

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 15 April 2024**

Case Number: T 1357/22 - 3.5.05

Application Number: 13727442.9

Publication Number: 2850549

IPC: G16H10/60, G16H20/10,
G16H20/17, G16H20/40,
G16H40/40, G16H40/63,
G16H40/67, G06F8/65, G06Q30/06,
G06Q50/22, A61M1/14, A61M1/16,
A61M1/28, A61M1/34, A61M1/36

Language of the proceedings: EN

Title of invention:

Home medical device systems and methods for therapy
prescription and tracking, servicing and inventory

Patent Proprietor:

Baxter International Inc
Baxter Healthcare SA

Opponent:

Fresenius Medical Care AG

Headword:

Deactivated connectivity agent/BAXTER

Relevant legal provisions:

EPC Art. 54

RPBA 2020 Art. 12(3), 12(5)

Keywords:

Novelty - main request (no)

Admittance of claim request filed on appeal - auxiliary
request 2 (no): not substantiated



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1357/22 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 15 April 2024

Appellant: Fresenius Medical Care AG
(Opponent) Else-Kröner-Str. 1
61352 Bad Homburg (DE)

Representative: Nordmeyer, Philipp Werner
df-mp Dörries Frank-Molnia & Pohlman
Patentanwälte Rechtsanwälte PartG mbB
Theatinerstraße 16
80333 München (DE)

Respondent 1: Baxter International Inc
(Patent Proprietor 1) One Baxter Parkway
Deerfield, IL 60015 (US)

Respondent 2: Baxter Healthcare SA
(Patent Proprietor 2) Thurgauerstrasse 130
8152 Glattpark (Opfikon) (CH)

Representative: K&L Gates LLP
Friedrichstraße 110 A
10117 Berlin (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
29 March 2022 concerning maintenance of the
European Patent No. 2850549 in amended form.**

Composition of the Board:

Chair K. Bengi-Akyürek
Members: E. Konak
F. Bostedt

Summary of Facts and Submissions

- I. The appeal was filed by the appellant (opponent) against the interlocutory decision of the opposition division finding that, on the basis of "auxiliary request 1", the patent in suit (hereinafter "the patent") met the requirements of the EPC.
- II. In the present decision, reference is made to the following prior-art document:
- D1:** US 2011/0066693 A1.
- III. Oral proceedings were held before the board on 15 April 2024. At the end of them, the board's decision was announced.
- The appellant requested that the decision under appeal be set aside and that the patent be revoked.
 - The respondent (patent proprietor) requested that the appeal be dismissed (**main request**) or, in the alternative, that the patent be maintained in amended form on the basis of the claims of **auxiliary request 2** filed during the opposition proceedings.
- IV. Claim 1 of the **main request** reads as follows:
- "A home medical device system (110) comprising:
a plurality of home renal therapy machines (100) that perform a home renal therapy on a patient at a home or dwelling of the patient, wherein each home renal therapy machine includes a connectivity agent installed on the home renal therapy machine;

a connectivity server (118) located remote from the home or dwelling of the patient, wherein the connectivity agent of each home renal therapy machine allows the home renal therapy machine to connect to the connectivity server and transfers data to and from the connectivity server only when the connectivity agent is activated, and wherein the connectivity agent is deactivated during the home renal therapy to prevent the home renal therapy machine from sending any data to or receiving any data from the connectivity server during the home renal therapy;

a system hub (120) coupled to the home renal therapy machines (100) through the connectivity server (118);

a web portal (150) configured to access the system hub (120);

a plurality of clinics (152) connected to the system hub (120) via the web portal (150); and

a website accessible via the web portal (150), the website including a patient portion (800) available to patients using the plurality of home renal therapy machines (100), the website further including a clinician portion (900) that enables the clinics (152) to manage the home renal therapy machines (100)."

Claim 1 of **auxiliary request 2** reads as follows:

"A home medical device system (110) comprising:
a plurality of home renal therapy machines (100) that perform a home renal therapy on a patient at a home or dwelling of the patient, wherein each home renal therapy machine includes a connectivity agent installed on the home therapy machine;

a connectivity server (118) located remote from the home or dwelling of the patient, wherein the connectivity agent of each home therapy machine allows the home therapy machine to connect to the connectivity server and transfers data to and from the connectivity server only when the connectivity agent is activated, and wherein the connectivity agent is deactivated during the home therapy to prevent the home therapy machine from sending any data to or receiving any data from the connectivity server during the home therapy; a system hub (120) coupled to the home therapy machines (100) through the connectivity server (118);

a web portal (150) configured to access the system hub (120);

a plurality of clinics (152) connected to the system hub (120) via the web portal (150); and
an enterprise resource planning system coupled to the system hub;

a website accessible via the web portal (150), the website including a patient portion (800) available to patients using the plurality of home therapy machines (100), the website further including a clinician portion (900) that enables the clinics (152) to manage the home therapy machines (100)."

Reasons for the Decision

1. Main request - Novelty (Article 54 EPC)
- 1.1 Claim 1 of the main request includes the following limiting features:

- 1.0 A home medical device system comprising:
 - 1.1 a plurality of home renal therapy machines
 - 1.1.1 that perform a home renal therapy on a patient at a home or dwelling of the patient,
 - 1.1.2 wherein each home therapy machine includes a connectivity agent installed on the home renal therapy machine;
 - 1.2 a connectivity server located remote from the home or dwelling of the patient,
 - 1.2.1 wherein the connectivity agent of each home renal therapy machine allows the home renal therapy machine to connect to the connectivity server and
 - 1.2.2 transfers data to and from the connectivity server only when the connectivity agent is activated,
 - 1.2.3 wherein the connectivity agent is deactivated during the home renal therapy to prevent the home renal therapy machine from sending any data to or receiving any data from the connectivity server during the home renal therapy;
 - 1.3 a system hub coupled to the home renal therapy machines through the connectivity server;
 - 1.4 a web portal configured to access the system hub;
 - 1.5 a plurality of clinics connected to the system hub via the web portal;
 - 1.6 a website accessible via the web portal, the website including
 - 1.6.1 a patient portion available to patients using the plurality of home renal therapy machines, the website further including
 - 1.6.2 a clinician portion that enables the clinics to manage the home renal therapy machines.

1.2 The opposition division came to the conclusion that document **D1** does not disclose features 1.2.3, 1.4 to 1.6, 1.6.1 and 1.6.2 of claim 1.

The appellant considered claim 1 not to be new in view of D1.

The respondent argued, in response, that D1 did not disclose features 1.2.1, 1.2.2, 1.2.3, 1.4 to 1.6, 1.6.1 and 1.6.2.

1.3 The appellant's novelty-attack was based on the following feature mapping:

- "control unit" 4 and "remote access and control unit" 10 (on renal therapy machines 2) in D1 correspond to the "connectivity agent" of claim 1 (feature 1.1.2)
- "computer server" 311 in D1 corresponds to "connectivity server" of claim 1 (feature 1.2)
- "database" 312 in D1 corresponds to "system hub" of claim 1 (feature 1.3)
- "visual access terminal" 316 in D1 corresponds to "web portal" of claim 1 (feature 1.4).

1.4 Regarding features 1.2.1 and 1.2.2, the respondent argued that D1 merely disclosed a control unit 4 operating relative to the machine 2 itself, however not relative to the "connectivity server", and asserted that, in features 1.2.1 and 1.2.2, it was the "connectivity agent" which transferred data to and from the "connectivity server", "only when the connectivity agent is activated". The respondent argued that D1, paragraph [0095], cited by the opposition division, did not disclose this.

The board was not convinced by this argument. Document D1, paragraph [0095], discloses that the "client control software" 14 installed on "remote access and control means" 10 allows the "control unit" 4 (the latter two corresponding to the "connectivity agent" of claim 1) to connect to and exchange data with, i.e. "transfer data to and from" (feature 1.2.2) the remote unit, which according to Fig. 1A is the "computer server" 311 (corresponding to "connectivity server" of claim 1). Moreover, the redundant text "only when the connectivity agent is activated" is not limiting in the context of claim 1. An entity can compellingly do something "only when it is activated". Therefore, D1 indeed discloses features 1.2.1 and 1.2.2, at least implicitly.

- 1.5 Regarding feature 1.2.3, the board holds that the skilled reader would interpret the wording "is deactivated [...] to prevent [...] from sending any data to or receiving any data from", which is an unclear method step in an apparatus claim, as meaning "is configured to prevent [...] from sending any data to or receiving any data from". The board agrees with the appellant that document D1, paragraph [0161], discloses this feature.

The opposition division concluded that, although D1 taught preventing access, it did not disclose "preventing the home renal therapy machine from sending any data to or receiving any data from the connectivity server", as required by feature 1.2.3. The respondent agreed with this conclusion. It argued that feature 1.2.3 was to be interpreted such that the "connectivity agent" is turned off completely and *no communication* at all could take place between the "connectivity server" and the "home renal therapy

machine" during therapy. According to D1, paragraphs [0161], [0163] and [0164], even in critical situations, real-time monitoring data was still sent to the remote unit.

However, feature 1.2.3 does not say "turned off" but "deactivated [...] to prevent". Furthermore, D1, paragraph [0161], states that in critical situations (the preceding paragraph [0160] mentioning "the stage of treatment true and proper" as such a critical situation), the system would "*prevent the remote means for access and control 10 to take control of the medical machine or, in a case in which a remote unit 7 is controlling, the control unit 4 would exclude any possibility of proceeding with said control/intervention from remote*" (emphasis added), which would implicitly mean that the "connectivity agent" prevents data being sent to the "connectivity server" and data sent from the "connectivity server" being received by the "home renal therapy machine". Thus, D1 indeed discloses feature 1.2.3.

- 1.6 Regarding features 1.4 to 1.6, the opposition division agreed with the appellant's feature mapping insofar as the "system hub" was concerned, i.e. it agreed that the "database" 312 in D1 could be regarded as such a "system hub", and also agreed that the "visual access terminal" 316 in D1 provided access to the "database" 312, but it disagreed with the argument that the "visual access terminal" 316 could be seen as a "web portal". In particular, it objected that D1, paragraph [0032], did not disclose any teaching about the access terminal being a "web portal". The respondent agreed with this finding. However, neither the opposition division nor the respondent elaborated on what a "web portal" actually means in technical

terms and why the "visual access terminal" 316 does not qualify as a "web portal", which is a technically vague term.

According to the board, a "web portal" is in fact a specially designed website that brings information from diverse sources together. In technical terms, it remains a mere "website". In this regard, feature 1.6, which states that "a website [is] accessible via the web portal", constitutes a mere reiteration of this definition. The respondent argued that the board's interpretation of the term "web portal" was an oversimplification. Instead, a "web portal" was to be interpreted as a "protected and regulated environment" within the meaning of paragraphs [00156] to [00159] of the description as filed. However, the description does not define "web portal" as being a "protected and regulated environment"; the "web portal" is only mentioned in this context. In the board's view, from the description it cannot be concluded that the simple term "web portal" means something more restricted than what it normally means to the skilled person.

Thus, the question to be answered is whether D1 in fact discloses that the "visual access terminal" 316 provides access to the "database" 312 via a website.

- 1.7 The appellant argued that the skilled reader would understand from D1, paragraphs [0032] to [0035], that the "visual access terminal" 312 provides personnel with access to the database and "access to the net" and that "remote accesses" 320, which it considered to be equivalent to "clinics" within the meaning of feature 1.5, also access the database in the same manner (i.e. features 1.4 to 1.6). It further pointed in particular to paragraph [0035] of D1, which refers

to different terminals for patients and clinicians. Therefore, in the appellant's view, D1 disclosed access via a website to different portions for patients and clinicians within the meaning of features 1.6.1 and 1.6.2. The board agrees with the appellant that these passages in fact disclose features 1.4 to 1.6, 1.6.1 and 1.6.2.

1.8 Therefore, the subject-matter of present claim 1 is not new (Article 54 EPC).

2. Admittance of auxiliary request 2

2.1 For the first time in these appeal proceedings, the respondent mentioned, at the beginning of the oral proceedings before the board, that it still had a further claim request on file, namely "auxiliary request 2", which had already been filed during the opposition proceedings and had never been withdrawn.

2.2 According to Article 12(3) RPBA, a respondent's written reply to the appellant's statement of grounds of appeal shall contain its complete appeal case. It should specify expressly all requests relied on. The board has discretion not to admit any submission which does not meet this requirement (Article 12(5) RPBA).

2.3 In the case at hand, the only request presented in the respondent's written reply to the appellant's statement of grounds of appeal was directed at maintaining the patent in the version as upheld by the opposition division, i.e. "auxiliary request 1". This written reply did not mention "auxiliary request 2" at all. It is additionally noted that, although the respondent filed a written response to the board's preliminary opinion, it still did not mention this request.

2.4 Under these circumstances, the board did not admit auxiliary request 2 into the appeal 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 Chair:



B. Brückner

K. Bengi-Akyürek

Decision electronically authenticated