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**Datasheet for the decision  
of 27 June 2007**

**Case Number:** T 0369/05 - 3.3.10

**Application Number:** 97100106.0

**Publication Number:** 0852148

**IPC:** A61L 15/46

**Language of the proceedings:** EN

**Title of invention:**

Products having anti-microbial activity

**Patentee:**

SION MICROTEC LTD., et al

**Opponent:**

Paul Hartmann AG

**Headword:**

Anti-microbial agents/SION

**Relevant legal provisions:**

EPC Art. 84, 100(b)

**Keyword:**

"Sufficiency of disclosure (no) - no technical concept fit for  
generalisation - undue burden in carrying out the invention  
throughout the whole area claimed - research program"

"Auxiliary requests (not admitted) - late filed - not clearly  
allowable due to fresh unclarity"

**Decisions cited:**

G 0009/91, T 0301/87, T 0409/91, T 0435/91, T 0092/93,  
T 0401/95

**Catchword:**

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Case Number: T 0369/05 - 3.3.10

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.10  
of 27 June 2007

**Appellant:**  
(Opponent)

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**Representative:**

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**Respondent:**  
(Patent Proprietor)

SION MICROTEC LTD., et al.  
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**Representative:**

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**Decision under appeal:**

Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
20 January 2005 concerning maintenance of  
European patent No. 0852148 in amended form.

**Composition of the Board:**

**Chairman:** R. Freimuth  
**Members:** C. Komenda  
D. Rogers

## Summary of Facts and Submissions

- I. The Appellant (Opponent) lodged an appeal on 21 March 2005 against the interlocutory decision of the Opposition Division of 20 January 2005 which found that European patent No. 852 148 could be maintained in amended form.
- II. Notice of Opposition had been filed by the Appellant requesting the revocation of the patent as granted in its entirety on the grounds of insufficient disclosure (Article 100(b) EPC), lack of novelty and lack of inventive step (Article 100(a) EPC).
- III. The decision under appeal was based on the set of amended claims according to the then pending auxiliary request, independent claim 1 of which reads:
- "1. A dry, disposable, polymeric anti-microbial-applying product having sustained-release anti-microbial activity, said product consisting essentially of:
- a polymeric material selected from the group consisting of cotton, viscose, cellulose triacetate, polypropylene, polyethylene, and mixtures thereof, in the form of fibers, yams, woven, non-woven and knitted fabrics, sheets; and
- an amine salt anti-microbial agent;
- wherein said anti-microbial agent is releasably impregnated into said polymeric material, coated on said polymeric material, or a combination thereof, without an intermediary adhesive or linking agent, and
- said anti-microbial agent is releasable from said polymeric material in anti-microbially effective

amounts for a period of at least three days upon said anti-microbial product being brought into contact with a moist surface."

The Opposition Division held that the amendments made to the claims satisfied the requirements of Article 123(2) and (3) EPC, that the invention was disclosed in a manner sufficiently clear to be carried out by a skilled person, that the invention was novel and involved an inventive step. More particularly, the Opposition Division found that the amendments made to claim 1 were based on original claims 6, 7 and 10. Further, the Opposition Division found that the patent specification contained several examples teaching which type of polymeric material and which type of anti-microbial agent should be used and which concentration of the anti-microbial agent should be applied. Thus, the skilled person had sufficient information to carry out the invention. Further, the Opposition Division held that none of the cited documents disclosed all the features of claim 1 and that taken alone or in combination none of the cited documents rendered the subject matter of claim 1 obvious.

IV. At the oral proceedings before the Board, held on 27 June 2007, the Respondent (Proprietor of the patent) defended the maintenance of the patent in suit in amended form on the basis of a main request corresponding to the set of claims held to be allowable by the Opposition Division (see point III above) and on the basis of two auxiliary requests submitted during these oral proceedings.

Auxiliary request I comprised a set of eight claims. Claim 1 according to auxiliary request I differed from claim 1 according to the main request exclusively in adding the feature that "said amine salt anti-microbial agent is selected from the group consisting of chlorohexidine gluconate, chlorohexidine hydrochloride, benzyl dimethyl hexocylammonium chloride, benzylalkonium chloride, cetyl piridinium chloride (monohydrate), and septabididecyl dimethyl ammonium bromide (carbamide clatharate)".

Auxiliary request II comprised a set of five claims. Claim 1 according to auxiliary request II differed from claim 1 according to the main request in adding the feature that "said anti-microbial agent is chlorohexidine gluconate" and, further, in adding that the anti-microbial agent is releasable in anti-microbially effective amounts "against Staphylococcus aureus".

- V. The Appellant argued that the invention defined the anti-microbial agent to be anti-microbially effective against any type of microorganism. Therefore, in order to be able to carry out the invention the skilled person had to identify the microorganism to be tested. Only then would he be in a position to determine whether the tested anti-microbial agent was releasable in anti-microbially effective amounts for at least three days. Further, he argued that the releasability was influenced by various other operation parameters, e.g. level of humidity, type of polymeric material, concentration. According to variations of each of these parameters the results obtained varied as well, but in an unpredictable manner. Thus, a failure concerning the

tested combinations of parameters did not put the skilled person in a position to derive any guidance thereof for achieving future success. Moreover, the Appellant argued that the patent in suit did not give any evaluation criteria for the results obtained leaving the skilled person in doubts as to whether the obtained results were falling within the meaning of an "anti-microbially effective amount" or not. Therefore, the patent in suit did not contain sufficient information to carry out the invention, but the skilled person had to exercise inventive skills in order to carry out the invention within the whole scope claimed.

Concerning the auxiliary requests filed during oral proceedings the Appellant argued that auxiliary request I was unclear concerning the definition of the anti-microbial agent generating doubts as to clarity (Article 84 EPC). The same argument applied to auxiliary request II, which in addition was regarded as containing an undue generalisation of an example and, thus, was not in keeping with the requirements of Article 123(2) EPC. Therefore, these late filed auxiliary requests should not be admitted into the proceedings.

VI. The Respondent replied that the patent in suit contained sufficient information for a skilled person to carry out the claimed invention. Concerning the type of microorganism to be tested the skilled person would have certainly used those tested in the examples of the specification of the patent in suit. The failures concerning the microorganism *Pseudomonas aeruginosa* would have been identified as being accidental, since it was common general knowledge that *Pseudomonas*

*aeruginosa* were highly resistant against anti-microbial treatment. Thus, a skilled person would not have taken these particular microorganism in determining the effectiveness of the released anti-microbial amounts, but would have selected other conventionally used microorganisms. Concerning the influence of the polymeric material on the anti-microbially effective amounts he argued that some variation of the level of growth inhibition was of no relevance, since in any case some inhibition was achieved, which thus fulfils the criterion of being anti-microbially effective.

Concerning the auxiliary requests the Respondent was of the opinion that the anti-microbial agent was clearly defined therein, since the definition given comprised individual chemical compounds. In view of auxiliary request II the Respondent disputed any violation of Article 123(2) EPC as the application as filed containing numerous examples using *Staphylococcus aureus* as microorganism.

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

The Respondent requested that the appeal be dismissed and the patent be maintained in amended form according to the main request or, subsidiarily, that the patent be maintained upon the basis of any of the auxiliary requests I and II, both submitted during the oral proceedings.

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 Request*

2. *Amendments*

The subject matter of claim 1 is based on original claims 1, 6, 7 and 10, corresponding to granted claims 1, 6, 7 and 10. Therefore, the Board concludes that the subject matter of claim 1 does not extend beyond the content of the application as filed such that the requirements of Article 123(2) EPC are satisfied.

These amendments bring about a restriction of the scope of the claims as granted, and therefore of the protection conferred thereby, which is in keeping with the requirements of Article 123(3) EPC.

3. *Insufficiency of disclosure of the invention (Article 100(b) EPC)*

- 3.1 The main issue to be decided in this appeal is whether or not the decision under appeal was right to find that the patent in suit discloses the claimed invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The Appellant objected in particular to the finding of the Opposition Division that the subject-matter of claim 1 could be carried out by a person skilled in the art



within the whole area claimed, because the amine salt to be used was defined by means of inadequate functional features, namely of being releasable in anti-microbially effective amounts within a period of at least three days.

3.2 Claim 1 comprises the functional definition reading "said anti-microbial agent is releasable from said polymeric material in anti-microbially effective amounts for a period of at least three days". This clear and unambiguous wording makes plain that the functional definition of being releasable from the polymeric material in effective amounts over a specific period of time relates to and determines exclusively the anti-microbial agent to be used in the claimed product. Therefore, the Respondent's allegation that this functional definition rather refers to the claimed product itself is at variance with the facts. Furthermore, the term "releasable" (emphasis added) used in claim 1 for that functional definition specifies what the anti-microbial agent must be able to do. Thus, the functional definition given in claim 1 indicates an ability to be satisfied by the anti-microbial agent and, contrary to the Respondent's submission, is not a property to be attributed to the claimed product.

Moreover, in support of his argument the Respondent referred to the description of the patent in suit, in particular to paragraphs [0011] and [0024], which are supposed to show that the functional definition given in claim 1 for the anti-microbial agent was nevertheless a property of the claimed product.

However, that functional feature in claim 1 refers to and defines the anti-microbial agent and not to a property of the claimed product as specified above. Thus, there is no room for any different interpretation of claim 1 in the light of the description, particularly for one being inconsistent with the clear wording of the claim. Moreover, the cited paragraphs of the description do not support the Respondent's allegation, since they address the activity of the claimed product also indicated in claim 1 and do not relate to the functional definition of an ingredient, i.e. the anti-microbial agent, comprised in the product, which is a different matter.

- 3.3 It is the established jurisprudence of the Boards of Appeal that the requirements of sufficiency of disclosure are only met if the invention as defined in the independent claim can be performed by a person skilled in the art in the whole area claimed without undue burden, using common general knowledge and having regard to further information given in the patent in suit (see decisions T 409/91, OJ EPO 1994, 653, point 3.5 of the reasons; T 435/91, OJ EPO 1995, 188, point 2.2.1 of the reasons). That principle applies to any invention irrespective of the way in which it is defined, be it by way of a functional feature or not. The peculiarity of the functional definition of a technical feature resides in the fact that it is defined by means of its effect. That mode of definition comprises an indefinite and abstract host of possible alternatives, which is acceptable as long as all alternatives are available and achieve the desired result. Therefore, it has to be established whether or not the patent in suit discloses a technical concept

fit for generalisation which makes available to the person skilled in the art the host of variants encompassed by the functional definition of a technical feature in that claim.

3.4 In the present case, the patent in suit aims at providing an anti-microbial-applying product having a sustained-release anti-microbial activity (patent specification, paragraph [0024]). The means provided to achieve this aim are indicated in claim 1 which is directed to a polymeric anti-microbial-applying product consisting essentially of a polymeric material and an amine salt anti-microbial agent. The anti-microbial agent is further defined by a functional feature, namely that it is releasable from the polymeric material in anti-microbially effective amounts for a period of at least three days. The latter feature defining the agent is a functional feature, since it reflects the aim of the patent in suit, which is to provide a product having sustained release anti-microbial activity.

3.5 The definition of the anti-microbial agent in claim 1 contains in fact two parts: first the result to be achieved and second, the indication of a structural requirement to be met in order to obtain the desired result, i.e. an amine salt. However, that structural definition comprises a practically unlimited number of individual compounds, since, apart from being an amine salt, their structure remains completely undefined and, thus, embraces any conceivable structural variation. Thus, the structural definition of the agent in claim 1 covers any chemical compound once it comprises an amine salt group.

However, the Respondent stated during oral proceedings that not all the amine salts covered by the structural definition of claim 1 are suited to effectively inhibit the growth of microorganisms for the required release period of at least three days, i.e. to satisfy at the same time the functional feature indicated in claim 1. This finding is supported by the patent specification, paragraph [0016], indicating that the anti-microbial agent is any amine salt as long as it is a "suitable" broad spectrum amine salt. Therefore, the above structural definition of the agent comprises a host of possible chemical compounds which may or may not lead to the releasability of an anti-microbially effective amount for a period of at least three days.

In order to pick from that host those chemical compounds which satisfy the above functional feature for being a suitable agent, the person skilled in the art is confronted, however, with the uncontested fact that the anti-microbial effective amount and the release period are affected by a number of variables unrelated to the structure of the agent.

- 3.5.1 Firstly, the releasability of the anti-microbial agent as defined in claim 1 is affected by the type of the polymeric material used for preparing the anti-microbial-applying product. This finding is supported by the examples disclosed in the specification of the patent in suit, e.g. in example 5. This example uses different polymeric materials, such as cellulose triacetate, polypropylene and polyethylene, which have been impregnated at the same concentration either with the anti-microbial agent chlorohexidine hydrochloride

(CHXH) or chlorohexidine gluconate (CHXG). The substrates were tested as to their impact on the growth of microorganisms. The results given in Table 4 of the patent specification show that the level of growth inhibition achieved by the anti-microbial agents depends on the polymeric material used: a sample of cellulose triacetate treated with a CHXH solution shows a greater growth inhibition (area of 5-6 mm), while other samples of polypropylene or polyethylene treated with the same CHXH solution shows less growth inhibition (area of 2-4 mm and 3-4 mm, respectively) all samples being tested against the microorganism *Staphylococcus aureus* (SA). Similar results are observed when treating the same samples with CHXG solutions against the microorganisms *Staphylococcus epidermidis* (SE) and *Escherichia coli* (EC). Furthermore, in the same Table 4 of the patent specification it can be observed that samples of polypropylene and polyethylene treated with the agent CHXH show no growth inhibition of the microorganism *Pseudomonas aeruginosa*, whereas a sample of cellulose triacetate does.

- 3.5.2 Secondly, the releasability of the anti-microbial agent as defined in claim 1 is affected by the operating conditions of the test used for its determination, such as the microorganism used in the test. This finding is supported by the examples in the specification of the patent in suit. Thus, in example 1 a cotton gauze treated with a solution of CHXG was tested against various microorganisms. The results listed in Table 1 demonstrate that 1 hour after the start of the test some growth inhibition was observed for all the tested microorganisms. Before the expiry of two days (42 hours) the growth inhibition of *Staphylococcus epidermidis* was

already significantly reduced and disappeared completely after 90 hours, while it still was observed against *Staphylococcus aureus*. The same test sample with the same anti-microbial agent was less effective against *Pseudomonas aeruginosa* and failed to inhibit the growth of that microorganism already after 42 hours. Thus, whether or not an identical anti-microbial agent on the same polymeric support material satisfies the functional feature as defined in claim 1 depends on the microorganism used for testing.

The Respondent held that from his common general knowledge the skilled person was aware that the sensitivity of anti-microbial agents varied depending on the selected microorganism and referred in this respect to well known Minimum Inhibitory Concentrations (MIC) of anti-microbial agents.

However, the Minimum Inhibitory Concentration (MIC) is unsuited to qualify or disqualify a microorganism to be used in a test for identifying anti-microbial agents satisfying the functional feature as defined in claim 1. The results in Table 1 of the patent specification addressed above show, that in the beginning of the tests the same level of growth inhibition against each of the microorganisms *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Escherichia coli* was observed. Therefore, at the beginning of the tests the minimum inhibitory concentrations were achieved in view of all of these microorganisms, whereas after some days the levels of growth inhibition were different from each other and varied from some growth inhibition to no growth inhibition at all, dependent exclusively on the

microorganism used. Thus, the Minimum Inhibitory Concentrations (MIC) is unsuited to select or reject a microorganism for testing to identify an anti-microbial agent satisfying the functional feature.

3.5.3 Thirdly, the releasability of the anti-microbial agent as defined in claim 1 is affected by the concentration of the amine salt used in the test. This finding is supported by example 6 of the specification of the patent in suit, wherein a non-woven polymeric material was treated with CHXG solutions of different concentrations. The results concerning the growth inhibition as indicated in Table 5 demonstrate that with higher concentrations of the amine salt a higher level of growth inhibition is achieved against *Staphylococcus epidermidis* and against *Escherichia coli*, while in case of *Staphylococcus aureus* the situation is just the opposite, namely that a higher concentration of the anti-microbial agent results in a lower level of growth inhibition. Further, in case of the microorganism *Pseudomonas aeruginosa* the lower concentration of the amine salt achieves hardly any growth inhibition (area beyond the matrix below 1 mm) and only with higher concentration some growth inhibition (area of 1-2 mm) is achieved. Thus, whether the anti-microbial agent satisfies the functional definition of claim 1 depends on the concentration of the agent used.

3.6 It follows from the above, that there is no necessary correlation between the structural definition of the anti-microbial agent being an amine salt and the further functional requirement in claim 1 that said anti-microbial agent is releasable from said polymeric

material in anti-microbially effective amounts for a period of at least three days. Therefore, the releasability in anti-microbially effective amounts as defined in claim 1 necessarily varies unsystematically and unpredictably without any conclusive interdependency with the exact structure of the anti-microbial agent. Neither the common general knowledge nor the patent in suit provides any technical guidance according to which a person skilled in the art could identify the suitable amine salts without undue effort. The person skilled in the art trying to trace out suitable amine salts meeting the functional definition set out in claim 1, does not have at his disposal any information leading necessarily and directly towards success through the evaluation of initial failures. Thus, the functional definition of the anti-microbial agent given in claim 1 is no more than an invitation to perform a research program in order to find the suitable amine salts (cf. decision T 435/91, loc.cit., point 2.2.1, last paragraph, of the reasons).

- 3.7 For these reasons, in the Board's judgement, the invention as defined in independent claim 1 cannot be performed by a person skilled in the art within the whole area claimed without undue burden.
- 3.8 The Board accepts that the person skilled in the art may be acquainted with test methods for determining the effectiveness of anti-microbial agents against microorganisms. The Respondent argued that although there is a plurality of microorganisms to select from, this choice could not impose an undue burden on the skilled person, since based on his common general knowledge he would select conventional test



microorganisms such as *Escherichia coli* or *Staphylococcus aureus*.

However, the Respondent's conclusion that given the ability of a person skilled in the art to determine the effectiveness of a selected anti-microbial agent against some microorganisms, the claimed invention cannot be objected to on the basis of Article 100(b) EPC, is not valid. The decisive fact in the present case is that the person skilled in the art, whilst being able to measure an anti-microbial activity, cannot carry out the invention without undue burden within the whole area claimed, since the functional definition of the anti-microbial agent in claim 1 merely invites him to perform a research program due to the lack of any technical guidance comprised in the patent in suit (cf. points 3.1 to 3.6 above).

4. In these circumstances, the Appellant's main request must fail as the patent in suit 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 pursuant to Article 100(b) EPC.

#### *Auxiliary Requests I and II*

5. *Admissibility*

Both auxiliary requests were submitted by the Respondent during oral proceedings before the Board. Admission into the proceedings of requests filed at such a very late stage of the appeal proceedings is a matter of discretion for the Board of Appeal and is not available as of right. In exercising due discretion, it

is established jurisprudence of the Boards of Appeal that crucial criteria are whether or not the amended claims of those requests are clearly allowable and whether or not those amended claims give rise to fresh issues which the other party can reasonably be expected to deal with properly without unjustified procedural delay (see T 92/93, point B or the reasons; T 401/95, point 5.2 of the reasons, neither published in OJ EPO).

5.1 Though Article 84 EPC may not be raised as ground for opposition in the sense of Article 100 EPC, Article 102(3) EPC stipulates that, taking into consideration the amendments made to the patent in suit during opposition (appeal) proceedings, the patent and the invention to which it relates meet the requirements of the European Patent Convention. Thus, according to established jurisprudence of the Boards of Appeal, the Board has the power to examine whether the patent satisfy all requirements under the EPC, as long as the objections arise out of the amendments made thereto. That examination requires to consider whether or not those amendments introduce any contravention of any requirement of the EPC, including Article 84 EPC (see decisions T 301/87, OJ EPO 1990, 335, point 3.8 of the reasons; G 9/91, OJ EPO 1993, 408, point 19 of the reasons). Therefore it must be examined whether or not these amendments are in keeping with the requirements of Article 84 EPC, in particular with that of clarity.

5.2 In the present case, amended claim 1 of auxiliary request I defines the anti-microbial agent twofold, firstly by way of a functional definition and secondly as comprising a member selected from a list of individual chemical compounds (cf. points I and IV

supra). Such a definition, wherein the second part thereof appears either contradictory to the first part or would render said first part superfluous, leads to confusion, with the consequence that the subject-matter covered by that claim is opaque.

The Respondent argued that there was no unclarity in the claim as to the anti-microbial agent due to the presence of both a functional feature and a list of individual chemical compounds, since the functional feature defined a property of the claimed product. This argument is, however, devoid of merit, for the reasons given in detail in section 3.2 above.

- 5.3 Claim 1 thus fails to meet the requirement of clarity imposed by Article 84 EPC, such that late filed auxiliary request I is not clearly allowable, with the consequence that the Board exercises its discretion not to admit this request into the proceedings.
- 5.4 Claim 1 of auxiliary request II corresponds to that of auxiliary request I apart from reducing the list of anti-microbial agents in auxiliary request I to a single chemical compound. Thus, claim 1 of auxiliary request II still comprises a twofold definition of the anti-microbial agent. Therefore, the considerations having regard to clarity set out in points 5.1 and 5.2 above and the conclusion drawn in point 5.3 above with respect to claim 1 of auxiliary request I apply also to claim 1 of auxiliary request II, i.e. that the subject matter of that claim is opaque.

Claim 1 being not clearly allowable, auxiliary request II shares the fate of auxiliary request I in that the Board exercises its discretion not to admit that request into the proceedings.

**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:

C. Moser

R. Freimuth