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**Datasheet for the decision
of 3 July 2013**

Case Number: T 1012/09 - 3.4.02

Application Number: 99945510.8

Publication Number: 1112479

IPC: G01N1/30, G01N1/31

Language of the proceedings: EN

Title of invention:

REMOVAL OF EMBEDDING MEDIA FROM BIOLOGICAL SAMPLES AND CELL
CONDITIONING ON AUTOMATED STAINING INSTRUMENTS

Applicant:

Ventana Medical Systems, Inc.

Headword:

Relevant legal provisions:

EPC 1973 Art. 56

Keyword:

Remittal to the department of first instance - unconvincing
inventive step argumentation

Decisions cited:

Catchword:



**Beschwerdekammern
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Chambres de recours**

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Case Number: T 1012/09 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 3 July 2013

Appellant: Ventana Medical Systems, Inc.
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Representative: Müller-Boré & Partner
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 28 October 2008
refusing European patent application No.
99945510.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: A. Klein
Members: A. Hornung
B. Müller

Summary of Facts and Submissions

- I. The appellant lodged an appeal against the decision of the examining division refusing European patent application 99945510.8 on the basis of Article 56 EPC.
- II. The appellant requested that a patent be granted on the basis of a main request or an auxiliary request.
- III. The following document will be referred to in the present decision:
D1: WO95/24498.
- IV. The sole independent claim according to the applicant's main request reads as follows:
- "1. An automated method of removing embedding media from a biological sample, the method comprising the steps of:
- heating the biological sample containing embedding media to a temperature in excess of the melting point of the embedding media to form a liquefied embedding media; and
 - applying a liquid including DI water and a surfactant to the biological sample to separate the liquefied embedding media from the biological sample."

Reasons for the Decision

1. Inventive step based on D1
- 1.1 The international search report and the supplementary European search report cite a large number of prior art documents, most of them being categorized as "particularly relevant" in those search reports. During the examination

proceedings, however, only D1 was used for the assessment of patentability of the claimed subject-matter.

1.2 D1 discloses an *automated* method in the sense that this method allows "compatibility with automated use" (see D1, page 3, lines 20-21; page 13, lines 7-9). The method of D1 is provided for removing wax, such as paraffin, from wax-embedded biological samples (see D1, page 3, lines 16-17) comprising the steps of

- contacting the wax-embedded specimen with a dewaxing composition by using temperature-controlled baths, wherein the temperatures range from 5°C to 50°C (see D1, page 11, lines 12-15 and lines 19-24) and wherein the dewaxing composition comprises a surfactant diluted with water (page 3, lines 7-9); and

- contacting the dewaxed specimen immediately after dewaxing with an aqueous washing composition comprising a detergent to remove residual dewaxing composition (see D1, page 11, lines 15-18).

There is no explicit disclosure in D1 that the embedding wax is heated to a temperature in excess of its melting point so as to form a liquefied embedding media, nor can the board see any indication in D1 that heating the dewaxing composition at 50°C in D1 would inherently imply that the embedding wax was heated to a temperature in excess of its melting point. Such an indication was not suggested in the decision under appeal either.

Therefore, the claimed method is novel over the disclosure of D1 and differs from the method of D1 in that it comprises the steps of

(i) heating the sample to a temperature *in excess of the melting point* of the embedding media to form a *liquefied* embedding media,

(ii) applying a liquid to the sample to separate the *liquefied* embedding media from the sample,

(iii) wherein the liquid includes *deionised* water.

1.3 According to the decision of the examining division, "the difference between the characterising features of D1 and the subject matter of present claim 1 consists in the use of a liquid including DI water and a surfactant for removing the molten embedding medium" and the technical problem to be solved "is seen in the need for providing a method of removing embedding media from a biological sample suitable for compact environmentally friendly automats especially in a high throughput system".

Then the examining division states that "the skilled person would first of all try to avoid the use of organic solvents, since this would eliminate the need for hoods. Thus the person is automatically led to aqueous compositions" In view of the fact that D1 teaches that the compositions used can contain a predetermined amount of water and surfactants, and that D1 further discloses post-dewaxing washes with such compositions, the examining division concludes that "D1 is considered to provide a variety of hints towards the use of an aqueous based composition with surfactants for removing embedding media in general and paraffin in particular, and consequently towards the solution provided by claim 1. Therefore D1 renders the solution provided by claim 1 obvious to one skilled in the art."

1.4 The board is unable to follow the chain of arguments of the examining division for at least the following reasons:

- 1.4.1 The claimed heating step, as actually worded in present claim 1 and including the forming of "liquefied embedding media", is entirely missing in the chain of argumentation.

In this respect, D1 merely teaches that the dewaxing process can be conveniently carried out at room temperature or, for a more precise control of the processing time, in temperature-controlled baths in the range from 5°C to 50°C, more preferably in the range from about 25°C to about 40°C (see D1, page 11, lines 19 to 24). In the board's view, the skilled person would not derive from that recommendation in D1 any suggestion that the wax should be effectively liquefied, which in accordance with the indications in the present application requires temperatures in excess of 50°C and up to 130°C (see page 7, lines 19 to 24).

- 1.4.2 Whilst it might be accepted that organic solvents are generally known to be undesirable, it is not apparent to the board why the skilled person would obviously eliminate the use of organic solvents included in all the dewaxing compositions of D1 and instead liquefy the embedded media before washing it out with a liquid including DI water and a surfactant.

As correctly mentioned by the examining division, washes with water and a surfactant are disclosed in D1, but they are recommended there only for washing out the residual dewaxing composition from the dewaxed specimen (see D1, page 11, lines 15-18), not for separating the liquefied embedding media from the biological sample, as claimed.

- 1.4.3 The decision under appeal also refers to daily life experience of the skilled person in relation to the removal of wax-like or fatty materials from surfaces, which he would carry out by applying hot water. For a complete removal, the

skilled person would add soap so as to dissolve or emulsify the fatty or wax-like material.

It is not apparent from the appealed decision which specific daily life experience the examining division had in mind. However, would it be the everyday situation mentioned in the communication dated 13 December 2007, annexed to the summons to oral proceedings, dealing with the cleaning of fatty pans (see page 3, last paragraph, of said communication), then the board doubts that the analogy put forward by the examining division would be relevant at all. Indeed, D1 relates to the removal of waxes like paraffins from delicate histological preparations of biological tissue specimens, which is hardly comparable to the removal of fat from household articles made of heat-resistant non-biological material.

2. Further prosecution

2.1 Since the board is not convinced by the argumentation of lack of inventive step with respect to D1 as used in the refusal, the appealed decision must be set aside.

2.2 The board notes that a certain number of issues, such as objections under Articles 123(2), 84 and 83, have been raised by the examining division during the examination procedure. It is not clear whether a final conclusion has been reached on these issues, nor whether the remaining prior art documents on file have been considered by the examining division.

Accordingly the board decides to make use of its discretion under Article 111(1) EPC 1973 in remitting the case to the examining division for further prosecution.

2.3 Since a decision to remit the case to the first instance does not adversely affect the appellant, the board sees no need to

appoint oral proceedings as conditionally requested by the appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution.

The Registrar:

The Chairman:



M. Kiehl

A. Klein

Decision electronically authenticated