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Datasheet for the decision
of 1 August 2019

Case Number: T 2677/16 - 3.5.05

Application Number: 03706023.3

Publication Number: 1490822

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
DRUG DISCOVERY METHODS

Applicant:
QIAGEN Redwood City, Inc.

Headword:
Drug target/QIAGEN

Relevant legal provisions:
EPC Art. 52(2)(a), 52(2)(c), 56

Keyword:
Modelling disease-related pathways - technical character (no)
Drug target discovery - technical purpose (no)
Inventive step - (no)

Decisions cited:
T 0049/99, T 0258/03

Catchword:

Case Number: **T 2677/16 - 3.5.05**

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 1 August 2019

Appellant:	QIAGEN Redwood City, Inc.
(Applicant)	1001 Marshall Street, Suite 200
	Redwood City, California 94063 (US)
Representative:	Grünecker Patent- und Rechtsanwälte
	PartG mbB
	Leopoldstraße 4
	80802 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 July 2016 refusing European patent application No. 03706023.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	F. Blumer

Summary of Facts and Submissions

I.   The appeal is against the decision of the examining division to refuse the present application for lack of inventive step (Article 56 EPC) over a general purpose computer comprising a queryable database.

II.   With its statement setting out the grounds of appeal, the appellant filed claims 1 to 9 of a main request and claims 1 to 4 of auxiliary requests 1, 2, 3 and 4, the main request and auxiliary request 1 corresponding to the requests on which the contested decision is based. 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 Article 56 EPC.

IV.   In reply to the summons to oral proceedings the appellant submitted arguments responding to these objections. By letter of 31 July 2019 the board was informed that nobody would attend the oral proceedings on behalf of the appellant.

V.   Oral proceedings were held in the absence of the appellant.

VI.   Claim 1 of the main request reads as follows:

"A method for identifying a drug discovery target, the method comprising:

providing an ontology for storing and accessing genomics information in a database, wherein the

genomics information comprises information relating to
genes, proteins expressed from the genes, and
biological effects of the expressed proteins, and
wherein the ontology is organized so that each gene,
protein, and biological effect is categorized by class,
wherein a class includes genes, gene products, and
biological effects sharing similar properties, and a
biological relationship between each gene, protein, and
biological effect is defined by slots and facets,
wherein a slot identifies a relationship between
classes and a facet identifies a restriction on a slot
for a specific gene, gene product, or biological effect
within a class;

querying the database to generate a profile including a
collection of nodes connected by directed edges,
wherein each node represents a gene or a gene product,
wherein each directed edge represents the biological
relationship between two nodes, and wherein the
collection of nodes include concepts that are
biologically related to a disease state;

identifying, within the profile, a disease-related
pathway to the disease state, wherein the disease-
related pathway includes the biological relationships
and actor concepts, the actor concepts including genes
and proteins; and

identifying each of the actor concepts involved in each
biological relationship as a drug discovery target."

VII.   Claim 1 of auxiliary request 1 differs from claim 1 of
        the main request as follows (with the additions
        underlined and the deletions ~~struck through~~):

        "...

providing an ontology for storing and accessing genomics information in a database, wherein the genomics information comprises information relating to genes, proteins expressed from the genes, and biological effects of the expressed proteins, and wherein the ontology is organized so that each gene, protein, and biological effect is categorized by class, wherein a class includes genes, gene products, and biological effects sharing similar properties, ~~and a biological relationship between each gene, protein, and biological effect is defined by slots and facets, wherein~~ a slot identifies a relationship between classes and a facet identifies a restriction on a slot for a specific gene, gene product, or biological effect within a class;

querying the database to generate a profile including a collection of nodes connected by directed edges, wherein each node represents ~~a~~ <u>one of the</u> gene<u>s</u> or ~~a~~ <u>one of the</u> gene product<u>s</u>, wherein each directed edge represents ~~the~~ <u>a</u> biological relationship between two nodes, and wherein the collection of nodes include concepts that are biologically related to a disease state;

..."

VIII. Claim 1 of auxiliary request 2 differs from claim 1 of auxiliary request 1 as follows (with the additions <u>underlined</u> and the deletions ~~struck through~~):

"A <u>computer-implemented</u> method for identifying a drug discovery target, the method comprising:

providing an ontology for storing and accessing
genomics information in a database, wherein the
genomics information comprises information relating to
genes, proteins expressed from the genes, and
biological effects of the expressed proteins, and
wherein the ontology is organized so that each gene,
protein, and biological effect is categorized by class,
wherein a class includes genes, gene products, and
biological effects sharing similar properties, a slot
identifies a relationship between classes, and a facet
identifies a restriction on a slot for a specific gene,
gene product, or biological effect within a class,
wherein the biological effects comprise effects that
are biologically related to a disease state;

querying the database to generate a profile including a
collection of nodes connected by directed edges,
wherein each node represents one of the genes or one of
the gene products, wherein each directed edge
represents a biological relationship between two nodes,
and wherein the collection of nodes include concepts
that are biologically related to the a disease state,
wherein the profile is a gene-centric profile having a
seed gene as a starting node with which further nodes
representing further genes or proteins are connected by
directed edges representing biological relationships
between the respective nodes so that the generated
profile represents a view on the genomics information
stored in the ontology from the perspective of the seed
gene;

..."

IX.   Claim 1 of auxiliary request 3 differs from claim 1 of
        auxiliary request 1 as follows (with the additions
        underlined and the deletions struck through):

"A computer-implemented method for identifying a drug
discovery target, the method comprising:

providing a knowledge representation system, KRS,
wherein the KRS comprises a knowledge base, KB, and an
ontology, for storing and accessing genomics
information ~~in a database~~, wherein the genomics
information comprises information relating to genes,
proteins expressed from the genes, and biological
effects of the expressed proteins, wherein the KB
comprises findings, wherein the findings are structured
according to biological relationships between the genes
and/or the proteins, and wherein the ontology is
organized so that each gene, protein, and biological
effect is categorized by class, wherein a class
includes genes, gene products, and biological effects
sharing similar properties, a slot identifies a
relationship between classes, and a facet identifies a
restriction on a slot for a specific gene, gene
product, or biological effect within a class;

querying the ~~database~~ KRS for one or more actor
concepts to ~~generate a profile including a collection~~
~~of nodes connected by directed edges, wherein each node~~
~~represents one of the genes or one of the gene~~
~~products, wherein each directed edge represents a~~
~~biological relationship between two nodes, and wherein~~
~~the collection of nodes include concepts that are~~
~~biologically related to a disease state;~~ identif~~ying,~~
~~within the profile,~~ a disease-related pathway ~~to the~~
~~disease state, wherein the disease-related pathway~~
~~includes the biological relationships and~~ wherein the
one or more actor concepts~~, the actor concepts~~
~~including~~ represent genes and proteins related to a
disease,~~;~~

wherein the disease-related pathway is modeled by one
or more profiles, wherein each profile is a gene-
centric profile having a seed gene as a starting node
with which further nodes representing further genes or
proteins are connected by directed edges representing
the biological relationships between the respective
nodes so that the generated profile represents a view
on the genomics information stored in the KB from the
perspective of the seed gene,~~;~~ and

~~identifying each of the actor concepts involved in each
biological relationship as~~ wherein each gene or protein
in the disease-related pathway is a drug discovery
target."

X.   Claim 1 of auxiliary request 4 differs from claim 1 of
        auxiliary request 3 in that it has the following
        additional text before the full stop at its end:

        ", and the drug discovery targets are prioritized based
        on involvement in other pathways"

Reasons for the Decision

1.   The contested decision includes an *obiter dictum* that
        claim 1 of the main request only contains abstract
        algorithmic steps and is thus directed to a mental act
        in the sense of Article 52(2)(c) EPC. However, the
        examining division assumed, in light of the
        description, that the method of claim 1 was computer-
        implemented, and thus did not base the decision to
        refuse the application in suit on Article 52(1) and (2)
        (c) EPC, but rather on Article 56 EPC (see the
        contested decision, point 12.2 of the reasons). The
        board disagrees with this *obiter,* as the step of

"querying the database" implicitly involves a computer,
i.e. technical means, which renders the method of claim
1 of the main request an invention within the meaning
of Article 52(1) EPC (See T 258/03, OJ EPO 2004, 575,
Headnote I).

2.   As for the reason for refusing the application in suit,
        the contested decision came to the conclusion that the
        claimed method lacks inventive step (Article 56 EPC)
        over a notoriously known general-purpose computer
        comprising a queryable database, since the examining
        division found the claimed method not to achieve its
        technical purpose by its features. However, the board
        disagrees with the very starting premise of this
        analysis that the claimed method serves a technical
        purpose.

3.   The purpose of the method of claim 1 of all requests on
        file is "identifying a drug discovery target". A drug
        target is a molecule in the body, usually a protein or
        a gene, that is associated with a particular disease
        process, and could theoretically be targeted by a drug
        to treat the disease by interrupting the disease-
        related metabolic pathway. The rationale of the
        contested decision is that "the identified genes and
        proteins represent potential targets for a drug
        intervention that have the likelihood to produce a
        therapeutic effect" and hence, by virtue of this
        therapeutic effect, the identification of such genes or
        proteins represents a technical purpose (see the
        contested decision, point 12.5 of the reasons).
        However, this rationale unduly broadens the concept of
        a technical purpose to encompass any scientific
        endeavour in medicine. A drug target is not a therapy:
        it has no therapeutic effect, but is merely a promising
        direction for future research. The discovery of a drug

target may well turn out to be a valuable scientific discovery, but neither discoveries nor science have technical character as such, as is explicitly enshrined in Article 52(2)(a) EPC. This should not be confused with the invention of a drug, which would represent a technical purpose (See also Benkard, Europäisches Patentübereinkommen, 3rd edition, 2019, Article 52, point 228 et seq.).

4. The method of claim 1 of all requests on file models the disease-related metabolic pathways in the body for the purpose of identifying drug targets (see also the statement setting out the grounds of appeal, page 7, penultimate paragraph). As the contested decision correctly concludes (see the decision under appeal, point 12.3, second paragraph), such modelling itself is an abstract intellectual activity. It cannot contribute to the technical character of the invention unless it serves a technical purpose (See T 49/99, point 7 of the reasons), which is not the case in the present application.

5. In its reply to the summons to oral proceedings, the appellant submitted that the purpose of the claimed method is "not only to identify drug discovery targets, but rather to representatively model biological pathways in [...] a manner such that using the structure of such a model enables identifying a possible drug target for exploitation". Besides drug target identification, there were "further end-uses" of the invention, such as "identifying new uses for known drugs, predicting likely side effects of treatment with a given drug, and predicting efficacy of a given drug in a given individual". Previously known databases missed some data that appear in scientific publications and could not be used to determine disease pathways

because the data were not structured in a way that allows the analysis of "complex, spiderweb-like relationships". However, these submissions illustrate that the appellant sees inventive step in the intellectual activity of modelling disease-related metabolic pathways, irrespective of its purpose, and indeed confirm the board's conclusion that the claimed method does not serve a technical purpose. Furthermore, the purpose of the claimed invention is explicitly specified in the preamble of claim 1 of all requests on file as "identifying a drug discovery target", so the appellant's submissions with regard to "further end-uses" are irrelevant.

6.   The appellant argued in the statement setting out the grounds of appeal that the invention solved the problem of "how to store genomics and disease related information in a database so that drug discovery targets can be identified in an efficient manner". The features related to the ontology structure of the claimed invention including slots and facets had technical character and allowed efficient storage and efficient search of the ontology for identifying drug targets. Slots and facets are, however, abstract concepts for modelling data and cannot contribute as such to the technical character of the invention. The appellant elaborated on this argument in its reply to the summons to oral proceedings and argued that the invention involves "active modelling", "representative modelling" or "a dynamic operation performed by the modelling function of the database". These arguments likewise illustrate that the appellant sees inventive step in the intellectual activity of modelling disease-related metabolic pathways, and fail to convince the board that the claimed invention serves a technical purpose.

7.   Therefore, claim 1 does not involve an inventive step
        over a general-purpose computer comprising a queryable
        database in any of the requests on file (Article 56
        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