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Datasheet for the decision of 9 February 2024

Case Number:	T 0330/21 - 3.5.06
Application Number:	13841952.8
Publication Number:	2902004
IPC:	A61J3/00, G06K9/00, G06F19/00, G06T7/00
Language of the proceedings:	EN

Title of invention:
DRUG INSPECTION DEVICE AND METHOD

Applicant:
FUJIFILM Toyama Chemical Co., Ltd.

Headword:
Drug inspection/FUJIFILM

Relevant legal provisions:
EPC Art. 84
RPBA 2020 Art. 13(2)

Keyword:
Amendment after summons - exceptional circumstances (yes)
Claims - clarity (no)

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Case Number: T 0330/21 - 3.5.06

D E C I S I O N
of Technical Board of Appeal 3.5.06
of 9 February 2024

Appellant: (Applicant)	FUJIFILM Toyama Chemical Co., Ltd. 14-1, Kyobashi 2-chome Chuo-ku Tokyo 104-0031 (JP)
Representative:	Klunker IP Patentanwälte PartG mbB Destouchesstraße 68 80796 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 11 November 2020 refusing European patent application No. 13841952.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Müller
Members:	M. Domingo Vecchioni
	K. Kerber-Zubrzycka

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division issued on 11 November 2020 to refuse European patent application No. 13 841 952.8.

II. The examining division refused the application on the basis that the then main request and auxiliary requests 1 to 3 did not meet the requirements of Articles 84 and 56 EPC and that auxiliary requests 2 and 3 did also not meet the requirements of Article 123(2) EPC. The decision referred inter alia to WO 2012/056317 A2 (D1).

III. With the statement of grounds of appeal, the appellant requested that the decision of the examining division be set aside and that a patent be granted on the basis of a new set of claims for a new main request replacing all previous requests. This request was based on previous auxiliary request 2.

IV. In the annex to summons to oral proceedings, the board presented its preliminary opinion on the appeal. Document WO 00/06078 A2 (D3) was introduced in accordance with Article 114(1) EPC. The board raised objections under Articles 84 and 123(2) EPC as well as under Article 56 EPC starting from either D1 or D3.

V. With a letter of 8 January 2024, the appellant filed a new set of claims 1 to 20.

VI. At the oral proceedings, the appellant requested that the decision under appeal be set aside and that a patent be granted based on the set of claims submitted with the letter of 8 January 2024. At the end of the

oral proceedings, the chairman announced the decision of the board.

VII. Claim 1 reads as follows:

"A drug inspection apparatus (10b) for inspecting drugs that are prepared based on prescription information and are packaged in a prescription bag, comprising:

drug area extraction means (12) for extracting drug areas from a captured image in which the prepared drugs are captured, such that the drugs are separated from each other,

primary drug determination means (20) for determining the drug in each of extracted drug areas by extracting an outer shape feature, a color feature and a size feature of each drug from each extracted drug area of the captured image of the prepared drugs and comparing the extracted outer shape feature, the extracted color feature and the extracted size feature with an outer shape feature, a color feature and a size feature of each of the drugs to be prepared according to the prescription,

comparison target selection means (16) for acquiring drug images of drugs to be prepared according to a prescription and drugs similar to the drugs prepared according to the prescription from a drug database (15) that stores drug images of drugs that can be prepared;

first drug determination means (13) for performing a comparison of an image for each of the drug areas with the drug images acquired from the drug database (15) and determining to which drug each of the drugs present in the captured image that cannot be determined by the primary determination means (20) corresponds and the number thereof,

inspection result determination means (17) for

determining whether or not the prepared drugs and the number of the prepared drugs match the prescription information based on the prescription information."

Reasons for the Decision

The application

1. The application relates to an apparatus and method for automatically verifying ("inspecting") whether drugs that have been prepared based on a prescription and packaged in a prescription bag are actually the drugs that should have been prepared according to that prescription (paragraphs [0001]-[0008] of the English translation of the application as filed, filed on 27 February 2015).

2. The verification is based on a captured image of the content of the prescription bag. Drug areas are extracted from the captured image to separate the prepared drugs from each other (paragraph [0044]). The drug areas and image features extracted from them are compared with images of drugs that can be prepared and correspondingly extracted image features, which are acquired from a drug database (paragraphs [0046], [0048] and [0079]).

3. The application indicates that, on the one hand, comparing the images of the prepared drugs with the images of all drugs that can be prepared would be too time-intensive. On the other hand, comparing the prepared drugs *only* with the prescribed drugs (as done in the acknowledged prior art) is prone to erroneous determination if there exists, among all the drugs that can be prepared, another drug whose appearance is very

similar to that of one of the prescribed drugs: if that similar drug has been included by error in the prescription bag, it could be erroneously matched to the corresponding prescribed drug (paragraph [0007]).

4. According to the description, the technical problem underlying the invention is "to provide a drug inspection apparatus and method for realizing efficient inspection while suppressing erroneous determination upon inspection of the drugs" (paragraph [0008]).

5. A central idea of the invention is to do the comparison in principle only with the prescribed drugs but to expand the set of "comparison targets" to include also drugs in the database that are "similar" to the prescribed drugs (paragraph [0046]).

6. Claim 1 of the final request is directed to the "third embodiment", in which a "primary drug determination means (20)" is used in addition to the "first drug determination means (13)" (described in particular in paragraphs [0069] to [0081] and in figures 7 and 9).

In this embodiment, to increase efficiency, a two-stage approach is used (paragraph [0071]).

6.1 In a first stage, called "primary (drug) determination", a comparison of extracted drug areas and prescribed drugs is performed on the basis of outer shape, color and size features. In this stage, as explained in more detail below, only certain prescribed drugs that "can be determined" on the basis of these features are involved in the comparison (paragraphs [0070], [0076] and [0081]).

6.2 In a second stage, called "first (drug) determination", involving only those extracted drug areas and prescribed drugs that could not be "determined" in the first stage, a comparison is performed on the basis of image comparison, involving now also drugs in the database that are "similar" to prescribed drugs (paragraphs [0070], [0073], [0078] and [0079]).

6.3 It is finally determined whether or not the drugs determined in the two stages and the number thereof match the prescription information (paragraph [0080]).

6.4 The two-stage approach of third embodiment rests on the observations that "determination of drugs based on the outer shape features and the size features can be performed more easily than determination based on image checking" and that "since the number of drugs that are image checking targets can be reduced using the primary determination means 20, it is possible to perform drug determination more efficiently by reducing the number of image checking targets" (paragraph [0081]).

Admittance

7. The present set of claims 1 to 20 was filed in reply to the annex to the summons to oral proceedings in which the board's preliminary opinion was set out. The amendments made with this request overcome objections under Article 84 EPC that had been raised for the first time in that communication (points 17.1, 17.2.1, 17.3 and 17.5.1 of the communication) and do not introduce further issues. The board considers this to constitute exceptional circumstances within the meaning of Article 13(2) RPBA and admitted this request.

Article 84 EPC

8. According to claim 1, as regards the first stage, the "primary drug determination means (20)" is for "determining" the drug in each of the extracted drug areas by comparing its outer shape, color and shape features with those of "each of drugs to be prepared according to the prescription".

As regards the second stage, the "first drug determination means (13)" is for determining to which drug "each of the drugs present in the captured image *that cannot be determined by the preliminary determination means (20)*" (emphasis added by the board) corresponds, where the determination in the second stage is based on an image comparison of each of the drug areas with drug images acquired from the drug database by the "comparing target selection means (16)".

9. Claim 1 thus limits the "determination" in the second stage to those drugs in the captured image "that cannot be determined" in the first stage. However, it is not clear from claim 1 when a drug is such that it "cannot be determined" in the first stage, which renders the second stage and thus of claim 1 unclear.

10. The appellant argued that the expression "cannot be determined" is to be understood as referring to drugs in the captured image for which the comparison on the basis of outer shape, color and size features in the first stage does not result in a match with any of the prescribed drugs.

10.1 However, such an interpretation is not clearly derivable from the wording of claim 1, which does not say anything about drugs that "cannot be determined"

by the primary drug determination means.

10.2 Furthermore, this interpretation would result in an apparatus that is inconsistent with the description in that it would not solve the technical problem underlying the invention according to paragraph [0008].

Indeed, if this interpretation were adopted, it would mean that a drug in the captured image that matches one of the prescribed drugs in the first stage on the basis of the outer shape, color and size features would be excluded from the second stage. This approach would produce erroneous results in the case where the prescription bag comprises, by mistake, a non-prescribed drug that is very similar to one of the prescribed drugs in terms of outer shape, color and size.

This is exactly the situation described in paragraph [0007] of the description in which the invention is said to overcome the limitation of the cited prior art (paragraph [0008]): that prior art is said to be such that "when the wrong drugs that are very similar are prepared by mistake, the possibility that erroneous determination indicating than inspection result is OK will be made, even though the wrong drugs are packaged, in fact is increased", where "very similar" refers to "drugs having very similar appearances (for example, similar shapes, colors, or sizes"; in contrast thereto the invention is said to "provide a drug inspection apparatus and method for realizing efficient inspection *while suppressing erroneous determination upon inspection of the drugs*" (emphasis added).

11. The board notes that in the description of the third embodiment of the invention, on which claim 1 is based,

it is foreseen that the "primary determination targets" (i.e. the drugs with which the comparison is made in the first stage) are *only* those prescribed drugs *for which drugs having similar outer shape, color and size features are not present in the prescription;* these are said to be the "drugs that can be determined" in the first stage (paragraphs [0076] and [0077]).

Hence, in the description, an entirely different definition of drugs that can or "cannot be determined" in the first stage is used, but that definition is not reflected in claim 1 and cannot thus be relied on for interpreting claim 1.

(It is noted en passant that even under this interpretation the apparatus of claim 1 would not appear to solve the technical problem specified in paragraph [0008] as it would still not address the aforementioned situation in which an erroneous result is obtained because a *non-prescribed* drug very similar to one of the prescribed drug is included in the prescription bag.)

12. Hence, claim 1 fails to meet the requirements of Article 84 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

L. Stridde Martin Müller

Decision electronically authenticated