introduced which a skilled person would not have objectively and unambiguously derived from the application as filed.
- 4.3 Figure 2 of the application as filed discloses an apparatus having facing arrays comprising therein light emitting diodes and sensors, coupled to a microprocessor based computer.

A generalisation of this originally disclosed embodiment has thus been made since now claim 1 covers any apparatus with sensors disposed to sense the amount of light delivered to a container and the amount of light transmitted through said container on the support surface, while an apparatus comprising such sensors is disclosed in the application as filed only in combination with other characteristics, in particular with an array containing a given number of diodes and sensors in a particular arrangement, which are not required in the present claim.

- 4.4 Such an amendment resulting in isolating a specific feature from a particular embodiment and generalising it in a claim would only be allowable, provided the skilled man would have readily recognised this feature as not so closely associated with the other features of this embodiment as to determine the effect of that feature of the invention as a whole in a unique manner and to a significant degree.

4.5 In the present case, however, the presence of sensors and their position within the apparatus depicted in figure 2 are closely associated with the presence of the arrays including plurality of diodes. Hence, the presence of sensors is originally disclosed only in the particular context of the apparatus described in figure 2 and the skilled person derives from the disclosed apparatus nothing more than the bare disclosure of all their technical characteristics in their particular combination.

4.6 To dismantle this feature from the apparatus originally disclosed in combination and to generalize that feature over the whole scope of claim 1 covering apparatus with different construction thus provides the skilled person with technical information which is not directly and unambiguously derivable from the application as filed.

As a consequence the amendment in the claim 1 of this request setting the presence of sensors in the claimed apparatus cannot be based on the disclosure of figure 2 of the original application, but is an undue generalisation thereof which extends beyond the content of the application as filed.

Hence, this request must be rejected for not satisfying the requirements of Article 123(2) EPC.

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

P. Cremona

R. Freimuth