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**Datasheet for the decision
of 17 July 2012**

Case Number: T 0721/10 - 3.2.08

Application Number: 04024344.6

Publication Number: 1523967

IPC: A61F 5/443

Language of the proceedings: EN

Title of invention:

Ostomy pouch attachment adhesives resistant to stomal effluent

Patentee:

Bristol-Myers Squibb Company

Opponent:

Hollister Incorporated

Headword:

-

Relevant legal provisions:

EPC Art. 100(b), 104(2)

EPC R. 88(2)

Keyword:

"Sufficiency of disclosure (no)"

"Apportionment of costs (yes)"

Decisions cited:

-

Catchword:

-



Case Number: T 0721/10 - 3.2.08

D E C I S I O N
of the Technical Board of Appeal 3.2.08
of 17 July 2012

Appellant: Bristol-Myers Squibb Company
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 25 January 2010
revoking European patent No. 1523967 pursuant
to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: R. Ries
A. Pignatelli

Summary of Facts and Submissions

- I. By its decision posted on 25 January 2010 the opposition division revoked European patent No. 1 523 967.

The opposition division held that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and hence the objection under Article 100(b) EPC was justified. It was reasoned that the exact meaning and the composition of the effluent and the amount of effluent migration which was acceptable to fall within the definition "resist migration of effluent" were not defined in the patent so that the skilled person was unable to reproduce these features and to determine what measurement actually corresponded to the term "resist migration of effluent" within the scope of claim 1.

In the opposition proceedings the patent proprietor neither responded to the opposition division's preliminary opinion annexed to the summons for oral proceedings nor to the opponent's request to cancel the oral proceedings in view of the patentee's silence. Nor did the patent proprietor inform the opposition division in advance that it would not attend the oral proceedings. Upon the opponent's request, the opposition division thus decided that the patent proprietor should bear 100% of the costs incurred by the opponent for attending the oral proceedings.

- II. The appellant (patent proprietor) lodged an appeal on 6 April 2010 against the decision of the opposition

division, paying the appeal fee on the same date. The statement setting out the grounds of appeal, which was received on 4 June 2010, included arguments with respect to the objections raised under Article 100(b) and (c) EPC, but no counterarguments on the opposition division's decision on the apportionment of the respondent's costs.

III. In an official communication the Board gave its provisional view on the case. With particular respect to the ground of opposition under Article 100(b) EPC, the Board entertained some doubt on the test criteria that should be applied in order to evaluate reliably whether the functional feature "to resist migration of effluent for at least 12 h", which was not clearly defined in the patent specification, was satisfied. The appellant did not submit any counterarguments to the Board's provisional opinion.

IV. Oral proceedings took place on 17 July 2012. By its letter dated 4 July 2012, the appellant informed the Board that it would not attend the oral proceedings. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without this party.

The following requests were made:

In its written submissions, the appellant requested that the decision under appeal be set aside in its entirety and the patent be maintained as granted.

The respondent (opponent) requested that the appeal be dismissed.

In its letter dated 6 July 2012, the respondent referred to the opposition division's decision, part 9 deciding on the apportionment of costs, and requested the fixing of the costs in accordance with Article 104(2) and Rule 88(2) EPC.

V. Claim 1 as granted read as follows:

"An ostomy device comprising an attachment component for attachment to the body, an effluent containment component secured to the attachment component, and a coupling mechanism for securing the effluent containment component to the attachment component, wherein:

the coupling mechanism includes an adhering component with an adhesive that comprises either a multi-block copolymer of vinyl aromatic and olefin comonomers, or poly(ethylene vinyl acetate), or combinations thereof, the adhesive resists migration of effluent for at least 12 hours; and when the adhesive comprises a multi-block copolymer of vinyl aromatic and olefin comonomers:

said multi-block copolymer comprises from about 20 to about 85 percent by weight of the dry adhesive, the adhesive further includes a plasticizer comprising from about 0 to about 40 percent by weight of the dry adhesive, and the adhesive further includes a tackifier comprising from about 5 to about 60 percent by weight of the dry adhesive."

VI. The appellant's written arguments relevant to the present decision are summarized as follows:

As explained in the patent specification, many conventional ostomy devices entailed the problem that they did not resist migration of stomal effluent at the adhesive interface for a period of at least 12 hours. In order to compensate for the reduction in adhesion caused by the migration of effluent, conventional adhesives initially exhibited high peel strengths which adversely affected the handling of the ostomy device by the user. The present patent had sought to identify a trend in adhesives which, on the one hand, reliably resisted migration of effluent and, on the other hand, exhibited a lower peel strength which facilitated removal and repositioning of the ostomy pouch and still provided durable attachment.

As regards the meaning of the term "effluent", the present patent related to an ostomy device and, consequently, the "effluent" featuring in claim 1 must be clearly stomal or intestinal effluent rather than any other fluid. It was also clear to the skilled person that the claimed device should be able to withstand the most "invasive" composition of effluent likely to be encountered in use and that the most invasive effluent corresponded to the "high" concentration in the tests performed in the patent. For evaluation purposes, the patent proprietor had used its own synthetic intestinal effluent which was more hygienic and was chosen such that it was at least representative of the migration properties of real stomal effluent. Instead of course, the skilled person was able to evaluate effluent migration simply by using

real stomal effluent and, therefore, he or she did not need to know the exact composition of the patentee's synthetic effluent or simulated ileo fluid (SIF). A range of different real stomal effluents from ostomates, especially those known to leak through conventional ostomy adhesive interfaces, could be used. Besides, the respondent had not demonstrated any technical difficulty in reproducing the migration testing using "real effluent".

Regarding the meaning of "resist", this term had the well established meaning to "obstruct" or "try to prevent". Thus the adhesive that "resisted migration of effluent for at least 12 hours" obstructed or tried to prevent migration of the effluent. All that this feature meant was that there was still resistance to migration until the effluent had migrated from one edge to the other edge of the adhesive coupling and that at that time migration was complete. Whether or not an adhesive was effective in resisting effluent migration across the adhesive interface for a certain period of time was, therefore, readily testable by the skilled person.

According to established case law of the Boards of Appeal, lack of sufficiency of disclosure presupposed that there were serious doubts substantiated by verifiable facts. As proof that an invention had been insufficiently disclosed, evidence was required that an attempt to reproduce it must fail. However, no such evidence was provided by the respondent.

VII. The respondent's arguments are summarized as follows:

The subject matter of claim 1 did not fulfil the requirements of Article 100(b) EPC since no information was found in the application as originally filed teaching the skilled reader that the "effluent" in claim 1 was equal to the "high concentrations of synthetic stomal fluid (SIF), as alleged by the appellant. Moreover, no instructions could be found as to how the high concentration of SIF should be prepared. Given this situation, the skilled person was unable to achieve the effect of the functional feature within the whole ambit of the claim with or without using his or her common general knowledge, since no fully self-sufficient concept was provided by the patent specification as to how the result was to be achieved.

Turning to the wording "to resist migration" in claim 1, the appellant's interpretation of this term had no basis in the application as filed and nothing was found that this particular interpretation was the correct way to define the functional feature and thus the scope of granted claim 1.

Reasons for the Decision

1. The appeal is admissible.
2. Sufficiency of disclosure; Article 100(b) EPC
 - 2.1 Claim 1 of the present patent is concerned with ostomy pouch attachment adhesives which are resistant to stomal effluent and help to secure the effluent

containment (pouch) to the body attachment component (wafer). One essential technical feature for solving the problem of fluid migration underlying the patent at issue resides in the ability of the adhesive set out in claim 1 to "*resist migration of effluent for at least 12 hours*". To this end, Table 2 of the patent specification defines a migration test rating scale starting with "no migration" (rating 0) and ending with "leaking through the coupling entirely" (rating 5). However, the patent specification fails to give a precise definition which rating is actually to be achieved by the adhesive, i.e. how much migration is considered acceptable so that the functional feature "*to resist migration of effluent for at least 12 h*" is satisfied.

2.2 The appellant argued that in the present context the term "resist" had a well established meaning such as to "obstruct" or "try to prevent" migration of effluent. Therefore, this feature was to be interpreted as meaning that there was still resistance to migration until the effluent had migrated from the inner to the outer edge of the adhesive surface. Whether or not an adhesive was effective in resisting effluent migration across the adhesive interface, for a certain period of time, was readily testable by a skilled person.

This specific interpretation, however, cannot be unambiguously deduced from the disclosure of the patent application as filed and the appellant did not refer to passages in the application either in support of its view. Hence, there is no basis showing that the appellant's particular interpretation was the correct way to define this functional feature.

2.3 In addition, the patent specification does not define the composition of the synthetic effluent in the form of Simulated Ileo Fluid (SIF) which was used by the patent proprietor for testing whether the functional feature is fulfilled or not (paragraphs [0031], [0032] of the application as filed). Specifically, it remains unknown which meaning the "low", "medium" or "high" concentrations of the SIF referred to in Tables 1 and 3 of the patent specification are supposed to have. It therefore remains doubtful which test criteria should be applied to reliably evaluate whether the functional feature given in claim 1 is satisfied.

The appellant argued that the term "stomal effluent" used in the patent-at-issue corresponded to the "high" concentration in the tests performed in the patent since the adhesive should be able to withstand the most aggressive and invasive composition of effluent likely to be encountered in use. Hence, the effluent migration could be evaluated by using real stomal effluent and the skilled person did not at all need to know the exact composition of the patentee's synthetic effluent SIF.

However, nothing is found in the original application that the stomal effluent should correspond to the "high SIF concentration" and even if this were taught, the chemical composition of the synthetic "high concentration SIF" remains unknown. As to the appellant's argument to use real effluent for testing, it is generally known that the individual intestinal fluids can vary greatly in their ability to attack the component materials of ostomy devices (the application

as filed, paragraph [0024])). In order to take this fact into account, "*testing was conducted at various concentrations of SIF to account for individual variations in stomal output*", as mentioned in paragraph [0033], second sentence of the original application. Hence, using real individual stomal fluid would inevitably lead to different and varying test results.

Given the uncertainties of the test conditions described in the patent at issue, the appellant's argument that the respondent had not provided evidence that an attempt to reproduce the claimed invention must fail has no bearing on the matter.

- 2.4 Having regard to the previously mentioned deficiencies, it must be concluded that the disclosure of the patent at issue does not contain sufficient information for the skilled person to achieve the result of the functional feature within the whole ambit of the claim. The subject matter of claim 1 therefore does not meet the requirements of Article 100(b) EPC.

3. Apportionment of costs

The Board noted that the appellant appealed against the decision in its entirety. However, no reasons, arguments or comments challenging the opposition division's decision about the apportionment of costs were advanced by the appellant in the grounds of appeal. The Board itself could not see any reasons either why the opposition division's decision should be incorrect in that respect.

The respondent's request for the fixing of the costs is to be dealt with by the opposition division according with Article 104(2) and Rule 88(2) EPC. The opposition division must, upon request, fix the costs to be paid since its decision apportioning them has become final due to the dismissal of the appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner