BESCHWERDEKAMMERN PATENTAMTS

BOARDS OF APPEAL OF OFFICE

CHAMBRES DE RECOURS DES EUROPÄISCHEN THE EUROPEAN PATENT DE L'OFFICE EUROPÉEN DES BREVETS

Internal distribution code:

- (A) [] Publication in OJ
- (B) [] To Chairmen and Members
- (C) [] To Chairmen
- (D) [X] No distribution

Datasheet for the decision of 21 August 2018

Case Number: T 0470/12 - 3.3.08

Application Number: 99931904.9

Publication Number: 1090293

IPC: C12Q1/68

Language of the proceedings: EN

Title of invention:

Decoding of array sensors with microspheres

Patent Proprietor:

Illumina, Inc.

Opponent:

BioArray Solutions Ltd

Headword:

Array sensors/ILLUMINA

Relevant legal provisions:

EPC Art. 54, 113(1) RPBA Art. 12(4)

Keyword:

Main request - novelty (no) Fresh auxiliary requests - not admitted Auxiliary request 5 - reformatio in peius

Decisions cited:

G 0009/92

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

Boards of Appeal of the European Patent Office Richard-Reitzner-Allee 8 85540 Haar GERMANY Tel. +49 (0)89 2399-0

Fax +49 (0)89 2399-4465

Case Number: T 0470/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 21 August 2018

Appellant: Illumina, Inc.
(Patent Proprietor) 5200 Illumina Way

San Diego, CA 92122 (US)

Representative: Tollervey, Rebecca Marie

Mewburn Ellis LLP

City Tower

40 Basinghall Street London EC2V 5DE (GB)

Appellant: BioArray Solutions Ltd

(Opponent) 35 Technology Drive Suite 100

Warren NJ 07059 (US)

Representative: Renken, Joachim

Hoffmann Eitle

Patent- und Rechtsanwälte PartmbB

Arabellastraße 30 81925 München (DE)

Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on 20 December 2011 concerning maintenance of the European Patent No. 1090293 in amended form.

Composition of the Board:

Chairman B. Stolz

Members: M. R. Vega Laso

W. Van der Eijk

- 1 - T 0470/12

Summary of Facts and Submissions

- I. The appeal of the patent proprietor (appellant) lies from the interlocutory decision of an opposition division pursuant to Article 101(3)(a) and 106(2) EPC posted on 20 December 2011, concerning the European patent No. 1 090 293 (European application No. 99931904.9) with the title "Decoding of array sensors with microspheres".
- II. The patent, which was granted with 13 claims, was opposed on the grounds for opposition of Article 100(a) in conjunction with Articles 54 and 56, and Article 100(c) EPC.
- III. In the interlocutory decision under appeal, the opposition division found that, while the subjectmatter of claims 1 and 6 according to the main request filed under cover of a letter dated 21 October 2010 lacked novelty, the amended claims 1 to 7 according to the first auxiliary request filed at the oral proceedings and re-filed as clean copy on 6 April 2011, met the requirements of the EPC. Accordingly, the patent could be maintained in amended form on the basis of the claims of the first auxiliary request and an amended description filed on 6 April 2011.
- IV. Both the patent proprietor and the opponent lodged an appeal against the decision of the opposition division. However, by letter dated 3 April 2012 the opponent withdrew its appeal.
- V. The appellant (patent proprietor) submitted a statement setting out the grounds of appeal, including nine sets of amended claims as main request, auxiliary requests 1 to 5 and parallel requests 1a, 2a and 3a. The claims

- 2 - T 0470/12

according to the main request and auxiliary request 5 were identical to those of, respectively, the main request and the first auxiliary request underlying the decision under appeal. As a subsidiary request, the appellant requested oral proceedings if the board did not intend to allow the main request.

- VI. Independent claims 1 and 6 according to the main request read as follows:
 - "1. An array composition comprising:
 - a) a substrate with a surface comprising discrete sites; and
 - b) a population of microspheres comprising at least a first and a second subpopulation, wherein each subpopulation comprises:
 - i) a different bioactive agent; and
 ii) an identifier binding ligand that will
 bind a decoder binding ligand such that the
 identification of the bioactive agent can
 be elucidated;

wherein said identifier binding ligand and said bioactive agent are different molecules, and wherein said microspheres are distributed on said surface.

- 6. A method of making a composition comprising:
 - a) forming a surface comprising individual sites on a substrate;
 - b) distributing microspheres on said surface such that said individual sites contain microspheres, wherein said microspheres comprise at least a first and a second subpopulation each comprising:
 - i) a different bioactive agent; andii) an identifier binding ligand that willbind at least one decoder binding ligand

- 3 - T 0470/12

such that the identification of the bioactive agent can be elucidated; and wherein said identifier binding ligand and said bioactive agent are different molecules."

Dependent claims 2 to 5 are directed to particular embodiments of the array composition of claim 1. Claims 7 to 13 concern methods of decoding an array composition.

- VII. Although it was given the opportunity to reply to the statement of grounds of appeal, the respondent (opponent) did not make any submissions.
- VIII. On 23 August 2013, the appellant filed additional evidence.
- IX. The parties were summoned to oral proceedings. In a communication sent in preparation of the oral proceedings, the board provided comments on various procedural and substantive issues, and expressed its provisional opinion on the novelty of the claims according to the main request.
- X. In reply to the board's communication, both parties informed the board that they would not attend the oral proceedings.
- XI. Oral proceedings were held on 21 August 2018 in the absence of the parties.
- XII. The following document is referred to in this decision:
 - (1): EP 0 392 546 A2, published on 17 October 1990.

- 4 - T 0470/12

XIII. The submissions made by the appellant concerning issues relevant to this decision, were essentially as follows:

Main request

Article 54 EPC - novelty

The question for the consideration of novelty was whether or not the information given to the person skilled in the art in document (1) was sufficient to enable him to practice the technical teaching which was the subject of that disclosure. In other words, whether the skilled person faced with that document was interested in the possibility of implementing the method of sequencing by hybridization described therein. A mere hypothetical possibility of reproducing a part of the disclosure, in particular the array composition and the method of making it, was not enough to take away novelty if the skilled person would have had no practical motivation to work this part in isolation.

There were many statements throughout document (1) showing that the method of sequencing by hybridization described therein was hypothetical and very far away from practical implementation. For example, column 12, lines 10 onwards described extensive problems associated with sample preparation. Also detecting single molecule hybridisation events was, according to column 13, lines 51 to 54 a difficult, still unresolved problem, and the alternative approaches were said to "presume many technically untested operations" (see column 13, lines 54 and 55). Overall the skilled person was at a total loss as to how to even prepare the discrete particles needed for the method described in document (1). Severe difficulties associated with the

- 5 - т 0470/12

detection of the target molecules were apparent from the statements in column 18, line 4 onwards, and it could be derived from column 20, lines 19 to 22 that the image analysis requirements of claim 1 were not met.

Overall, the approach of document (1) was speculative and relied on many operations which were acknowledged not to be feasible. The skilled person, who was interested in technical reality, would conclude that the teaching of document (1) was not enabling. This conclusion was re-enforced by column 23, lines 26 to 28, which referred to described conceptual solutions and possible, or eventually possible, practical procedures; column 24, lines 52 to 55 also referred to lack of experimental verification. So the teaching of document (1) was non-enabled and the claims of the main request were novel over that document.

- XIV. The respondent did not make any submissions in substance.
- XV. The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained on the basis of the claims according to the main request or, subsidiarily, according to any of auxiliary requests 1, 1a, 2, 2a, 3, 3a, 4 or 5, all filed together with the statement of grounds of appeal.
- XVI. The respondent (opponent) did not put forward any requests.

- 6 - T 0470/12

Reasons for the Decision

Admission of new evidence

- 1. In appeal proceedings, the appellant submitted a declaration by Dr Kevin Gunderson as evidence in support of its allegation that the content of document (1) is not enabling and, consequently, cannot prejudice the novelty of the subject-matter of the claims according to the main request. In its communication in preparation for the oral proceedings, the board observed that this argument had been brought forward by the appellant early during the opposition proceedings (see its submission dated 21 October 2010), and that the question arose why Dr Gunderson's declaration was filed for the first time in appeal proceedings. In the absence of cogent reasons for the late filing of this piece of evidence, the board considered it unlikely that the document would be admitted into the proceedings.
- 2. The appellant did not submit any reasons why the new evidence could not have been filed during the opposition proceedings. It did not reply to the board's communication nor attended the oral proceedings. Hence, pursuant to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA) the board exercises its discretion and decides not to admit Dr Gunderson's declaration into the appeal proceedings.

- 7 - T 0470/12

Main request

Article 54 EPC - novelty

- 3. In its statement of grounds of appeal, the appellant contested only the opposition division's finding that the subject-matter of claims 1 and 6 lacks novelty in view of document (1).
- Document (1) describes a method of determining the 4. sequence of nucleic acid molecules attached to discrete particles. The passage starting from column 7, line 6 describes an array composition comprising a solid support on which discrete particles, in particular small beads of definite size and shape are spread as a monolayer (see lines 27 to 29). Attached to the discrete particles is a library of genomic clones (the "bioactive agent" in claims 1 and 6 of the main request), meaning that different subpopulations of particles have a different bioactive agent (clone) attached. In order to recognize discrete particles having the same clone in different hybridization areas on the array (i.e. to decode the array), three different systems are described in document (1) (see passage starting from column 7, line 45). In the system described in the paragraph bridging columns 7 and 8, different combinations of oligonucleotides attached to the discrete particles (the "identifier binding ligand" in claims 1 and 6) are recognized by hybridization with complementary oligonucleotide probes (the "decoder binding ligand" in claims 1 and 6). Thus, the oligonucleotides attached to the particles and the probes have to be different molecules, as required in claims 1 and 6.

- 8 - T 0470/12

- 5. In its submissions, the appellant did not dispute that document (1) describes both an array composition as defined in claim 1 and a method of making a composition as defined in claim 6, but argued that the information given to the person skilled in the art in document (1) is not sufficient to enable him/her to practice the technical teaching of this document.
- 6. The board disagrees with this view. In particular, the board cannot accept appellant's argument that the skilled person faced with document (1) would be interested only in the possibility of implementing the method of sequencing by hybridisation described in this document, and would have "... no practical motivation to work this part [of the disclosure] in isolation". Contrary to the appellant's view, the board is unable to see any reason why a person skilled in the art would not have a motivation to make an array as described in column 7 of document (1). Since preparing such an array is the first step of the sequencing method described in the document (1), there is in fact a practical motivation for the skilled person to do so.
- 7. The appellant pointed to various passages of document (1) which allegedly show extensive problems associated with sample preparation. However, none of the cited passages cast doubts that the technical information provided in document (1) supplemented by the common general knowledge enables a person skilled in the art to make the array composition described in the passage starting from column 7, line 6. The passage from column 12, line 10 onwards describes three possible ways of marking samples as mixes of discrete particles, i.e. without separation of individual genomic DNA fragments in liquid samples as described in the passage on column 7. Hence, the statements in

- 9 - T 0470/12

column 13, lines 51 to 55 to which the appellant referred, do not apply to the embodiment described in column 7. The same appears to be true, mutatis mutandis, as regards the statements from column 18, line 4 onwards which concern the detection of the oligonucleotide content on a level of one DNA molecule. Finally, the fact that, as stated in column 24, lines 52 to 55, particular embodiments described in document (1) had not been experimentally verified at the relevant time of this document, does not necessarily mean that they could not be put into practice at the relevant date. In fact, no documentary evidence to this effect has been brought forward.

8. In view of the above, the finding in the decision under appeal that the subject-matter of claims 1 and 6 is not novel over the content of document (1), is considered to be correct.

Admission of the fresh sets of claims according to auxiliary requests 1, 1a, 2, 2a, 3, 3a and 4 into the proceedings

9. The primary function of the appeal proceedings is to give a judicial decision upon the correctness of a separate earlier decision taken by a department of the European Patent Office (G 9/91, OJ EPO 1993, 408). It is not the purpose of the appeal proceedings to give the appellant the opportunity to re-cast its claims as it sees fit and to have such claim requests admitted as of right into the appeal proceedings. In fact, it is a matter of discretion of the board whether or not requests and evidence filed for the first time in appeal proceedings, but which could have been presented in the previous proceedings, are admitted and considered (see Article 12(4) RPBA).

- 10 - T 0470/12

- 10. In the present case, the claims of the patent as granted were directed to array compositions (claims 1 to 5), a method of making a composition (claim 6) and methods of decoding an array composition (claims 7 to 13). Together with its reply to the notice of opposition, the patent proprietor and present appellant submitted four sets of amended claims as main request and first to third auxiliary requests. While claims 1 to 13 according to the main request were essentially identical to the claims as granted - only a minor amendment was introduced into claim 5 -, the three sets of claims according to the auxiliary requests did no longer include claims directed to either array compositions or a method of making a composition (claims 1 to 6 of the patent as granted), but only amended claims derived from claims 7 to 13 and directed to a method of decoding an array composition.
- 11. In a communication sent in preparation of the oral proceedings, the opposition division expressed the provisional opinion that both the array composition according to claim 1 and the method of decoding an array composition according to claim 7 of the main request lacked novelty over document (1). In reply to the communication, the appellant submitted five amended sets of claims as first to fifth auxiliary requests which replaced the previous auxiliary requests. Again, none of the new sets of claims included claims directed to array compositions or a method of making a composition (claims 1 to 6 of the patent as granted). The same is true for the set of claims according to the first auxiliary request underlying the decision under appeal, which was filed during the oral proceedings before the opposition division.

- 11 - T 0470/12

- 12. In contrast, the sets of claims according to the auxiliary requests 1, 1a, 2, 2a, 3, 3a and 4 submitted together with the statement of grounds of appeal include amended claims derived from claims 1 to 6 as granted. As stated in the communication sent in preparation for the oral proceedings, the board is not aware of any circumstances that may have prevented the appellant from submitting these sets of claims in opposition proceedings. Nor has the appellant put forward any reasons for the late filing of these claims.
- 13. Moreover, it should be noted that the amendments introduced into claims 1 to 6 of the fresh auxiliary requests appear to be an attempt to overcome the objection of lack of novelty in view of document (1) that had been raised already in the notice of opposition. In opposition proceedings, the appellant had at least two opportunities to react by filing amended claims, namely in reply to either the notice of opposition or the opposition division's communication. At the latest, the appellant could have tried to file the claims during the oral proceedings before the opposition division. But it did not. As a result, a reasoned decision on the novelty of the subject-matter of amended claims directed to array compositions or a method of making a composition could not be taken in opposition proceedings, meaning that the board would now have to either decide on the matter as first and final instance, or remit the case to the opposition division, which would run contrary to procedural efficiency.
- 14. In view of these circumstances, the board holds that the sets of claims filed together with the statement of grounds of appeal could and should have been filed

- 12 - T 0470/12

in opposition proceedings. Hence, the board, exercising the discretion conferred by Article 12(4) RPBA, does not admit auxiliary requests 1, 1a, 2, 2a, 3, 3a and 4 into the proceedings.

Auxiliary request 5 - Reformatio in peius

15. The claims according to auxiliary request 5 in appeal proceedings are identical to those of the first auxiliary request underlying the decision under appeal. Since the opposition division decided that the patent could be maintained on the basis of these claims and the adapted description, and since the patent proprietor is the sole appellant against the interlocutory decision of the opposition division, applying the principles established in G 9/92 (OJ EPO 1994, 875) neither the board nor the respondent may challenge these claims.

Article 113(1) EPC - right to be heard

16. The grounds and evidence on which the present decision is based, are known to the appellants as they are essentially those on which the decision under appeal and/or the board's provisional opinion expressed in the communication in preparation for the oral proceedings were based. Even though the appellant was given the opportunity to make written and/or oral submissions thereon, it neither replied in substance to the board's communication nor attended the oral proceedings.

- 13 - T 0470/12

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



K. Boelicke B. Stolz

Decision electronically authenticated