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**Datasheet for the decision  
of 6 May 2009**

**Case Number:** T 0656/07 - 3.2.02

**Application Number:** 01127303.4

**Publication Number:** 1195152

**IPC:** A61F 5/443

**Language of the proceedings:** EN

**Title of invention:**

Low profile ostomy system with repositionable pouch

**Patentee:**

Bristol-Myers Squibb Company

**Opponent:**

Coloplast A/S

**Headword:**

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**Relevant legal provisions:**

EPC Art. 84

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Clarity (no)"

**Decisions cited:**

G 0010/91, G 0009/92, T 0367/96, T 0853/02, T 0472/88,  
T 0301/87, T 0688/91, T 0227/88

**Catchword:**

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Case Number: T 0656/07 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 6 May 2009

**Appellant:** Coloplast A/S  
(Opponent) Holtedam 1  
DK-3050 Humlebaek (DK)

**Representative:** -

**Respondent:** Bristol-Myers Squibb Company  
(Patent Proprietor) 345 Park Avenue  
New York NY 10154 (US)

**Representative:** Mays, Julie  
Barker Brettell LLP  
10-12 Priests Bridge  
London SW15 5JE (GB)

**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
on 14 February 2007 concerning maintenance of  
European patent No. 1195152 in amended form.

**Composition of the Board:**

**Chairman:** M. Noel  
**Members:** D. Valle  
A. Pignatelli

## **Summary of Facts and Submissions**

- I. The appellant (opponent) lodged an appeal on 19 April 2007 against the decision of the opposition division posted on 14 February 2007 to maintain the patent in amended form. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 22 June 2007. The patent was challenged on the basis of lack of feasibility and lack of inventive step.

In the communication annexed to the summons to the oral proceedings, the Board made it clear that lack of clarity of the main request would be also an issue to be discussed.

In response, the respondent (patentee) filed auxiliary requests 1 to 4 with letter of 2 April 2009.

- II. Oral proceedings were held on 6 May 2009.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be revoked. He further requested that the auxiliary requests 1 to 4 filed by the respondent should not be admitted into the proceedings and that documents D9 to D13 be introduced into the proceedings.

The respondent requested that the appeal be dismissed or that the patent be maintained on the basis of one of the four auxiliary requests filed with letter of 2 April 2009.

III. Independent claim 1 of the main request as maintained by the interlocutory decision reads as follows:

Claim 1

"An ostomy pouch (12) comprising:

- a) a pouch envelope (16) formed of flexible plastic material defining a waste collection chamber (46) for body waste that passes through a stoma (120),
- b) a waste inlet opening (32) formed in said envelope for positioning around said stoma to permit passage of waste material from said stoma to said collection chamber, and
- c) flexible annular pouch coupling means (50) on said pouch envelope (16) at said waste inlet opening (32), said pouch coupling means (50) having a resealable coupling adhesive (62) and support means for the resealable adhesive for avoiding wrinkling of said resealable coupling adhesive when said pouch coupling means (50) is flexed or separated from a coupling bond with a body-side mounting wafer (14) as according to one of claims 2, 3, said support means including a polyethylene foam layer (60) joined to an outside surface of said pouch envelope (16) characterized by said pouch coupling having a manipulation tab (54) extending from a generally circular peripheral portion to manipulate securement and removal of said pouch coupling means (50) with respect to a body-side mounting wafer (14), said tab (54) being integral with said polyethylene foam layer (60) and freely moveable with respect to said pouch envelope (16)."

IV. The arguments submitted by the parties in writing and during the oral proceedings are essentially as follows:

The appellant argued that the independent claims according to the main request did not comply with Articles 84 and 123 (2) EPC and that there was no justification for filing the auxiliary requests.

The respondent argued that clarity was not a ground for opposition. Furthermore lack of clarity did not arise from the amendments carried out after grant. He pointed out in particular that claim 1 of the main request was a combination of claims 1 and 2 as granted. T 367/96 stated that Article 102(3) EPC did not allow objections to be based upon Article 84 EPC if such objections did not arise out of the amendments made (see point 6.2 of the reasons). T 853/02 also rejected an objection that had been raised under Article 84 EPC and was directed to a feature already present in claim 1 of the patent as granted. Finally, G 10/91 stated that fresh grounds for opposition could be considered in appeal proceedings only with the approval of the patentee.

He also argued that auxiliary requests 1 and 2 were already present in opposition proceedings as auxiliary requests 5 and 6, that auxiliary request 3 had been submitted in order to address a document filed late by the appellant and auxiliary request 4 to meet the objections contained in the communication of the Board.

### **Reasons for the Decision**

1. The appeal is admissible.
2. Clarity of claim 1 of the main request

2.1 Claim 1 of the main request is directed to a pouch having coupling means whereas:

" ... said pouch coupling means (50) is flexed or separated from a coupling bond with a body-side mounting wafer (14) as according to one of claims 2, 3 ... ".

This feature represents an attempt to define an object (the pouch coupling means) in terms of its suitability to interact (by coupling and bonding) with a complementary element (wafer). This can only be acceptable, however, if the complementary element itself has clearly identified corresponding features. In the present case, the person skilled in the art will not be able to determine on the basis of the features as claimed what is actually the scope of protection since it depends on the nature and characteristics of the wafer to be coupled by bonding.

It is further not clear to what extent the features of claims 2 and 3 should be incorporated into claim 1 and to what extent they will affect the delimitation of the claimed subject matter either, since it is not clear to which previous feature or group of features the expression "as according to" actually refers. This situation causes a general lack of clarity as far as the content and the extent of the claim are concerned (see also T 688/91, point 4.15 of the reasons).

It is the position of the Board that the lack of clarity arose - at least in part - from the amendments carried out after grant. The invention as granted was defined in independent claim 1, directed to a pouch,

and in independent claim 3, directed to a wafer. Claim 1 was objectively unclear since it sought to define the pouch coupling means by making reference to the wafer. The amendment to claim 1 of the main request submitted during the opposition proceedings introduces in claim 1 further features - in relation to the pouch coupling means - which were formerly contained in dependent claim 2. This makes it necessary to reconsider the coupling means claimed in claim 1 on the light of these new incorporated features - which are now considered essential due to the amendment - and also to reconsider in this new light the fact that the coupling is to be taken in connection with a body-side mounting wafer.

It follows that one cannot ignore the fundamental lack of clarity generated by the cross-references. More specifically, while the cross-reference to the wafer was already present in claim 1 as granted, the incorporation into claim 1 of further features concerning the coupling means makes it necessary to reconsider the interaction of the pouch with the wafer and as a result an objection of lack of clarity due to this new interaction emerges.

Therefore, the amendments introduced into claim 1 substantially affect the clarity of claim 1 as a whole, since its subject-matter is not clearly defined. This general lack of clarity makes it impossible to compare the subject matter of claim 1 to the state of the art and to proceed further with the substantive examination of said claim.

- 2.2 This lack of clarity can be objected to in opposition proceedings because it is generated by the amendments

made during this procedure, even if the contested feature as such was already present in the claims as granted but in another combination.

In fact, it is not enough formally to state that a feature was present in the granted version in order to limit the power of investigation of the Board as far as clarity objections arising from an amendment is concerned. It is also necessary to ascertain the effect produced by the amendments introduced into the claim as a whole since a feature of a claim is not to be seen in isolation, but through its interaction with the other features of the claimed combination. A new combination of features is also an amendment in itself.

As pointed out in T 472/88, point 2 of the reasons, in the statement contained in decisions T 227/88 and T 301/87: "fresh objections based on Article 84 EPC are not allowed if such objections did not *arise* out of the amendments so made", the word "arise" should be broadly construed. Among the meanings of this word registered in the cited decision and taken from the Concise Oxford Dictionary there is "bring into notice". This means that a lack of clarity also arises out of an amendment when this amendment brings into notice an ambiguity that has existed all along. This is also the case here with the aggravating circumstance that the lack of clarity already present in claim 1 has been extended and reinforced by the amendment.

- 2.3 The respondent cited decision T 367/96 in order to support its opinion that, in the present case, clarity should not be examined by the Board. However, T 367/96, point 6.2, is principally concerned with a lack of



support by the description, which is a separate aspect of Article 84 EPC, and not with lack of clarity. Furthermore the decision cited does not state that an objection of lack of clarity cannot be raised against a combination of granted claims, but only that the lack of support was already there and has not been introduced after grant of the patent. T 367/96 refers in point 6.2 to a previous decision (T 301/87), but only to reiterate the generally recognized principle that the clarity objection should arise out of the amendments made. T 853/02, in point 3.1.1 of the reasons, stresses also that the unclarity did not concern the amendments. These decisions do not contain any definition of an amendment. In fact, whether an amendment is given and in what it consists is a question of fact to be determined on a case by case basis.

In the opinion of this Board it cannot be stated that there is a general rule in the jurisprudence that a combination of granted claims should not be challenged for lack of clarity.

The respondent also referred to G 10/91. This decision however is not applicable here because G 10/91 deals with grounds for opposition, and clarity is not a ground for opposition. On the other hand, whenever amendments are requested by a patentee in the course of opposition proceedings, Article 101(3)(a) EPC (former 102(3) EPC 1973) confers upon both the opposition division and the Boards of Appeal jurisdiction and thus the power to apply the whole of the EPC including Article 84.

3. The auxiliary requests

According to G 9/92, point 15 of the reasons, the patent proprietor who has not filed an appeal is primarily limited to defending the version of the patent accepted by the opposition division in its decision. Any amendment he proposes in the appeal proceedings may be rejected by the Board of Appeal as inadmissible if they are neither appropriate nor necessary, which is the case if the amendments do not arise from the appeal.

Auxiliary requests 1 to 3 still contain the cross-reference objected to by the Board in respect of claim 1 of the main request in the communication attached to the summons for oral proceedings and are considered inappropriate for this reason.

Regarding auxiliary request 4, the respondent did not give any reason why the amendments introduced should be adequate to overcome the objections raised by the appellant against the version of the patent maintained in opposition, see letters of the patent proprietor of 24 October 2007 and of 2 April 2009. The Board has therefore reached the conclusion that the amendments introduced in the fourth auxiliary request are not only unsubstantiated but also inappropriate.

**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:

D. Sauter

M. Noël