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Case Number: T 1587/10 - 3.3.08

Application Number: 01964535.7

Publication Number: 1315828

IPC: C12Q1/00, C12Q1/70, C12Q1/68, G01N33/48

Language of the proceedings: EN

Title of invention:
SYSTEM AND METHOD FOR TRACKING AND CONTROLLING INFECTIONS

Applicant:
Egenomics, Inc.

Headword:
Controlling Infections/EGENOMICS

Relevant legal provisions:
EPC Art. 123(2), 84, 111(1)

Keyword:
Amendments - added subject-matter (no)
Claims - clarity (yes)
Remittal to the department of first instance

Decisions cited:

Catchword:

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Case Number: T 1587/10 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 8 April 2014

Appellant: (Applicant)	Egenomics, Inc. 59 Franklin Street, Fifth Floor New York, NY 95054 (US)
Representative:	von Menges, A. UEXKÜLL & STOLBERG Patentanwälte Beselerstrasse 4 22607 Hamburg (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 15 September 2009 refusing European patent application No. 01964535.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: M. Wieser
Members: B. Stolz
C. Heath

Summary of Facts and Submissions

I. The appeal lies against the decision of the examining division to refuse European patent application No. 01964535, published as WO 02/20827. The examining division decided that neither the main request nor the auxiliary request before it complied with the requirements of Articles 84 and 123(2) EPC.

II. With its grounds of appeal, the applicant (appellant) filed a new main request.

III. The appellant was summoned to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, informed it of the preliminary non-binding opinion of the board in particular with regard to the requirements of Articles 123(2) EPC and 84 EPC.

IV. With letter dated 27 March 2014, the appellant withdrew its request for oral proceedings.

V. Independent claims 1 and 28 of the main request read:

"A method of performing real-time infection control over a computer network, comprising:

(a) obtaining a sample of a microorganism at a remote facility;
(b) sequencing a first region of a nucleic acid from the microorganism sample;
(c) comparing the first sequenced region with historical sequence data stored in a database;
(d) determining a measure of phylogenetic relatedness between the microorganism sample and a plurality of historical samples stored in the database;

(e) providing infection control information based on the phylogenetic relatedness determination to the remote facility, thereby allowing the remote facility to use the infection control information to control or prevent the spread of an infection;
(f) determining whether the remote facility has a potential outbreak problem; and
(g) transmitting an outbreak warning to the remote facility,
wherein the first region that is sequenced is a repeat region,
wherein the first region has a mutation rate which is suitably fast for performing real-time infection control, and
wherein the microorganism is a bacterium, virus, or fungus."

"28. A system for performing real-time infection control over a computer network, comprising:

a computer network; a centralized database; a remote facility connected to the computer network, the remote facility obtaining a sample of a microorganism;
a server connected to the computer network, the server being configured to:

receive sequence data for a first sequenced region of a nucleic acid from the microorganism sample,
access the centralized database and compare the first sequenced region with historical sequence data stored in the centralized database,
determine a measure of phylogenetic relatedness between the microorganism sample and

historical samples stored in the centralized database, and

transmit infection control information based on the phylogenetic relatedness determination to the remote facility over the computer network, thereby allowing the health care facility to use the infection control information to control or prevent the spread of an infection,

determine whether the remote facility has a potential outbreak problem; and

transmit an outbreak warning to the remote facility,

wherein the first region that is sequenced is a repeat region,

wherein the first region has a mutation rate which is suitably fast for performing real-time infection control, and

wherein the microorganism is a bacterium, virus, or fungus."

VI. Dependent claims 2 to 27 refer to specific embodiments of the subject matter of claim 1.

VII. Claims 1 and 28 of the main request differ from claims 1 and 28 of the main request before the examining division by the way in which the first sequenced region is further specified (amendments in bold):

"... wherein the first region that is sequenced is a repeat region, ~~that has been identified to have~~ **wherein the first region has** a mutation rate which is suitably fast for performing real-time infection control ..."

VIII. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

Article 123(2) EPC

All features of claims 1 and claim 28 could be found in claims 1, 5, 6, 9, and 27, and claims 32, 5, 6, 9 and 27, respectively, as originally filed. The subject matter of these claims could also be directly derived from the description as originally filed.

Article 84 EPC

The claims of the Main Request clearly conveyed to the skilled person what was claimed. In particular, it was clear that the method was directed to infection control that could be performed sufficiently fast ("real-time") to allow a medical care facility to react to the information generated as the result of the analysis. It could also be understood that a nucleic acid region used for genotyping and establishing relatedness between the samples obtained from the facility should have a mutation rate that was fast enough for this purpose, e.g. it should be a variable region and not a conserved region. All terms and expressions used in the claims were well known in the art and contained no ambiguities.

IX. The appellant requested that the decision under appeal be set aside and that the application be remitted to the examining division for further prosecution.

Reasons for the Decision

1. Apart from a minor editorial amendment in the last half-sentence of claim 1 (see section VII above), the main request filed with the grounds of appeal is identical with the main request before the examining division.

Article 123(2) EPC

2. In its decision, the examining division stated that the claims as originally filed did not provide a basis for the subject matter of claim 1. Also when considering the disclosure of the entire application as originally filed it could not find any suitable basis for claim 1.

3. The method of claim 1 is defined by steps (a) to (g)and furthermore, at its end, by a more specific definition of the terms "first region" and "microorganism" mentioned in steps (a) and (c) , respectively. The combination of features (a) to (g) is explicitly disclosed in claim 27 of WO 02/20827 (whose content is considered to be identical to the application as originally filed) and can also be directly derived from page 7, lines 14 to 28, in combination with page 9, lines 7 to 9 as originally filed.

In the general part of the description as originally filed, on pages 17 to 19, when discussing the invention as exemplified by Figure 2, the necessary features of the DNA region that is sequenced are described in detail. Accordingly, *"the sequenced DNA is selected from the bacteria's (or other microorganism) chromosomal or extrachromosomal DNA that is genetically*

variable" (page 17, lines 10-12). *"The goal behind sequencing the DNA is to distinguish epidemiologically related or clonal isolates, from unrelated isolates"* (page 18, lines 4-5). *"The DNA region which is chosen for sequencing must have fast enough "clock speed" to allow real-time infection control"* (page 18, lines 21-22; see also page 8, lines 1-2), and *"one type of DNA region that has suitable variability for outbreak discrimination is a "repeat region""* (page 19, lines 1-2; see also also page 8, lines 2-3). From these citations, it is directly derivable that a suitable DNA region for performing the invention, for instance according to claim 27 as originally filed, is a repeat region which by necessity, in order to allow the assessment of phylogenetic relatedness, must have a sufficiently fast mutation rate (cf. also page 8, lines 1 to 3).

The invention described in Figure 2 is carried out on a system architecture as shown in Figure 1 (page 14, lines 24 to 25), which stores sequence data of an infectious agent such as a bacterium, virus or fungus (page 12, lines 15 to 17). It is therefore directly and unambiguously derivable that the claimed invention relates to the monitoring of infection control whereby the infectious agent can be a bacterium, virus or fungus.

The subject matter of claim 1 (and of claim 28) is therefore directly and unambiguously derivable from the application as originally filed.

4. The board takes the view that the decision under appeal focused disproportionately on the structure of the claims as filed rather than on what is really disclosed to the skilled person by the application as originally

filed as a whole (cf. first sentence of the headnote of decision T 2619/11 of 25 February 2013).

Article 84 EPC

5. The examining division considered the term *"wherein the first region has a mutation rate which is suitably fast for performing real time infection control"* ambiguous. It argued that mutation rates depended on the physical and chemical environment in which mutations occurred and hence were not an invariable property of a particular nucleotide sequence. Furthermore, it considered the term *"real time infection control"* open to interpretation. In the examining division's view the term meant that an infection could be observed while it developed whereas the applicant, in its letter of 22 May 2009, argued that the term related to *"determinations made quickly enough to affect outbreak dynamics".*

6. The purpose of the claimed method is to provide information to a health care facility in order to prevent the spread of an infection (e.g. page 3, lines 24 to 28 as originally filed). Further, slowly mutating regions of the nucleic acid of a sample microorganism can be used for tracking the long-term global spread of an infection, while faster mutating regions of the nucleic acid can be used for tracking the short-term local spread of an infection (page 9, lines 14 to 17 of the application). In the same context, document D1 refers to short-term and longer-term epidemiologic studies or questions, and discuses the use of PFGE and arbitrarily primed PCR, both relying on the detection of relatively rapidly accumulating genetic differences, for short-term epidemiologic studies "in outbreak

settings" (see document D1, page 482, left column, bottom).

Against this background, the term "real-time" can only mean that the claimed method is performed while a local or a global infection spreads (is ongoing) but not that the method is performed retrospectively.

7. Contrary to applicant's submissions of 22 Mai 2009 (cf. page 2), the term *"real-time"*, when read in the context of the application, cannot, therefore, imply that the claimed method is faster than any of the prior art methods (which in any case would amount to an arbitrary and thus unclear definition). Moreover, the term on its own cannot delimit the claimed method from those prior art methods relying on PFGE or arbitrarily primed PCR, mentioned in document D1.

In view of the above, the feature *"wherein the first region has a mutation rate which is suitably fast for performing real time infection control" in claim 1* refers to a region of the genome of a pathogen which mutates suitably fast so that isolates from subsequent generations of the same pathogen can be distinguished genetically.

8. Accordingly, the two features objected to by the examining division are clear within the meaning of Article 84 EPC.

9. Whether appropriate regions of a genome of a pathogen are known to the skilled person or whether they can be readily identified in microorganisms other than S.aureus is rather an issue that has to be examined under Article 83 EPC.

10. Since the examining division has not yet ruled on the issues of sufficiency of disclosure, novelty and inventive step, and since the appellant requested that the application be remitted to the examining division for further prosecution, the board considers it appropriate to exercise the power conferred to it by Article 111(1) EPC and to remit the case.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Examining Division for further prosecution on the basis of the main request filed on 22 January 2010.

The Registrar: The Chairman:

A. Wolinski M. Wieser

Decision electronically authenticated