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**Datasheet for the decision
of 6 November 2023**

Case Number:	T 0611/19 - 3.2.02
Application Number:	10184180.7
Publication Number:	2305173
IPC:	A61D19/00, G01N15/14, C12N5/00
Language of the proceedings:	EN

Title of invention:
Apparatus and methods for providing sorted particles

Patent Proprietor:
Inguran, LLC

Opponent:
ABS Global, Inc.

Headword:

Relevant legal provisions:
RPBA 2020 Art. 13(1), 13(2)
EPC Art. 54

Keyword:
Main request and auxiliary request 20 - amendment after
summons - exceptional circumstances (no)
Auxiliary request 15 - novelty - (no)

Decisions cited:
J 0014/19

Catchword:

Beschwerdekammern

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Case Number: **T 0611/19 - 3.2.02**

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 November 2023

Appellant: (Patent Proprietor)	Inguran, LLC 22575 State Highway 6 South Navasota, TX 77868 (US)
Representative:	Jacob, Reuben Ellis Maucher Jenkins Seventh Floor Offices Artillery House 11-19 Artillery Row London SW1P 1RT (GB)
Appellant: (Opponent)	ABS Global, Inc. 1525 River Road DeForest, WI 53532 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)

Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 December 2018 concerning maintenance of the European Patent No. 2305173 in amended form.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	S. Böttcher
	N. Obrovski

Summary of Facts and Submissions

I.   Both the opponent and the patent proprietor filed an
        appeal against the interlocutory decision of the
        opposition division to maintain European patent
        No. 2 305 173 on the basis of auxiliary request 15,
        which had been filed during the oral proceedings on
        8 October 2018.

II.   Oral proceedings before the board took place on
        6 November 2023.

III.   The appellant (opponent) requested that the decision
        under appeal be set aside and that the patent be
        revoked.

        The other appellant (patent proprietor) requested that
        the decision under appeal be set aside and that the
        patent be maintained on the basis of the main request
        as filed on 24 October 2023 or on the basis of one of
        auxiliary requests 1 to 19 as filed with the patent
        proprietor's statement of grounds of appeal or on the
        basis of auxiliary request 20 as filed with the patent
        proprietor's letter dated 1 November 2023.

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

        "A flow cytometry system for sorting a mixture of
        particles including particles having a characteristic A
        and particles having a characteristic B, the system
        including a fluid delivery system for delivering a
        fluid containing the particles, a flow cytometry
        apparatus for receiving the fluid, forming it into a
        stream and using flow cytometry to classify the
        particles according to the characteristics, and a

sorting system including a laser for ablating selected
particles in the stream according to the classification
and according to a sorting strategy to provide at least
one population containing desired particles, the system
being characterised in that it includes:

a control responsive to information received from the
flow cytometry apparatus for controlling the fluid
delivery to vary the rate at which fluid is delivered
as a function of at least one of the following:

(1) the purity of the at least one population with
respect to either characteristic A particles or
characteristic B particles; and

(2) the quantity of unablated characteristic A
particles or unablated characteristic B particles in
the said at least one population relative to the total
quantity of characteristic A particles or
characteristic B particles in the stream."

Claim 14 of the main request reads as follows:

"A method of using a flow cytometry system to sort a
mixture of particles including particles having a
characteristic A and particles having a characteristic
B, the method including:

providing a flow cytometry apparatus;

delivering a fluid containing the particles;

forming the fluid into a stream and using flow
cytometry to classify the particles in the stream
according to the characteristics;

sorting the particles in the stream by ablating selected particles according to the classification and according to a sorting strategy thereby to provide at least one population containing desired particles; and

varying the rate at which fluid is delivered as a function of at least one of the following:

(1) the purity of the said at least one population with respect to either characteristic A particles or characteristic B particles; and

(2) the quantity of unablated characteristic A particles or unablated characteristic B particles in the said at least one population relative to the total quantity of characteristic A particles or characteristic B particles in the stream."

Claim 1 of auxiliary request 15 reads as follows:

"A flow cytometry system for sorting a mixture of particles including particles having a characteristic A and particles having a characteristic B, the system including a fluid delivery system for delivering a fluid containing the particles, a flow cytometry apparatus for receiving the fluid, forming it into a stream and using flow cytometry to classify the particles according to the characteristics, and a sorting system including a laser for ablating selected particles in the stream according to the classification and according to a sorting strategy to provide at least one population containing desired particles, the system being characterised in that it includes:

a control responsive to information received from the flow cytometry apparatus for controlling the laser to

vary its sorting strategy or for controlling the fluid
delivery to vary the rate at which fluid is delivered
as a function of the purity of the at least one
population with respect to either characteristic A
particles or characteristic B particles."

Claim 1 of auxiliary request 20 reads as follows:

"A flow cytometry system for sorting a mixture of
particles including particles having a characteristic A
and particles having a characteristic B, the system
including a fluid delivery system for delivering a
fluid containing the particles, a flow cytometry
apparatus for receiving the fluid, forming it into a
stream and using flow cytometry to classify the
particles according to the characteristics, and a
sorting system including a laser for ablating selected
particles in the stream according to the classification
and according to a sorting strategy to provide at least
one population containing desired particles, the system
being characterised in that it includes:

a control responsive to information received from the
flow cytometry apparatus for controlling the fluid
delivery to vary the rate at which fluid is delivered
as a function of the purity of the at least one
population with respect to either characteristic A
particles or characteristic B particles."

Claim 2 of auxiliary request 20 reads as follows:

"A flow cytometry system for sorting a mixture of
particles including particles having a characteristic A
and particles having a characteristic B, the system
including a variable rate fluid delivery system for
delivering a fluid containing the particles, a flow

cytometry apparatus for receiving the fluid, forming it
into a stream and using flow cytometry to classify the
particles according to the characteristics, and a
sorting system including a laser for ablating selected
particles in the stream according to the classification
and according to a sorting strategy to provide at least
one population containing desired particles, the system
being characterised in that it includes:

a control responsive to information received from the
flow cytometry apparatus for controlling the fluid
delivery to vary the rate at which fluid is delivered
as a function the purity of the said at least one
population with respect to either characteristic A
particles or characteristic B particles."

V.   The following documents are referred to in this
       decision:

       D1   J. F. Keij et al., "High-Speed Photodamage Cell
             Sorting: an Evaluation of the ZAPPER Prototype",
             Methods in Cell Biology, vol. 42, chapter 22, 1994
       D2   J. F. Keij et al., "High-Speed Photodamage Cell
             Selection Using a Frequency-Doubled Argon Ion
             Laser", Cytometry, 19, 1995, 209-216
       D7   J. F. Keij et al., "Coincidence in High-Speed Flow
             Cytometry: Models and Measurements", Cytometry,
             12, 1991, 398-404
       D15   M. J. McCutcheon et al., "Flexible Sorting
             Decision and Droplet Charging Control Electronic
             Circuitry for Flow Cytometer-Cell Sorters",
             Cytometry, 2, 1981, 219-225
       D16   US 5,199,576 A

VI.   The arguments of the opponent can be summarised as
       follows:

Main request and auxiliary request 20 - admittance

The main request and auxiliary request 20 should not be admitted into the appeal proceedings since they did not meet the requirements of Article 13(1) and (2) RPBA.

The novelty issue to which the patent proprietor responded with claim 1 of the main request and claim 1 of auxiliary request 20 had been discussed right from the outset of the appeal proceedings. The opinion of the board expressed in its communication could not be considered exceptional circumstances for filing new requests. On the contrary, the fundamental principle of Article 13(2) RPBA was that amendments made to a party's case at such a late stage of the appeal proceedings should not generally be allowed.

Furthermore, the amendments could not be considered to restrict the case to previously presented claims since the subject-matter defined in the independent claims of the main request and auxiliary request 20 had not previously been independently pursued in any request.

In any case, the new requests did not resolve all of the issues raised; in fact, they gave rise to new objections. The main request also included an independent method claim (claim 14) which was broader than the apparatus claim and required a separate substantive evaluation of its patentability. It had been found that the subject-matter of claim 14 of the main request lacked novelty over D7 and lacked an inventive step in view of D15.
Auxiliary request 20 lacked an inventive step in view of D7. Thus, these documents should not be admitted into the appeal proceedings. Additionally, objections

of added subject-matter and a lack of clarity also had
to be raised against auxiliary request 20.

Moreover, the objections raised against the second
option of claim 1 of the previous main request also
applied to the subject-matter of the new main request
and auxiliary request 20.

Hence, the admittance of these requests would be
detrimental to procedural economy since they were not
prima facie allowable. Consequently, the main request
and auxiliary request 20 also failed to meet the
requirements for admittance as set out in Article 13(1)
RPBA.

Auxiliary requests 1 to 14 and 16 to 19 - admittance

The opponent did not provide any comments on auxiliary
requests 1 to 14 and 16 to 19.

Auxiliary request 15 - novelty over D16

The subject-matter of claim 1 of auxiliary request 15
lacked novelty over D16.

In particular, D16 disclosed a flow cytometry system
having a control responsive to information received
from the flow cytometry apparatus. As shown in Figure 5
and described in column 8, lines 14 to 18, the sorter
provided "individual sort/no sort decisions from
conventional cell sorter". Column 15, lines 1 to 34,
set out "how the algorithm uses information from the
cell sorter operation which include individual sort or
no sort decision from the traditional sort control 10",
i.e. the assigned characteristic. It was also described
in this passage that the algorithm optimised the yield/

purity ratio according to the information received.
Hence, D16 disclosed the use of pre-sort data for
varying the sorting strategy.

Moreover, D16 also disclosed a laser ablation system.
In particular, D16 explicitly mentioned in column 15,
lines 62 and 63, the possibility of zapping as a method
for destroying particular cells instead of droplet
sorting. In the field of flow cytometry, "zapping" was
a term in the art for laser ablation sorting.

Hence, D16 disclosed all of the features of claim 1 of
auxiliary request 15. Consequently, the subject-matter
of claim 1 of auxiliary request 15 lacked novelty.

VII.   The arguments of the patent proprietor can be
        summarised as follows:

        New main request and auxiliary request 20 - admittance

        The claims of the main request and auxiliary request 20
        should be admitted into the proceedings since they met
        the requirements of Article 13(1) and (2) RPBA.

        In the case law in relation to new submissions in
        appeal proceedings it was held that exceptional
        circumstances within the meaning of Article 13(2) RPBA
        2020 generally concerned new or unforeseen developments
        in the appeal proceedings themselves, such as new
        objections raised by the board or another party.
        Exceptional circumstances had been deemed present when
        objections had been raised for the first time in a
        board's communication.

        The main request and auxiliary request 20 met these
        requirements since there were exceptional circumstances

in view of the communication of the board dated
19 September 2023, in which it was indicated that the
removal from claim 1 of the first option, relating to
varying the sorting strategy, would render that claim
novel and inventive over the cited prior art.

By deleting the first option from the claim, the new
requests made the proceedings more expedient since they
addressed and *prima facie* resolved the issues described
in the preliminary opinion of the board. Hence, the
amendments were not detrimental to procedural economy
and did not give rise to new objections as the board
had considered the remaining second option to meet the
requirements of Articles 83, 54 and 56 EPC.

It had not been necessary to file these requests
earlier in the proceedings since the opposition
division had held auxiliary request 15 to be allowable.
The preliminary opinion of the board, which was also
issued at a late stage of the proceedings, was the
first time a novelty objection against claim 1 had been
made.

Furthermore, according to the case law of the Boards of
Appeal, the deletion of an alternative from a claim did
not constitute an amendment of a party's appeal case.

Auxiliary requests 1 to 14 and 16 to 19 - admittance

The patent proprietor did not comment on auxiliary
requests 1 to 14 and 16 to 19.

Auxiliary request 15 - novelty over D16

D16 did not disclose the feature "a control responsive
to information received from the flow cytometry

apparatus".

Column 15, lines 29 to 34, of D16 clearly indicated
that post-sort information was used to adjust the
sorting strategy. To identify whether the sort decision
resulted in the correct yield/purity ratio, the output
of the sorting system had to be analysed rather than
the input.

Furthermore, in the upper right-hand corner of Figure 5
it was clearly indicated that the sort result was sent
to the learning algorithm. The term "sort result" had
to be interpreted as the actual result of the sort,
rather than anything relating to pre-sort data.

The alternative embodiment described in column 15,
lines 35 to 40, also related to the use of post-sort
information.

Moreover, D16 did not directly and unambiguously
disclose that the sorting system included a laser for
ablating selected particles since all of the
embodiments of the Figures described droplet cell
sorting.

Hence, the subject-matter of claim 1 of auxiliary
request 15 did not lack novelty over D16.

Reasons for the Decision

1.   Subject-matter of the patent

        The patent relates to a flow cytometry system and a
        method for sorting a mixture of particles, for instance

sperm cells. Before the sperm cells are fed by the
fluid delivery system to the flow cytometry apparatus,
they are stained using a DNA-selective dye such that,
for instance, male sperm cells have a different colour
from female sperm cells. The difference in colour is
then used to analyse the cells and to classify them in
the flow cytometry apparatus (detector). The cells are
then sorted according to their classification in a
sorting system using a laser for ablating selected
particles in the stream.

The sequence of particles arriving at the sorting
system is random, so when viewed as a continuous
procession, the particles can be divided into different
particle series, one following another, including a
first particle series consisting only of one or more
particles having characteristic A, a second particle
series consisting only of one or more particles having
characteristic B and a third particle series consisting
of two or more closely spaced particles, at least one
of which has characteristic A and at least one of which
has characteristic B. The two or more particles in the
third series (also referred to as the coincident set)
may be closely spaced in the sense that the spatial
separation between the particles is insufficient to
allow accurate discrimination/classification of the
particles, or because such separation is insufficient
to permit one particle in the series to be ablated by
the laser without damaging the other particle(s) in the
same series. The number of these coincident sets
increases when the flow rate of the particles is
increased. In any event, the closely spaced particles
in each (or at least some) of the coincident sets of
particles can be ablated or not ablated, depending on
the sorting strategy employed.

Different control sorting strategies can be employed in
a photo-damage system, including the "high recovery"
and "high purity" sorting strategies.

According to claim 1 of auxiliary request 15, the laser
is controlled responsive to information received from
the flow cytometry apparatus. This information concerns
the identity of the particles in a series
(characteristic A, characteristic B or coincident (both
A and B)) and is used to vary the sorting strategy or
the fluid delivery rate as a function of
the (desired) purity of the population with respect to
either characteristic A or characteristic B.

In essence, the control of claim 1 deals with the
question of whether or not the coincident sets, i.e.
the third sets comprising both particles A and B, are
sorted out (ablated).

If these coincident sets are sorted out (coincident
reject or high purity strategy), the purity of the
population of desired particles is kept high. However,
a number of desired particles will be lost to the
ablated population, thus reducing the recovery rate
(yield). In this strategy, the particle delivery rate
is inversely related to the percentage of desired
particles in the collected population, since the faster
the particle sets are delivered the more coincident
sets are present in the stream.

On the other hand, if the coincident sets are not
ablated but sorted into the desired population
(coincident accept or high recovery strategy), the
purity of the desired population will suffer while a
high recovery rate can be achieved. In this strategy,
the particle delivery rate is inversely related to the

purity of the collected population of desired
particles.

In a third strategy (constant flow rate strategy), the
flow rate is kept constant and the percentage of
collected (accepted) or ablated (rejected) coincident
sets is varied.

2.   Main request and auxiliary request 20 - admittance

2.1   The main request was filed by letter dated
        24 October 2023 and auxiliary request 20 was filed by
        letter dated 1 November 2023.

        Claim 1 of the main request is based on claim 1 of the
        previous main request (patent as granted) but the
        reference to varying the sorting strategy has been
        removed.

        Claim 1 of auxiliary request 20 is based on claim 1 of
        auxiliary request 15 except here too the reference to
        varying the sorting strategy has been removed.

        Both of these claim requests constitute an amendment to
        the patent proprietor's appeal case (see, for instance,
        J 14/19, Reasons 1.3 and 1.4) since one of the
        alternatives defined in granted claim 1 (control of the
        sorting strategy or the fluid, each option combined on
        the basis of purity or quantity of unablated particles
        or both) has been deleted. Since both requests were
        filed after the notification of the summons to oral
        proceedings, Article 13(2) RPBA 2020 applies with
        respect to the question of whether these requests
        should be admitted into the appeal proceedings.

2.2   According to Article 13(2) RPBA 2020, which was in
force at the time the admittance decision was taken,
any amendment to a party's appeal case made after
notification of a summons to oral proceedings shall, in
principle, not be taken into account unless there were
exceptional circumstances which had been justified with
cogent reasons by the party concerned, i.e. in the
present case by the patent proprietor.

In its communication of 19 September 2023, the board
had expressed its provisional opinion on what was then
the main request. It considered the first option
(varying the sorting strategy) of claim 1 of the main
request on file at that time to lack novelty over D16,
but the second option (varying the fluid flow rate) was
considered novel and inventive. The novelty objection
to the first alternative had already been raised in the
first-instance proceedings and had been referred to by
the opponent in its statement of grounds of appeal. The
fact that the board expressed an opinion on this matter
has to be regarded as the normal course of events,
rather than as new or unforeseen developments that
change the facts or circumstances of the case. Hence,
the board does not consider there to have been any
exceptional circumstances justifying the filing of new
requests at this late stage of the proceedings. Rather,
the patent proprietor could have filed these requests
as possible fallback positions earlier in the
proceedings.

In this regard, it is irrelevant when the communication
setting out the preliminary opinion of the board was
issued. Hence, there are no exceptional circumstances
justifying the admittance of the main request and
auxiliary request 20.

2.3   Moreover, in applying its discretion according to
       Article 13(2) RPBA 2020, a board may also apply the
       criteria set out in Article 13(1) RPBA 2020. According
       to Article 13(1) RPBA 2020, the board shall exercise
       its discretion to admit new requests in view of, *inter
       alia*, the current state of the proceedings, the
       suitability of the amendment to resolve the issues
       admissibly raised by another party in the appeal
       proceedings, whether the amendment is detrimental to
       procedural economy, and, in the case of an amendment to
       a patent, whether the party has demonstrated that any
       such amendment *prima facie* overcomes the issues raised
       by another party in the appeal proceedings or by the
       board and does not give rise to new objections.

       It is acknowledged that the new main request and
       auxiliary request 20 address the issues mentioned in
       the preliminary opinion as a result of the first option
       having been deleted from the independent claims.
       However, as pointed out by the opponent, the sole
       option of varying the fluid flow rate according to the
       independent claims of the new main request and
       auxiliary request 20 had not previously been pursued in
       any request.

       The board further agrees with the opponent that
       independent method claim 14 is broader than claim 1
       since it does not require a controller responsive to
       the flow cytometer. This divergence in scope between
       claim 14 of the new main request and the previous
       requests triggered new objections from the opponent. In
       particular, the opponent considered that the subject-
       matter of claim 14 of the new main request lacked
       novelty and inventive step in view of documents D7 and
       D15. Furthermore, the opponent maintained the
       objections it had already raised against the second

option of claim 1.

As to auxiliary request 20, the opponent raised new
objections of added subject-matter and a lack of
clarity. Furthermore, it maintained its objection that
the subject-matter of claim 1 lacked an inventive step
in view of D16 and also considered D7 to be relevant.

Hence, due to the broadening of the claimed subject-
matter in relation to the previously pursued requests,
the admittance of the new main request and auxiliary
request 20 would also be detrimental to procedural
economy.

2.4   For these reasons, the board has decided that the main
       request and auxiliary request 20 are not to be admitted
       into the appeal proceedings.

3.   Admittance of documents D7 and D15

       The opponent referred to D7 and D15 for the first time
       in the appeal proceedings after the issuance of the
       summons and only in connection with the new main
       request and auxiliary request 20. Since these requests
       have not been admitted, the board has decided not to
       admit D7 or D15 either.

4.   Auxiliary requests 1 to 14 and 16 to 19 - admittance

       As already pointed out by the board in its
       communication of 19 September 2023, none of auxiliary
       requests 1 to 14 and 16 to 19 were substantiated on
       appeal.

       Pursuant to Article 12(5) RPBA, the board has therefore

decided not to admit these requests.

5.   Auxiliary request 15 - novelty over D16

5.1   D16 relates to a method and apparatus for flexibly
        controlling sorting decisions for a flow cytometer at a
        purity vs. yield ratio of sorted particles (D16,
        abstract). D16 also addresses the problem of the
        occurrence of coincident particle sets at higher flow
        rates (column 2, line 63, to column 3, line 51).

5.2   It is common ground that the system of D16 includes a
        fluid delivery system, a flow cytometry apparatus for
        receiving the fluid, forming it into a stream and
        classifying the particles according to the
        characteristics (data acquisition system 10b; column 8,
        lines 13 to 18), and a sorting system for sorting
        selected particles in the stream according to a sorting
        strategy (column 11, lines 6 to 12).

5.3   The board notes that in the context of Figure 5,
        referred to by both parties, the system is disclosed in
        relation to a deflection sorting system (i.e. the
        particles are electrically charged according to their
        classification and then sorted electrostatically).
        However, as argued by the opponent, it is mentioned in
        column 15, lines 57 to 64, that the system 100 of
        Figure 5 could also be used for "selective destruction
        (e.g. zapping) of objects" instead of sorting. It is
        known in the field of flow cytometry that "zapping"
        means laser ablation (see D1, Introduction; D2,
        abstract). Hence, D16 discloses the feature "a laser
        for ablating selected particles".

5.4   As pointed out by the opponent, D16 discloses an
        algorithm to identify the optimal sorting strategy

(column 15, lines 1 to 29). This algorithm uses, *inter alia*, information from the "detection signals generated in response to the respective particles passing a selected point of the flow cytometer", hence, in the wording of the claim, information from the flow cytometry apparatus that classifies the particles, i.e. pre-sort information. This information is used to optimise the yield/purity ratio and to determine a sort decision to control the hardware circuitry of system 100 (D16, column 15, lines 25 to 29). This means that the sorting strategy (represented by the sort decision) is varied by the algorithm as a function of the desired purity and/or the desired yield, as required by the claim.

In addition to this algorithm, D16 discloses a learning algorithm (column 15, lines 29 to 34) to which both parties referred in their submissions. However, it does not matter whether the learning algorithm uses post-sort data or pre-sort data, since it is disclosed that the algorithm mentioned in line 2 of column 15 uses pre-sort data to determine an optimised sort decision, i.e. to vary the sorting strategy, as explained above.

Hence, D16 discloses the feature "a control responsive to information received from the flow cytometry apparatus ... to vary its sorting strategy".

5.5   Consequently, the subject-matter of claim 1 of auxiliary request 15 lacks novelty over D16.

6.   As the only claim request admitted into the appeal proceedings is not allowable, the patent has to be revoked.

Order

For these reasons it is decided that:

1.   The decision under appeal is set aside.

2.   The patent is revoked.

The Registrar: The Chairman:

A. Chavinier-Tomsic   M. Alvazzi Delfrate

Decision electronically authenticated