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**Datasheet for the decision
of 26 September 2017**

Case Number: T 0389/14 - 3.3.10

Application Number: 09157030.9

Publication Number: 2075014

IPC: A61L29/08, A61L29/16,
A61L27/34, A61L27/54

Language of the proceedings: EN

Title of invention:

Compositions and methods for coating medical implants

Patent Proprietor:

ANGIOTECH INTERNATIONAL AG

Opponent:

Covidien

Headword:

Relevant legal provisions:

EPC Art. 100(a), 56

Keyword:

Inventive step - (no) - all requests

Decisions cited:

T 0020/81

Catchword:



Beschwerdekammern
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Case Number: T 0389/14 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 26 September 2017

Appellant: Covidien
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Respondent: ANGIOTECH INTERNATIONAL AG
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
19 December 2013 concerning maintenance of the
European Patent No. 2075014 in amended form.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division to maintain European patent No. 2 075 014 in the form of the main request then pending.
- II. Notice of opposition had been filed on the ground of lack of novelty and inventive step (Article 100(a) EPC).
- III. The documents filed during the opposition proceedings included the following:

- D1: Wyszynski *et al.* Sustained Release of 5-Flurouracil from Ethylene Acetate Copolymer, *Journal of Ocular Pharmacology*, vol. 5, 1989, 141-146.
- D2: WO 96/30060
- D3: Bodet *et al.* Antibacterial activities of antineoplastic agents, *Antimicrob. Agents Chemother.* 1985, 28(3):437-439
- D4: EP 0 882 461 A2
- D5: US 6,369,116 B1
- D8: US 6,335,029 B1

Experimental evidence was filed as a declaration by David Parker.

- IV. The opposition division concluded that document D2 was the closest prior art, that the problem underlying the claimed invention was to provide further antibacterial agents to be used in the context of D2 and that the solution, which was characterised by requiring 5-fluorouracil or floxuridine, was inventive. Although document D3 hinted at the use of the former as

antibacterial agent, it did not teach its therapeutic use, as other concerns such as toxicity could have been involved.

- V. With a letter dated 6 October 2015, the respondent filed a first auxiliary request, labelled "second amended claims". On 10 November 2014, it filed its second auxiliary request, labelled "third amended claims".

Claim 11 of the main request, which is claim 11 of the patent as granted, claim 10 of the first auxiliary request and claim 1 of the second auxiliary request read as follows:

"5-fluorouracil or floxuridine for use in reducing or inhibiting bacterial or fungal infection associated with a medical implant, wherein the medical implant releases the 5-fluorouracil or floxuridine in an amount effective to reduce or inhibit bacterial or fungal infection associated with a medical implant."

- VI. With a letter dated 25 July 2014, the registrar of the board informed the parties that the notice of appeal did not indicate the name and address of the appellant. The notice of appeal referred to Covidien LP, which was not the opponent. The board set a two-month time limit for clarifying this issue.
- VII. In a letter dated 19 August 2014, the appellant stated that the name of the appellant was Covidien, not Covidien LP. The letter further stated that "the name of the Appellant is Covidien".
- VIII. The arguments of the appellant relevant for the present decision were the following:

Documents D1, D2 and D8 could be considered the closest prior art. The problem underlying the claimed invention was to provide further compounds for use in the treatment of bacterial infection associated with an implant, and the claimed solution was obvious having regard to D3.

- IX. The arguments of the respondent relevant for the present decision were the following:

It was not clear whether the appeal had been filed in the name of Covidien or of Coviden, as both names were mentioned in the appellant's answer to the board's communication. For that reason, the appeal should be rejected as inadmissible.

Document D2 was the closest prior art, and did not disclose either 5-fluorouracil or floxuridine. The problem underlying the claimed invention was to provide improved treatment of bacterial infection associated with an implant, and the solution, namely the claimed compounds for such use credibly solved that problem according to the evidence on file.

- X. The board informed the parties in a communication dated 27 October 2004 that it was inclined to consider the appeal admissible, and that admissibility would be discussed together with the substance of the appeal.

- XI. In preparation for the oral proceedings, the board further informed the parties with a communication dated 19 July 2017 that it considered that document D4 was the closest prior art, that it had to be discussed whether the problem put forward by the respondent had been credibly solved or should be reformulated in a

less ambitious manner, as there was no direct comparison between the infection inhibition achieved by the claimed coatings and those of the medical implants of the prior art. Lastly, the board informed the parties that it considered that the fact that 5-fluorouracil had been disclosed as antibiotic (D3) and used in coatings of medical implants (D1, D5) to be relevant for the issue of inventive step.

The parties replied to this communication merely by informing the board that they would not be attending the oral proceedings, which took place in their absence on 26 September 2017.

XII. The final requests of the parties were the following:

- The appellant requested, in writing, that the decision under appeal be set aside and the patent revoked.
- The respondent requested, in writing, that the appeal be dismissed or, subsidiarily, that the patent be maintained on the basis of either the first or second auxiliary requests, the former having been filed as "second amended claims" with a letter dated 6 October 2015, the latter having been filed as "third amended claims" with the response to the grounds of appeal dated 10 November 2014.

It further requests that document D10, filed by the appellant with a letter dated 20 April 2015, not be admitted into the proceedings.

XIII. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. Admissibility of the appeal

- 1.1 The notice of appeal was filed in the name of Covidien LP, which was not a party to the opposition proceedings. The board set a two-month time limit for remedying this deficiency.

In a letter dated 19 August 2014, the appellant stated that the appeal had been filed by Covidien, which was the opponent, although "Covidien" was also mentioned some lines below.

Due to this inconsistency, the respondent requested that the appeal be held inadmissible.

- 1.2 It is apparent that the true intention of the appellant was to file the appeal in the name of the former opponent Covidien, and that the mention of Covidien in the same letter is a mere typographical error. For this reason, the requirements of Rule 99(1) EPC have been complied with, with the consequence that the appeal is admissible.

2. Inventive step, all requests

2.1 Closest prior art

Claim 11 of the main request, claim 10 of the first auxiliary request and claim 1 of the second auxiliary request are directed to 5-fluorouracil or floxuridine for use in reducing or inhibiting bacterial or fungal infection associated with a medical implant, wherein the medical implant releases 5-fluorouracil or floxuridine in an amount effective for such use.

The opposition division and the respondent considered that document D2 was the closest prior art. The appellant argued that not only D2 but also D1 and D8 could be the closest prior art.

The board considers, however, as indicated in its communication to the parties dated 19 July 2017, that document D4, which relates to the prevention of infectious diseases (column 1, lines 35-36) mediated by catheters such as urinary catheters (column 3, line 26) coated with an antimicrobial substance (claim 1) selected from the list given in column 5, line 12 to column 6, line 27, comes even closer to the claimed invention. Document D4 does not disclose 5-fluorouracil as a suitable drug for use with the catheters disclosed.

2.2 Technical problem underlying the invention

The respondent argued that the technical problem underlying the claimed invention was to provide compounds which improved the treatment of bacterial infection associated with an implant (see point 123. of the patentee's response to the grounds of appeal).

2.3 Solution

The solution to this technical problem are the claimed compounds, 5-fluorouracil or floxuridine, for use in reducing or inhibiting bacterial or fungal infection associated with a medical implant through release from said implants.

2.4 Success

The respondent relied on paragraphs [0005] and [0027] of the patent in suit, and on the declaration by Mr Parker, to support its argument that the problem had been effectively solved by the features of claim 1.

- 2.4.1 Paragraph [0005] of the granted patent refers to the known problem of the risk of infection associated with implants, and to the colonisation of such implants by bacteria resistant to antibiotic coatings. Paragraph [0027] discloses that devices containing the claimed compounds have potent antimicrobial activity at low doses, and contain a drug which is not used to combat subsequent infection. However, it cannot be concluded from any of these passages whether any improvement has indeed been achieved, as they do not compare the compounds claimed with those of the art.
- 2.4.2 The data in Mr Parker's declaration show that coatings containing the claimed compounds were effective in reducing infection. However, these data did not allow a direct comparison with the compounds of the art, and thus no improvement is apparent.
- 2.4.3 For these reasons, it is concluded that the problem formulated by the respondent has not been credibly solved.

2.5 Reformulation of the technical problem

According to the case law, alleged but unsupported advantages cannot be taken into consideration in determining the problem underlying the invention (see e.g. decision T 20/81, OJ EPO 1982, 217, Reasons 3, last paragraph).

As the alleged improvement in terms of enhanced

antibacterial activity lacks the required support, the technical problem as defined above needs to be reformulated as to provide further compounds for use in reducing or eliminating infections associated with medical implants.

- 2.6 It thus remains to be decided whether or not the proposed solution to the objective problem defined above is obvious from the prior art.
- 2.6.1 D3 discloses that 5-fluorouracil has antibacterial properties as well as being a neoplastic agent, and the skilled person knows that 5-fluorouracil has already been used in coatings for topical use (D1, page 141, first paragraph of the section "Introduction"; D5, col. 1, lines 46-50). The skilled person would thus regard its use in a coating as sufficiently safe. For these reasons, it is concluded that he would have combined the teaching of D3 with that of D4 and arrived at the claimed invention without using inventive skills. Thus, 5-fluorouracil for use for reducing or inhibiting bacterial or fungal infection associated with a medical implant is not inventive within the meaning of Article 56 EPC.
- 2.6.2 The opposition division concluded, in the context of claim 1 of the main request then pending, that D3 did not suggest using 5-fluorouracil as an antibacterial agent, but merely disclosed that it had antibacterial properties as well as being a neoplastic agent. There could be other concerns, such as toxicity, which might argue against its use, and the opposition division therefore concluded that the skilled person would not have contemplated these compounds for the use required by claim 1.

However, medical implants containing 5-fluorouracil and capable of releasing it for topical use are already state of the art (D1, page 141, first paragraph of section "introduction"; D5 col. 1, lines 46-50). The skilled person would thus consider said compound to be a sufficiently safe therapeutic agent. This argument is therefore not convincing.

2.7 As the subject-matter of claim 11 of the main request, claim 10 of the first auxiliary request and claim 1 of the second auxiliary request is not inventive, none of the requests on file is allowable.

2.8 The board did not rely on the content of document D10 in this decision. There was thus no need to decide whether or not to admit it 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:



L. Stridde

P. Gryczka

Decision electronically authenticated