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**Datasheet for the decision
of 18 February 2020**

Case Number: T 0223/18 - 3.5.05

Application Number: 11778166.6

Publication Number: 2567353

IPC: G06F19/00, G06Q10/00

Language of the proceedings: EN

Title of invention:

SYSTEM AND METHOD FOR PROVIDING AUTOMATICALLY UPDATED PRODUCT
INSERTS

Applicant:

Bio-Rad Laboratories, Inc.

Headword:

Product insert update/BIO-RAD

Relevant legal provisions:

EPC Art. 56, 84, 83

Keyword:

Inventive step - (no)
Claims - clarity - auxiliary requests (no)
Sufficiency of disclosure - auxiliary requests (no)



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 0223/18 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 18 February 2020

Appellant:
(Applicant)

Bio-Rad Laboratories, Inc.
1000 Alfred Nobel Drive
Hercules, CA 94547 (US)

Representative:

dompatent von Kreisler Selting Werner -
Partnerschaft von Patent- und Rechtsanwälten mbB
Deichmannhaus am Dom
Bahnhofsvorplatz 1
50667 Köln (DE)

Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 4 August 2017
refusing European patent application No.
11778166.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair A. Ritzka
Members: E. Konak
A. Jimenez

Summary of Facts and Submissions

- I. The appeal is against the decision of the examining division to refuse the application for lack of an inventive step (Article 56 EPC) over a notoriously known general-purpose data processing system.
- II. With its statement setting out the grounds of appeal, the appellant filed a main request and auxiliary requests I and II. The appellant requested that the decision be set aside and a patent be granted based on one of these requests. It requested oral proceedings as an auxiliary measure.
- III. In its preliminary opinion, the board raised objections under Articles 123(2), 56, 84 and 83 EPC.
- IV. The appellant filed arguments in reply to the summons to oral proceedings. It maintained the requests on file.
- V. Oral proceedings were held before the board.
- VI. Claim 1 of the main request reads as follows:

"A method of providing parameters of operating results for one or more control products used in biological reactions, the method comprising;
creating, by a development system (840), one or more parameters by analyzing data points of different results relating to one or more tests;
storing the one or more parameters in a development database (850);
receiving, by the development system (840), approval of the one or more parameters;

based on the approval, sending the one or more parameters to a user database (820), wherein a server system is communicably coupled with the user database; receiving, by the server system, from a customer, a request for the one or more parameters relating to the one or more tests, each test operable to test one or more analytes in a biological reaction to generate one or more analyte results and operable to test the one or more control products in a biological reaction to generate one or more control results, the one or more control results operable to confirm a quality of the one or more analyte results, wherein the request identifies the one or more analytes and the one or more control products; accessing the user database (820) to identify, by the server system, the one or more parameters corresponding to the request, wherein the one or more parameters specify one or more updated acceptable values for the one or more control results for confirming the quality of the one or more analyte results; and sending the one or more parameters to the customer."

VII. Claim 1 of auxiliary request I differs from claim 1 of the main request in that it has the following additional feature:

"whereby the user database (820) is isolated from the development database (850) by a firewall (830)."

VIII. Claim 1 of auxiliary request II differs from claim 1 of auxiliary request I in that it has the following additional feature:

"whereby the user database (820) is not aware of the development database (850) and cannot request data from

it, but just receives data from a particular port that the development database (850) can write to."

Reasons for the Decision

1. Main request
- 1.1 Claim 1 of the main request is identical to claim 1 of the sole request on which the contested decision is based, except for the addition of reference signs.
- 1.2 The board sees no prejudicial error in the conclusion of the contested decision that the subject-matter of the claim is the straightforward implementation of an administrative method using notorious technical means such as servers and databases, and consequently does not involve an inventive step.
- 1.3 At the oral proceedings, referring to paragraphs [0028] to [0031] of the application, the appellant submitted that conventional product inserts were printed and packaged with control products on the basis of information available at the date of manufacture and were oblivious to individual needs of customers. Although the invention had some business aspects, it nevertheless provided an easy, cost-efficient and targeted way of distributing product insert information. The board does not doubt that, but the subject-matter of claim 1 does not go beyond the straightforward digitalization of the existing workflow for distribution of product inserts. It uses databases instead of paper for the storage of test data and the parameters derived from them, and servers for their distribution. It is evident that digitized information

can be distributed much more easily, frequently, without the costs associated with printing, and that database management systems reply to queries unlike paper which does not.

- 1.4 The appellant had argued in the statement setting out the grounds of appeal that the technical effect of claim 1 of the main request was preventing the distribution of data that might not be accurate. Only when an insert was approved would that insert be transmitted to the end user insert database. However, as paragraph [0028] of the application also points out, production of control product inserts is regulated by well-defined FDA-approved procedures that dictate *inter alia* how insert values are approved. There are equivalent legal or regulatory requirements in every jurisdiction. These requirements for accuracy of parameter values and their approval have to be met, as a matter of course, by conventional printed product inserts that the appellant describes as the prior art. Therefore, the subject-matter of claim 1 cannot have the alleged effect with respect to the prior art.
- 1.5 In its reply to the summons to oral proceedings, the appellant further argued that the method of claim 1 generates more accurate parameters by analyzing data to see if changes occur. However, in the absence of any information regarding how the data is analyzed in claim 1 of the main request (or the pertinent parts of the description) this alleged effect is merely speculative.
- 1.6 For these reasons, the subject-matter of claim 1 of the main request does not involve any inventive step (Article 56 EPC).
2. Auxiliary requests I and II

- 2.1 Claim 1 of both auxiliary requests includes the feature that "the user database (820) is isolated from the development database (850) by a firewall (830)".
- 2.2 In the field of computing, the term "firewall" refers to a network security system that monitors and controls incoming and outgoing traffic between a trusted internal network and an untrusted external network based on predetermined security rules. The appellant submits that the firewall 830 in the present invention is "very similar" and the skilled person, interpreting it "by a mind willing to understand, not a mind desirous of misunderstanding", will clearly understand its meaning and function.
- 2.3 In the present case, the description calls the assay development database system 840 which comprises the database 850 an "internal system" (see paragraph [0060], first sentence and paragraph [0062], first sentence), and the end user system comprising the database 820 an "external system" (see paragraph [0060], first sentence and paragraph [0065], first sentence). There is no incoming traffic from the external system to the internal system. Rather, "the end user insert database [of the external system] is not aware of the regulated assay development database 850 [of the internal system] and cannot request data from it" (see paragraph [0065], last sentence). The outgoing traffic from the internal system to the existing system is not monitored or controlled at all. Rather, the development database 850 of the internal system can write to the end user insert database 820 of the external system (*ibidem*). Therefore, contrary to the assertion of the appellant, the "firewall 830" of claim 1 of the auxiliary requests is not what the

person skilled in the art would recognise as a "firewall", and is not similar to it, rendering claim 1 of both auxiliary requests unclear (Article 84 EPC).

2.4 Furthermore, the feature appears only once in one single sentence in paragraph [0065] (penultimate sentence), without further information or explanation. Therefore, the invention of claim 1 of both auxiliary requests is not disclosed in a manner sufficiently clear and complete for it to be carried out by the person skilled in the art (Article 83 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



K. Götz-Wein

A. Ritzka

Decision electronically authenticated