

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

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Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/JP2019/044755

International filing date (day/month/year)  
14.11.2019

Priority date (day/month/year)  
28.11.2018

International Patent Classification (IPC) or both national classification and IPC  
INV. G16H40/40 A61L2/24

Applicant  
CANON KABUSHIKI KAISHA

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of  
this opinion

see form  
PCT/ISA/210

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - the international application in the language in which it was filed.
  - a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2.  This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3.  With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:
  - a.  forming part of the international application as filed:
    - in the form of an Annex C/ST.25 text file.
    - on paper or in the form of an image file.
  - b.  furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
  - c.  furnished subsequent to the international filing date for the purposes of international search only:
    - in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
    - on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
4.  In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	<u>1-38</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-38</u>
Industrial applicability (IA)	Yes: Claims	<u>1-38</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1** US 2003/187586 A1 (KATZENMAIER KEVIN R [US] ET AL) 2 October 2003 (2003-10-02)
- D2** WO 03/038717 A1 (3M INNOVATIVE PROPERTIES CO [US]) 8 May 2003 (2003-05-08)
- D3** WO 01/10476 A1 (3M INNOVATIVE PROPERTIES CO [US]) 15 February 2001 (2001-02-15)
- D4** Anonymous: "Autoclave tape - Wikipedia",  
, 17 November 2017 (2017-11-17), XP055661330,  
Retrieved from the Internet:  
URL:[https://en.wikipedia.org/w/index.php?title=Autoclave\\_tape&oldid=810780022](https://en.wikipedia.org/w/index.php?title=Autoclave_tape&oldid=810780022)  
[retrieved on 2020-01-23]
- D5** Anonymous: "Autoclave - Wikipedia",  
, 11 November 2018 (2018-11-11), XP055661350,  
Retrieved from the Internet:  
URL:<https://en.wikipedia.org/w/index.php?title=Autoclave&oldid=868384535>  
[retrieved on 2020-01-23]

**Inventive Step**

- 1 The present application does not meet the criteria of Article 33(3) PCT because the subject-matter of independent claims 1, 15, 29, 30 and 38 is not inventive.
- 1.1 **D1** is considered to be the closest prior art to the subject-matter of claim 1, and it discloses:

*[Claim 1] A management apparatus that manages records of a predetermined process carried out using test paper, the test paper having a discoloration area that changes color in accordance with an achievement degree of the predetermined process ([0004], [0008], [0009]), the apparatus comprising:*

*holding means for holding, for each predetermined process, a record in which information that indicates a date/time at which the predetermined process was carried out and a determination result of the predetermined process determined based on the color of the discoloration area of the test paper is recorded; and ([0056], Fig. 1-3, [0106], [0107])*

*generating means for generating information for determining ~~transition~~ of quality of the predetermined process based on the information recorded in the records ([0056], Fig. 1-3, [0106], [0107], [0113]).*

- 1.2 Terms such as "*holding*" or "*generating*" are very abstract and do not convey any particular technical characteristics. In the present case the terms are considered to refer to the storage and presentation of information on a computer device.
- 1.3 There are no particular details about the determination of the transition of quality nor the management of records.
- 1.4 It is noted that it is implicit from the use of chemical indicators, sterilizer strips... that they change color in accordance with the sterilization process, see **D4** (page 1, first paragraph) and **D5 (page 4, last paragraph)** for illustration.
- 1.5 The difference between the subject-matter of claim 1 and the closest prior art consists in that the transition of quality is not determined.
- 1.6 However, at the level claimed such a feature is not seen to contribute to an inventive step.
- 1.7 The repetition of e.g. the generation of records to check several quality values would be straightforward for the skilled person.
- 1.8 The same argument applies, mutatis mutandis, to the subject-matter of claims 15, 29, 30 and 38.
- 1.9 Therefore the subject-matter of the independent claims is not inventive (A. 33(3) PCT).

### **Dependent claims**

- 2 The additional features of dependent claims 2 to 14, 16 to 28 and 31 to 35 are not inventive (A. 33(3) PCT) because they refer to the presentation of information that, in itself, is not used for any technical purpose.
- 2.1 Regarding claims 36 and 37 see **D1 (Fig. 1, image scanner 18, Fig. 23)** and the comments on paragraph 1.4. It is noted that a scanner is considered measuring means for obtaining an image of an object.