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54 **System for marking a non-human biological object and for taking a sample of the biological object.**

57 System for marking a non-human biological object and removing a sample of the biological object, which object is in particular an animal, the system comprising:
- a first tag part,
- a second tag part,
- a pin connected to the first tag part by its first end and provided with a head at its second end,
- a sample removing stopper which - while attaching the tag parts on the biological object and removing the sample therefrom - is positioned on the head of the pin.
The stopper has a cutter at its front, which cutter delimits a sample receiving cavity.
The second tag part is provided with a passage for the stopper and the head of the pin.
The system also has a sample container with an introduction opening for introducing into the sample container the stopper and the sample of the object that has been cut by the cutter, which sample container is attached to the second tag part via a releasable connection.
The second tag part is provided in the region of the passage of the second tag part with a sample fixing spike member.

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SYSTEM FOR MARKING A NON-HUMAN BIOLOGICAL OBJECT AND FOR TAKING A SAMPLE OF THE BIOLOGICAL OBJECT.

The invention relates to marking of a non-human biological object and at the same time removing a sample of the biological object.

5 In particular, the invention relates to the marking and taking a sample of animals. However, the invention also relates to the marking and sampling of other non-human biological objects, such as plants.

The marking has at its main purpose to identify the object, as is in particular done for livestock.

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In the past few years, the desire and need to reliably identify individual animals has been increasing further. Particularly if the animals' meat is intended for human consumption or if the animals are going to be part of the human consumption chain in some other way, there is a need for reliable identification. One example is the BSE problem, where the accurate
15 determination of the origin and the life history of the animals are of importance. However, the reliable identification of animals also is desired for animals that are not destined for consumption, but e.g. is a pet, (race) horse, or the like.

20 The invention relates to a system which not only provides for a tag, such as an eartag, to be attached to the animal, but also achieves the simultaneous removal and storage of a sample of biological material from the animal. The removal of a small sample of the biological material and storage thereof in the sample container can have various purposes, e.g. identification of individual animals based on the "genetic fingerprint" which can be determined using the sample taken. The removed sample can also be used for other purposes, such as
25 that one or more test are performed on the sample, e.g. molecular genetic tests, blood test(s), etc.

Such systems are known, inter alia, from WO 02/39810, WO 2006/000869, and WO2009/010658.

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In presently marketed systems the stopper has a circular cutter at its front with a cutting ring made of metal. This cutter delimits a sample receiving cavity which is open at the front. The cutter removes a sample from the object with a diameter of about 4 to 5 millimeters.

An issue relating to the practical use of such tagging and sampling systems is the sampling failure rate. In practice specialized laboratories receive the filled and closed sample containers from farmers and check whether a sample is actually present in the sample container. If no sample is present in the container, the laboratory informs the farmer that no sample is present and requests that a new sample is taken from the same animal. Even at failure rates between 0.5 and 1.5 % this means an undesirable effort for the laboratories and farmers in view of the enormous number of animals that are to be tagged and sampled with these systems.

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The present invention aims to provide measures that allow for a reduction of the sampling failure rate in these systems.

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The invention provides a system according to the preamble of claim 1, which is characterized in that the second tag part is provided in the region of the passage of the second tag part with a sample fixating spike member having a spike directed away from the sample container, the sample fixating spike member being secured in an initial position thereof to the second tag part such that when the cutter is pressed onto one side of the object the spike is directed towards the sample receiving cavity of the stopper and engages on the opposite side of the sample to be removed from the object thereby fixating said sample to be removed, and the sample fixating spike member being movable away from said initial position into the sample container under the load of the sample when the cutter is continued to be pressed onto the opposite side of the object.

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The invention is based on the insight that in everyday practice, especially when applying such systems as ear tags on livestock animals, the ear tissue is sometimes not cut by the cutter in neat circular fashion as in a cookie cutter but remains partly connected to the rest of the ear and then slips from underneath the front end of the cutter.

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By the provision of the spike that engages on the ear on the side opposite from the side where the cutter engages, the ear, in particular the sample to be removed, is pressed onto the spike and effectively fixated by the tip of the spike. This effectively counteracts the undesired slippage of this portion of the ear and allows the cutter to perform its cutting function. In addition the spike presses onto the sample and facilitates the (partial) entry of the sample into the sample receiving space of the cutter.

As the sample fixating spike member – in its initial position – essentially stands in the path that the sample and the stopper with the cutter make towards the sample container, the invention proposes that the spike member is movable away from said initial position, into the

sample container under the load of the sample when the cutter is continued to be pressed onto the opposite side of the object.

5 In an embodiment one could envisage that the spike member is designed as a brittle component that effectively crumbles or shatters under the pressing load exerted thereon by the sample after having initially resisted said loading, e.g. the spike member being partly or entirely made of glass or a brittle plastic material. The remains of the spike member will then be pushed by the sample into the sample container.

10 In another more preferred embodiment the sample fixating spike member is secured in an initial position thereof to the second tag part via a temporary retaining connection, such that when the cutter is pressed onto one side of the object and the sample presses onto the spike member, said spike member is pressed from its initial position to slide into the sample container. As is preferred a threshold load needs to be overcome to release the temporary
15 connection.

In an embodiment the sample container has an open, non-sealed introduction opening, and the spike member is embodied as a closure of the passage in the second tag part when the spike member is in its initial position. The spike member thus performs a sealing function in
20 its initial position, e.g. avoiding the ingress of contaminants into the sample container.

In another, less preferred, embodiment the sample container is sealed at its introduction opening by a penetrable film or membrane. The spike member may then be provided at the side facing said film or membrane with one or more cutting formations, e.g. a circular cutter
25 edge, enhancing the penetration, or even causing circular cutting, of said film or membrane.

In an embodiment the spike member may effectively protrude significantly in front of the surrounding face of the second tag part, against which face the object comes to lie. However, in view of a preferred minimum effective height of the spike member of at least 3
30 millimeters, this arrangement would create a less desirable embodiment as the protruding spike can be seen as potential hazard for the animal and possibly for the person applying the tag onto the animal.

It is therefore a preferred embodiment that the spike member has a body with a base and a tip, wherein – in the initial position – the base is recessed in the passage of the second tag
35 part with respect to the entry opening of said passage for the stopper and the head. This recessed arrangement may be such that – in the initial position – the tip of the spike is located in or near the plane of the entry opening, e.g. within 2 millimeters in front of or behind said plane, and one or more spaces are left open around said spike member, between said

spike member and the second tag part. The ear tissue will in this arrangement be pressed partly into said space or spaces between the spike member and second tag part, so that the spike still is effective even though it does not, or only little, protrude in front of the second tag part.

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In an embodiment the spike member has a base that is adapted to slidingly fit in the sample container. The sliding fit may be designed to create a resistant force such that the spike member must be continuously forced into the sample container until it reaches its final position, and thereby keeps pressing against the sample during its insertion into the sample container. This may contribute to a lowering of the sampling failure rate and also more or less positions the sample within the sample container.

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In an embodiment the spike member is embodied as an openable capsule forming at least one sealed compartment therein filled with a functional compound, said capsule being adapted to open upon introduction of the spike member, sample, and stopper into the sample container, thereby bringing said functional compound in communication with the sample. Such "functional compounds" can be for example one or more preservatives, dehydrating agents and/or reacting agents. Possible embodiments of the openable capsule as well as the sample container are disclosed in WO2008/055690 incorporated herein by reference.

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It is noted that the functional compound need not be retained in a compartment of the capsule but may also be embodied as a solid body, e.g. with a binding agent to form a solid body, the solid body e.g. being placed in the container or assembled to the spike member.

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In an embodiment – in the initial position - the spike member is secured via one or more frangible bridges, e.g. to a retaining ring embedded in the second tag part or a retaining ring clamped between the second tag part and the sample container, said one or more frangible bridges breaking to allow the spike member to move away from its initial position.

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In another embodiment – in the initial position - the spike member is clampingly retained in the passage opening and/or in the sample container. In an embodiment wherein the spike member is adapted to slide into the sample container, the load onto the spike member then is envisaged to cause the spike member to move away from initial position.

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In another embodiment – in the initial position – the spike member is secured via one or more deformable connection members, e.g. a deformable circumferential flange clamped between the second tag part and the sample container, said one or more deformable connection members deforming under load applied by the sample onto the spike member and thereby

releasing the spike member. For example a hard plastic spike member is provided with a flexible plastic circumferential flange clamped between the second tag part and the sample container, so that the flange slips from between the tag part and the container as the spike member is moved into the sample container. A similar functioning embodiment could be made e.g. from thin metal plate material.

In an embodiment the spike member is at least partly made of transparent plastic, e.g. so as to allow for inspection of the content of the filled sample container.

10 In an embodiment the spike member has a body with a base and a tip, wherein the effective height of the spike member above the base is at least 3 millimeters, preferably between 4 and 7 millimeters. Such an effective height allows for a reliable engagement with the sample.

15 In an embodiment the spike member has a conical sample engagement portion having an outer diameter reducing towards the tip of the spike member.

In an embodiment the spike member has a base and the sample container has an abutment for said base, the spike member being slideable towards said abutment upon introduction of the spike member, sample, and stopper into the sample container so as to contact said abutment.

20 In an embodiment the spike member is embodied as an openable capsule filled with a functional compound, e.g. having one or more wall portions that fracture upon contact of the spike member with said abutment in order to bring the sample into communication with said compound .

25 In an embodiment the spike member is embodied as an openable capsule filled with a functional compound, and the sample container includes one or more piercing members arranged to pierce said capsule upon introduction of the spike member, sample, and stopper into the sample container, in order to bring the sample into communication with said compound.

30 In an embodiment the spike member is embodied as an openable capsule filled with a functional compound, wherein the capsule slidingly fits in said sample container, and wherein the capsule is embodied to open on a side opposite from the spike member, and wherein one or more communication passageways are present between the capsule and the sample container, e.g. one or more grooves in a section of the sample container wall, thereby establishing communication between the sample on one side of the spike member and the functional compound.

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For example a functional compound serves to stabilise the DNA of the sample, e.g. protect the sample against DNA-degrading enzymes. For instance said substance is a hygroscopic substance serving to dry the sample.

5 It will be appreciated that the functional compound can have any suitable composition both in chemical and in physical form, e.g. as a granular or powdery material, as a liquid, a gel, a solid (e.g. a tablet), a gas, an emulsion, etc. It is possible that the functional compound is arranged in a compound container attached to the spike portion of the spike member. The compound container can also have a porous or permeable wall or a porous or permeable
10 wall part, which compound container is preferably arranged in the capsule.

The chemical composition of the one or more functional compounds can be selected based on the desired effect of the compound on the sample. For instance the compound can be a reagent, a preservative or a dehydrating agent, such as a molecular sieve, salt, silica gel, a
15 compound for lysing the cells of the sample and/or a compound for eluting the sample tissue for obtaining RNA. Many suggestions for functional compounds have already been presented in prior art as suitable for samples of biological objects and new developments, e.g. in the field of genetics, blood testing, etc, will likely produce new functional compounds all of which can be retained in a suitably designed openable capsule.

20 The embodiment of the spike member as an openable capsule, which is manufactured and filled as an item distinct from the sample container, is beneficial for the manufacturing process of the system, e.g. as no functional compound has to be filled directly into the sample container.

25 Also the properties of the material spike member as well as the design of said spike member can be selected independent from the sample container, so that each item can be optimised for its function and practical use.

In this respect it is noted that the material of the spike member (or part of said spike member)
30 can be selected to be hard and rigid, possibly frangible, whereas the sample container should commonly be relatively flexible, so as to be strong and tough to resist damage during handling.

Also such sample containers with samples held therein might be stored for a long time at low, freezing temperature. Plastic material, which is the preferred material for the body of the
35 sample container, which is suited for such conditions preferably has a high impact resistance and thus is less suited to serve as material for the spike member.

In an embodiment the spike member is recessed in the passage of the second tag part and a

cover is placed over the entry opening of said passage, said cover e.g. being penetrable or being removable prior to application of the tag system. The cover may be formed as an integrally moulded thin and penetrable wall part of the second tag part, spanning across the passage for the stopper and the head.

5 In such embodiments one could envisage that the spike member is perforated and that a functional compound is present on the side of the spike member facing the container or in the container. Upon application of the tag system, the sample would then come into communication with the compound via the one or more perforations in the spike member.

10 The invention as well as advantageous embodiments of the invention are described in the subclaims and in the following description with reference to the drawing.

In the drawing:

15 Figs. 1a - c show an example of the system according to the present invention, including a first ear tag part provided with an integral pin and a releasable stopper, and a second ear tag part with a spike member and a sample container;

Fig. 2 shows a portion of the second tag part and another embodiment of the spike member;

20 Fig. 3 shows a portion of the second tag part and another embodiment of the spike member;

Fig. 4 shows a portion of the second tag part, the container, and another embodiment of the spike member;

Fig. 5 shows a portion of the second tag part, the container, and another embodiment of the spike member;

25 Fig. 6 shows a portion of the second tag part, and an other embodiment of the spike member;

Fig. 7 shows a portion of the second tag part, and an other embodiment of the spike member;

30 Figs. 8a - c show a further example of the system according to the present invention, including a first ear tag part provided with an integral pin and a releasable stopper, and a second ear tag part with a spike member and a sample container;

Figs. 9a-c show a further example of the system according to the present invention, including a first ear tag part provided with an integral pin and a releasable stopper, and a second ear tag part with a spike member and a sample container

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Below, a first exemplary embodiment of all parts of the system for marking a biological object, in particular for ear-marking an animal, and for taking a sample of the biological object

according to the invention will be described with reference to Figure 1a-c.

As the invention is focussed on the spike member some of the further drawings will not show the tag parts.

5

It is noted that those skilled in the art can take possible embodiments, details, variants, etc, as well as information regarding the method of application of the system, as well as potential use of the sample stored in the sample container from prior art documents in this field, e.g. as mentioned herein before.

10

The system illustrated comprises a first tag part 1, a second tag part 2 and a pin 3. The pin 3 has a first end and a second end, the pin 3 being connected to the first tag part 1 by its first end. The pin is provided with a head 4 at its second end. The pin 3 can be integrally moulded with the first tag part 1.

15

The system shown furthermore comprises a stopper 20 as will be explained in more detail below.

20

The second tag part 2 is provided with a passage 5, such that the pin 3 with the stopper 20 arranged on its head 4 can be pressed through a part of the biological object, in particular through the ear of an animal, and subsequently into and through the passage 5 of the second tag part 2, as a result of which the first and second tag parts 1, 2 are attached to one another and to the biological object via the pin 3.

25

It is noted that the tag parts can have a different design than shown here, and many embodiments are known in the art.

30

The system furthermore comprises a sample container 10 with an introduction opening 11 for introducing the stopper 20 with the sample of biological material of the object into the sample container 10, which sample container 10 is attached to the second tag part 2 (see Fig. 1) via a releasable connection, e.g. a snap connection, in such a manner that the opening 11 of the sample container 10 and the passage 5 of the second tag part 2 lie in line.

35

As is preferred a flange edge 12 of the sample container 10 is releasably held in a raised annular wall 7 of the second tag part 2.

While the pin 3 is being pushed through the object, the stopper 20 is on the head 4 of the pin 3, in such a manner that a sample 8 of the biological object is taken while the pin is being

pushed through the biological object and said sample is introduced into the sample container 10, following which the opening 11 of the sample container 10 is directly sealed by the stopper 20. At the same time, the stopper 20 may detach from the head 4 of the pin 3.

5 In the embodiment shown the stopper 20 has a circular cutter 21 at its front. Here the stopper 20 has a plastic body provided with a metal cutting ring 23. The cutter 21 delimits a cavity 22 which is open at the front and in which the sample will mainly be received. As is common the diameter of the cutter 21 is between 3 and 5 millimeters, here about 4 millimeters.

10 It is noted here that said stopper 20 could have a different embodiment. Examples thereof are shown in mentioned prior art documents and the skilled person will readily understand how to combine said stoppers with the measures according to the invention.

In a preferred embodiment, as illustrated in figure 1, the sample container 10 comprises a
15 body, for example produced by injection-moulding a suitable plastic, with a peripheral wall 14 and the opening 11 at one axial end and an integrally formed bottom 15 at the opposite axial end.

The body of the sample container 10 is preferably non-transparent, for example made from
20 POM or polyamide.

The stopper 20 can be transparent in order that the introduction of a sample into the sample
container 10 can be checked visually. The stopper 20 is preferably injection moulded from
suitable plastic and can, for example, be made from PC (polycarbonate), PS (polystyrene),
25 PMMA.

The metallic cutter ring 23 is preferably embedded in the stopper 20 upon injection moulding.

The second tag part 2 is provided in the region of the passage 5 with a sample fixating spike
30 member 30 having a spike directed away from the sample container 10.

The spike member 30 is secured in an initial position (see figs. 1a, b) thereof to the second
tag part 2 such that when the cutter 21 is pressed onto one side of the object (not shown) the
spike is directed towards the sample receiving cavity 22 of the stopper 20 and engages on
35 the opposite side of the sample to be removed from the object thereby fixating said sample to
be removed.

The sample fixating spike member 30 is movable away from said initial position into the

sample container (see fig. 1c) under the load of the sample when the cutter 21 is pressed onto the opposite side of the object.

The spike member 30 is secured in the initial position thereof to the second tag part 2 via a temporary retaining connection, such that when the cutter 21 is pressed onto one side of the object and the sample presses onto the spike member 30, said spike member 30 is pressed
5 from its initial position to slide into the sample container.

The sample container 10 has an open, non-sealed introduction opening 11. The spike member 30 is embodied as a closure of the passage 5 in the second tag part 2 when the
10 spike member 30 is in its initial position.

As can be seen the spike member 30 has a body with a base 30a, here annular, and a tip 30b, wherein – in the initial position – the base 30a is recessed in the passage 5 with respect to the entry opening of said passage 5 for the stopper and the head.
15

The tip 30b – in the initial position - is located in or near the plane of the entry opening, e.g. within 2 millimeters in front of or behind said plane. Here the tip 30b is slightly in front of said plane, but a recessed position of the tip is also possible.

20 The base 30a has a diameter such that said base slidingly fits in the sample container 10.

A retaining ring 32 is clampingly placed between the container 10 and the second tag part 2, and the spike member 30 is – in the initial position - secured via one or more frangible bridges, here a circumferential bridge 33 with a diameter corresponding to the diameter of
25 the introduction opening, to the retaining ring 32.

As is preferred the spike member 30 and the retaining ring 32 are manufactured as a monolithic component, preferably of plastic. The one or more bridges are preferably formed during the injection moulding but can also be formed later, e.g. by cutting, etc.
30

As can be seen in figures 1a-c the bridge 33 is designed to break or fracture as the load thereon surpasses its breaking strength. The load is caused by the sample pressing onto the spike member 30, which is in turn caused by the cutter pressing onto the opposite side of the ear.
35

As is preferred the spike member 30 has a body with a base and a tip, wherein the effective height of the spike member above the base is at least 3 millimeters, preferably between 4 and 7 millimeters.

As is preferred the spike member 30 has a conical portion above the base 30a having an outer diameter reducing towards the tip of the spike member. As is preferred the conical portion is hollow, but a rigid conical portion is also envisaged.

5

The spike member 30 is pressed into the container 10. As is preferred the fit is such that this motion is resisted so that the spike member continuous to be pressed against the sample 8 during this motion towards its final position in the container 10.

10 In a variant the container has an abutment for the base 30a at a predetermined position, possibly a shoulder in the wall of the container or another obstacle, possible the bottom of the container. The spike member 30 is slideable towards said abutment upon introduction of the spike member, sample, and stopper into the sample container so as to contact said abutment. This may allow to keep the sample in a predetermined section of the sample
15 container. It may also be used to keep the sample in contact with the spike member.

It is noted that the release of the retaining ring 32 may not need the provision of dedicate breakable bridges if the base itself is designed to be fractured, e.g. due to a suitable selected material and/or thickness.

20

As will be appreciated, once the sample 8 is in the container as shown in figure 1c, the closed container can be readily detached from the second tag part 2, e.g. for shipping to a laboratory.

25 As explained the presence of the spike member 30 contributes to a lowering of the sampling failure rate, as the sample 8 is in the process of application of the tag parts to the ear or other object fixated, e.g. impaled, on the spike member, thus hindering or inhibiting sideways motion that would allow for the sample not being properly removed and introduced into the
30 container 10.

30

In a design of the spike member 30 as a closure, no closure is needed on the container 10 at the introduction opening. This facilitates the manufacturing process of the system. Also drawbacks of the known film closure, such as interfering with the proper sealing by the stopper 20 as the film may become wedged between the closure and the stopper, are
35 avoided.

In an alternative embodiment – in the initial position – the spike member 30 is secured via one or more deformable connection members, e.g. if the ring 32 is embodied as a

deformable circumferential flange of the spike member that is clamped between the second tag part and the sample container. These one or more deformable connection members are then envisaged to deform under load applied by the sample onto the spike member and thereby release the spike member to move into the sample container 10. For example the

5 circumferential flange 32 of the spike member is embodied as a flexible portion, e.g. by making it of a relatively flexible plastic and the base and spike of the spike member as a relatively hard plastic, e.g. in a 2K-injection moulding process.

In figure 2 an embodiment is shown wherein the spike member 30 is perforated to allow for

10 communication between the front and rear side of the spike member 30. This is e.g. envisaged for an embodiment where a described film closure is provided on the container, or in embodiments wherein this perforation allows for communication between the sample 8 and a compound filled in the container. The perforations may be one or more channels formed in the spike member during injection moulding.

15 Figure 2 also illustrates the idea to embed the retaining ring 32 (formed here integrally with the spike member 30) in the second tag part 2, preferably during injection moulding of the second tag part.

20 The spike member 30, possibly including the retaining ring 32, may be embodied as a unitary (plastic) member with a reinforcement collar member that is to be embedded in the second tag part to reinforce one or more portions of the second tag part, e.g. the collar 7 thereof when present.

25 In figure 3 it is illustrated that the spike member 30 is – in the initial position - clampingly retained in the passage 5, e.g. the spike member 30 being of a relatively hard material. For example the member 30 is press fitted in the passage 5 of second tag part 2.

Figure 4 illustrates that the spike member 30 is fitted – in the initial position – both in the

30 passage 5 and in the sample container 10. Here the spike member 30 has a base embodied as a skirt that fits into both the passage 5 and the container 10.

The spike member 30 may have a tapering base 30a (as e.g. in figure 4) that – in the initial position – fits in a corresponding seat of the second tag part and/or of the container, the

35 taper providing some resistance against the spike member 30 being pressed (further) into the container 10. A similar effect can be obtained by other designs wherein the spike member has a portion of greater diameter that must overcome a narrower diameter portion of the seat in either the passage and/or the container.

Figure 5 illustrates a spike member 30 embodied as an openable capsule forming at least one sealed compartment 31 therein filled with a functional compound. This capsule is adapted to open upon introduction of the spike member, sample, and stopper into the sample container, thereby bringing said functional compound in communication with the sample.

In this example it is envisaged that the pressure on the spike member will after an initial period of resistance, cause a fracturing of the body of the spike member and release from the retaining ring 32. For example the plate member 35 of the base that extends underneath the cone spaced space 31 will bend and fracture, also causing fractures in the conical wall of the spike member and/or along the circumferential flange portion of the base 30a.

Figure 6 illustrates an embodiment of the spike member 30 with a column extending in the passage and having a conically pointed end with a sharp tip. The column extends from a base 30a in the direction of the cavity 22 when the tag system is applied to an animal ear or other object.

As shown in figure 6, provision may be made for one or more spike stabilizing fins 36 in the space between the spike and the wall defining the passage 5, e.g. three or four fins at different angular positions. The fins 36 may have a sharp edge facing away from the container. The spike extends beyond the fins 36 to obtain the desired fixation effect.

Figure 7 shows a spike member 30, wherein the spike has an inverted cone shaped recess at its tip.

Figures 8 a – c illustrate a system wherein the spike member 30 is embodied as an openable capsule contains a functional compound, and preferably also acting as closure of the passage 5; the container 10 not having a film or other seal.

Here the spike member 30 has a compartment 31 that is closed at the side of the container 10 by a frangible wall 35, here a foil seal, to contain the functional compound in the spike member.

In the initial position the spike member 30 is secured to a retaining ring 32

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The spike member 30 now embodied as capsule slidingly fits in the sample container 10.

The capsule 30 is embodied to open on a side opposite from the spike member, by breaking

the wall 35.

Here it is illustrated that the container has a piercing member 16 arranged to pierce the capsule 30, here wall 35, upon introduction of the spike member, sample, and stopper into the sample container.

In order to establish communication between the sample 8 on one side of the spike member 30 and the functional compound on the other side one or more communication passageways are present between the capsule and the sample container, here one or more grooves 17 in a section of the sample container wall 14.

As is preferred a spike member 30 is at least partly made of transparent plastic.

In another capsule embodiment (not shown) the capsule will abut in a final position on an abutment of the container 10, e.g. the bottom, prior to the stopper reaching its final position in the stopper. Continued pressure on the capsule may then cause the capsule to fracture, e.g. the spike being pressed further into the container so as to cause fracturing around the foot of the spike and so as to bring the compound into contact with the sample 8.

In figure 9a the entry opening of the passage 5 is sealed by a cover 60, here a user removable adhesive cover (with a lifting tab to facilitate removal). The cover effectively hides the spike member 30 from view. In an alternative the cover is a penetrable cover, e.g. a film that ruptures are the tag system is applied and the ear presses the film into the passage 5. The spike member 30 then aids in the rupturing of the cover.

If the cover 60 is embodied as an airtight closure, one can envisage (as depicted here) that the spike member 30 is perforated so that the spaces on the front and the rear of the spike member are in communication via the perforations. Also a functional compound can then be present in the container. In another embodiment – as shown here - the spike member 30 is provided with a compartment containing a functional compound (see at 37) which is then in open communication with the side of the spike facing the sample 8.

CONCLUSIES

1. Systeem voor het merken van een niet-menselijk biologisch object en het verwijderen van een monster van het biologische object, welk object in het bijzonder een dier is, waarbij het systeem omvat:

- een eerste merkdeel (1),

5 - een tweede merkdeel (2),

- een pen (3), met een eerste einde en een tweede einde, welke pen met het eerste merkdeel is verbonden door zijn eerste einde en welke pen is voorzien van een kop (4) aan zijn tweede einde,

10 - een monsterverwijderende stop (20), die – bij het aanbrengen van de merkdelen op het biologische object en het verwijderen van het monster daarvan – zich op de kop (4) van de pen (3) bevindt,

waarbij de stop een ringvormig, bij voorkeur cirkelvormig, snijorgaan (21) aan zijn voorzijde heeft, bij voorkeur met een snijring die is gemaakt van metaal, welk snijorgaan een
15 monsteropnemende holte (22) begrenst die open is aan de voorzijde,

waarbij het tweede merkdeel is voorzien van een doorgang (5) voor de stop en de kop (4) van de pen,

20 - een monsterhouder (10) met een inbrengopening (11) voor het in de monsterhouder inbrengen van de stop en het monster van het object dat door het snijorgaan is gesneden, welke monsterhouder (10) met het tweede merkdeel (2) is verbonden via een losneembare verbinding, op zodanige wijze dat de inbrengopening (11) van de monsterhouder en de doorgang (5) van het tweede merkdeel op een lijn liggen,

25

welk systeem – in gebruik – het mogelijk maakt dat de pen door een deel van het biologische object wordt gedrukt, in het bijzonder door het oor van een dier, waardoor met het snijorgaan een monster (8) van het object wordt gesneden, welk monster ten minste gedeeltelijk wordt opgenomen in de monsteropnemende holte (22), en waarbij de stop en de kop door de
30 doorgang (5) van het tweede merkdeel (2) passeren, als een gevolg waarvan de eerste en tweede merkdelen aan elkaar zijn verbonden en aan het biologische object via de pen, waarbij de stop en het monster in de monsterhouder worden ingebracht, waarbij de stop de inbrengopening van de monsterhouder afdicht,

35 **met het kenmerk, dat**

het tweede merkdeel in het gebied van de doorgang (5) van het tweede merkdeel (2) is voorzien van een monsterfixerend spiesorgaan (30) met een spies die van de monsterhouder vandaan is gericht, welk monsterfixerend spiesorgaan in een initiële positie daarvan is vastgezet aan het tweede merkdeel (2) zodat wanneer het snijorgaan (21) tegen een zijde van het object wordt gedrukt de spies naar de monsteropnemende holte (22) van de stop (20) is gericht en aangrijpt op de tegenover gelegen zijde van het monster dat van het object moet worden verwijderd, daardoor het monster dat moet worden verwijderd fixerend, en waarbij het monsterfixerende spieselement (30) van die initiële positie vandaan in de monsterhouder (10) beweegbaar is onder de belasting van het monster wanneer het snijorgaan tegen de tegenover gelegen zijde van het object wordt gedrukt.

2. Systeem volgens conclusie 1, waarbij het monsterfixerende spieselement (30) in een initiële positie daarvan aan het tweede merkdeel is vastgezet via een tijdelijke vasthoudverbinding (32), zodat wanneer het snijorgaan tegen een zijde van het object wordt gedrukt en het monster op het spieselement drukt, dat spieselement van zijn initiële positie wordt weggedrukt om in de monsterhouder te schuiven.

3. Systeem volgens conclusie 1 of 2, waarbij de monsterhouder een open, niet-afgedichte inbrenghoening heeft, en waarbij het spieselement (30) is uitgevoerd als een afsluiting van de doorgang in het tweede merkdeel wanneer het spieselement zich in zijn initiële positie bevindt.

4. Systeem volgens een of meer van de voorgaande conclusies, waarbij het spieselement een lichaam heeft met een basis (30a) en een spies met een punt (30b), waarbij – in de initiële positie – de basis (30a) verdiept ligt in de doorgang (5) ten opzichte van de ingangsoening van de doorgang (5) voor de stop en de kop.

5. Systeem volgens conclusie 4, waarbij – in de initiële positie – de punt (30b) van het spieselement is gelegen in of nabij het vlak van de ingangsoening, bijvoorbeeld binnen 2 mm naar voren of naar achteren ten opzichte van dat vlak, bij voorkeur enigszins naar voren ten opzichte van dat vlak.

6. Systeem volgens een of meer van de voorgaande conclusies, waarbij het spieselement een basis (30a) heeft die is ingericht om schuivend te passen in de monsterhouder.

7. Systeem volgens een of meer van de voorgaande conclusies, waarbij het spieselement (30) is uitgevoerd als een open te maken capsule die ten minste een afgedicht

compartiment (31) daarin vormt dat is gevuld met een functionele compound, welke capsule is ingericht om te openen bij het inbrengen van het spieselement, monster, en stop in de monsterhouder, waardoor de functionele compound in verbinding wordt gebracht met het monster (8).

5

8. Systeem volgens een of meer van de voorgaande conclusies, waarbij – in de initiële positie – het spieselement (30) via een of meer verbreekbare bruggen (33) is vastgezet, bijvoorbeeld aan een vasthoudring (32) die is ingebed in het tweede merkdeel of een vasthoudring (32) die is geklemd tussen het tweede merkdeel en de monsterhouder, waarbij
10 de een of meer verbreekbare bruggen breken om het toe te laten dat het spieselement van zijn initiële positie vandaan beweegt.

9. Systeem volgens een of meer van de conclusies 1 – 7, waarbij – in de initiële positie – het spieselement (30) klemmend wordt vastgehouden in de doorgangopening en/of in de
15 monsterhouder.

10. Systeem volgens een of meer van de voorgaande conclusies, waarbij – in de initiële positie – het spieselement via een of meer vervormbare verbindingsorganen is vastgezet, bijvoorbeeld een vervormbare omtreksflens die tussen het tweede merkdeel en de
20 monsterhouder is geklemd, welke een of meer vervormbare verbindingsorganen vervormen onder belasting die wordt aangebracht door het monster op het spieselement en daardoor het spieselement vrijgeven.

11. Systeem volgens een of meer van de voorgaande conclusies, waarbij het
25 spieselement ten minste gedeeltelijk is gemaakt van doorzichtige kunststof.

12. Systeem volgens een of meer van de voorgaande conclusies, waarbij het spieselement een lichaam heeft met een basis en een punt, waarbij de effectieve hoogte van het spieselement boven de basis ten minste 3 mm, bij voorkeur tussen 4 and 7 mm,
30 bedraagt.

13. Systeem volgens een of meer van de voorgaande conclusies, waarbij het spieselement een conisch gedeelte heeft met een buitendiameter die afneemt in de richting naar de punt van het spieselement.

35

14. Systeem volgens een of meer van de voorgaande conclusies, waarbij het spieselement een basis heeft en waarbij de monsterhouder een aanslag heeft voor die basis, waarbij het spieselement naar die aanslag verschuifbaar is bij inbrenging van het

spieselement, monster en stop in de monsterhouder om zo contact te maken met de aanslag.

5 15. Systeem volgens conclusies 7 en 14, waarbij de capsule is ingericht om te openen bij contact van het spieselement met die aanslag.

16. Systeem volgens ten minste conclusie 7, waarbij de monsterhouder een of meer doorprikorganen omvat die zijn ingericht om de capsule te doorprikken bij inbreng van het spieselement, monster, en stop in de monsterhouder.

10

15 17. Systeem volgens ten minste conclusie 7, waarbij de capsule schuivend past in de monsterhouder, en waarbij de capsule is ingericht om te openen aan een zijde die tegenover het spieselement ligt, en waarbij een of meer communicatieverbindingen aanwezig zijn tussen de capsule en de monsterhouder, bijvoorbeeld een of meer groeven in een gedeelte van de monsterhouderwand, waardoor verbinding wordt verschaft tussen het monster aan een zijde van het spieselement en de functionele compound.

20 18. Werkwijze voor het merken van een niet-menselijk biologisch object en het nemen van een monster van het niet-menselijke biologische element, waarbij gebruik wordt gemaakt van een systeem volgens een of meer van de voorgaande conclusies.

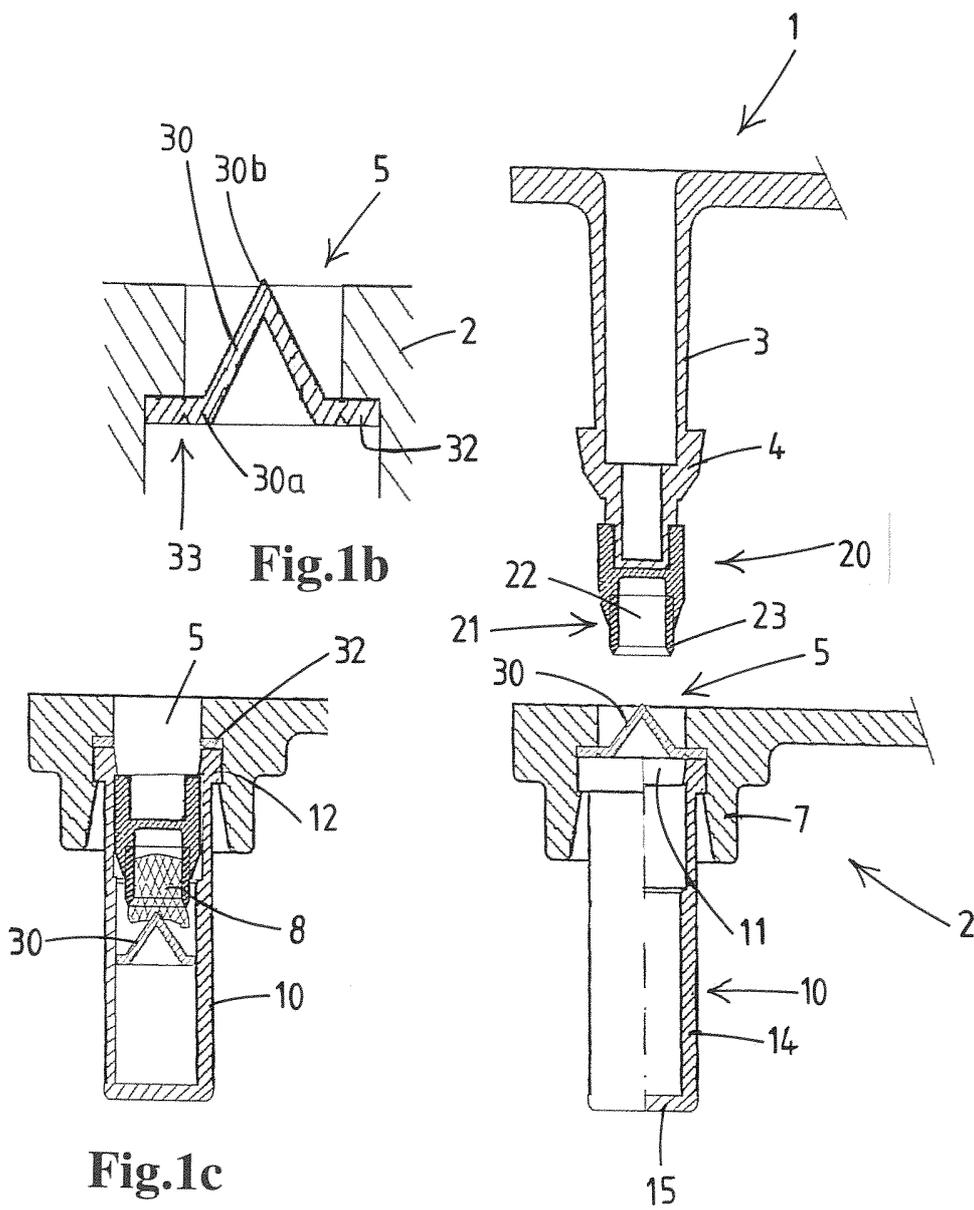


Fig.1b

Fig.1c

Fig.1a

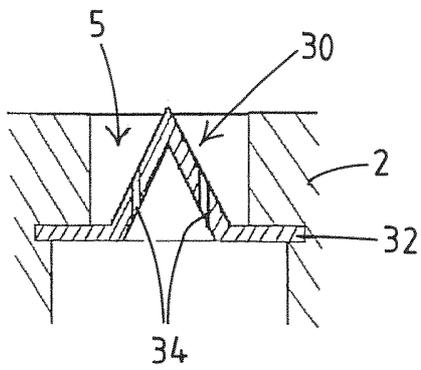


Fig. 2

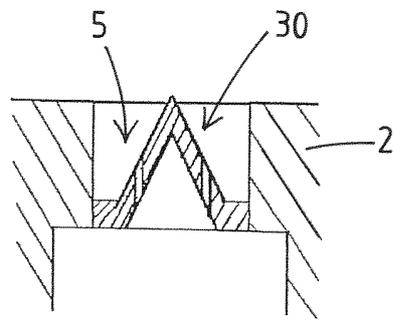


Fig. 3

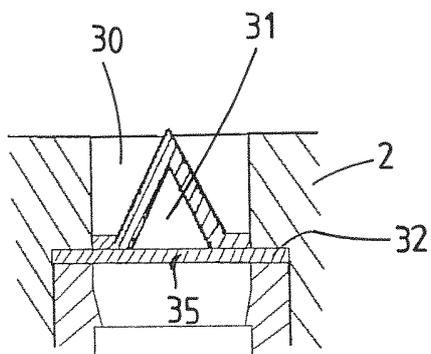


Fig. 5

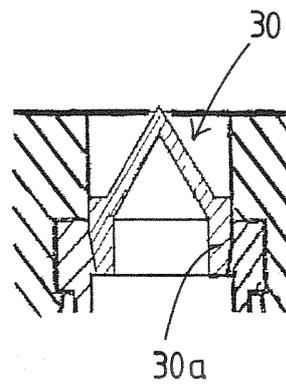


Fig. 4

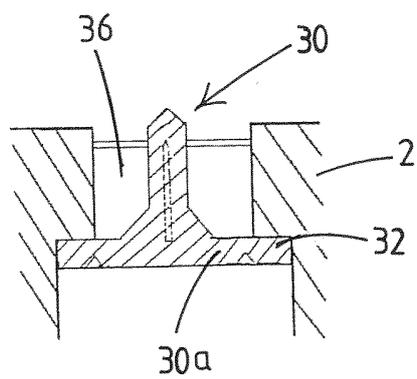


Fig. 6

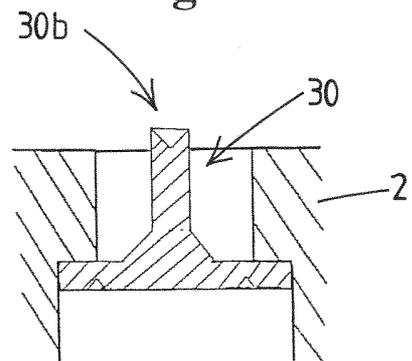


Fig. 7

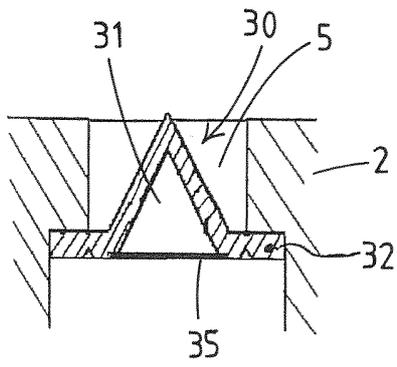


Fig. 8b

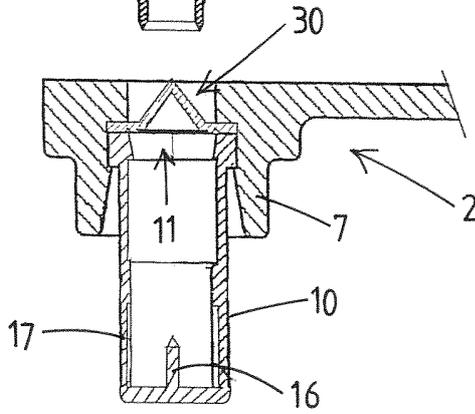
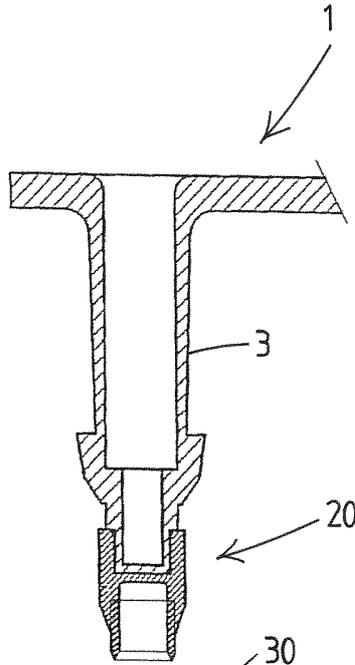


Fig. 8a

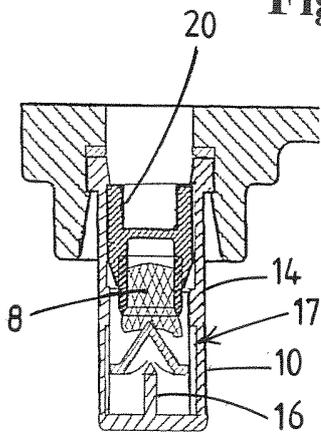


Fig. 8c

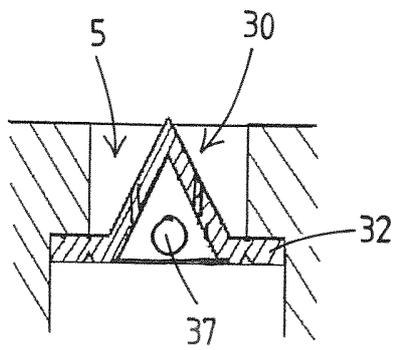


Fig.9b

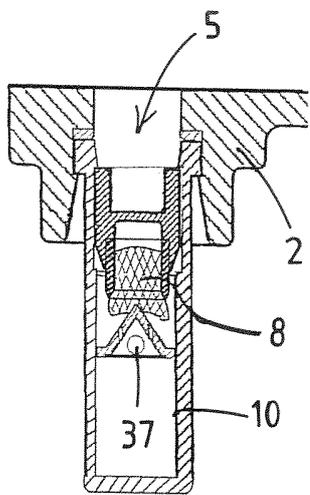


Fig.9c

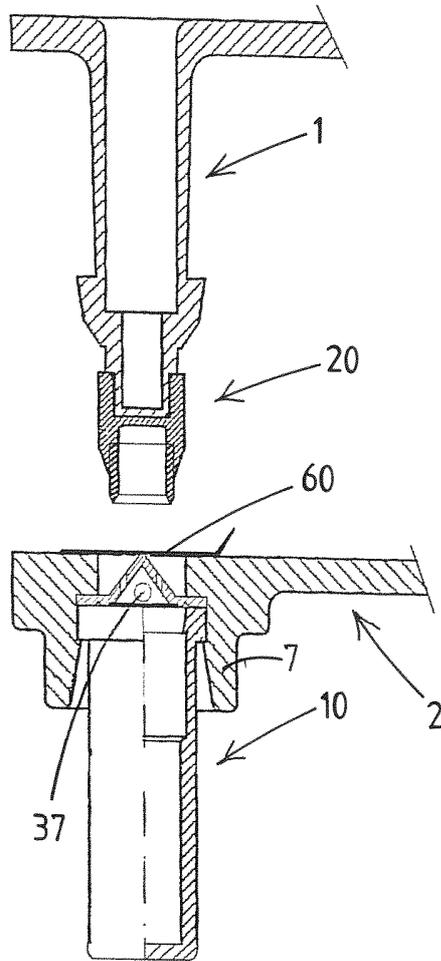


Fig.9a

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE P30968NL00
Nederlands aanvraag nr. 2007671	Indieningsdatum 28-10-2011
	Ingeroepen voorrangdatum
Aanvrager (Naam) Nehls	
Datum van het verzoek voor een onderzoek van internationaal type 11-02-2012	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. SN 57657
I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)	
Volgens de internationale classificatie (IPC) A01K11/00	
II. ONDERZOCHE GEBIEDEN VAN DE TECHNIEK	
Onderzochte minimumdocumentatie	
Classificatiesysteem	Classificatiesymbolen
IPC	A01K
Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen	
III. <input checked="" type="checkbox"/>	GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES (opmerkingen op aanvullingsblad)
IV. <input type="checkbox"/>	GEBREK AAN EENHEID VAN UITVINDING (opmerkingen op aanvullingsblad)

**ONDERZOEKSRAPPORT BETREFFENDE HET
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar
de stand van de techniek

NL 2007671

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A01K11/00
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimum documentatie (classificatie gevolgd door classificatiesymbolen)
A01K

Onderzochte andere documentatie dan de minimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)

EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
	ONVOLLEDIG ONDERZOEK zie aanvullingsblad C -----	
A,D	WO 2008/055690 A1 (NEHLS REINHARD [DE]; CAISLEY ROY [DE]; WINKELER HENRIK [DE]) 15 mei 2008 (2008-05-15) in de aanvraag genoemd * conclusies 1, 14, 27; figuren 1-11 *	1-17
A	US 2002/137033 A1 (BREM GOTTFRIED [DE]) 26 september 2002 (2002-09-26) * alineas [0014], [0020], [0021]; figuren 1, 2 *	1

Verdere documenten worden vermeld in het vervolg van vak C.

Leden van dezelfde octroofamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

A niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

D in de octrooiaanvraag vermeld

E eerdere octrooi(aanvraag), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

L om andere redenen vermelde literatuur

O niet-schriftelijke stand van de techniek

P tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

T na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvraag, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

X de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

Y de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

& lid van dezelfde octroofamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid

12 juni 2012

Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type

Naam en adres van de instantie

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

De bevoegde ambtenaar

von Arx, Vik

**ONVOLLEDIG ONDERZOEK
AANVULLINGSBLAD C**

Octrooiaanvraag Nr.:

SN 57657
NL 2007671

Volledig onderzoekbare conclusie(s):

1-17

Niet onderzochte conclusie(s):

18

Reden voor de beperking van het onderzoek (niet octrooieerbare uitvinding(en)):

Methode van behandeling van het menselijke of dierlijke lichaam door chirurgische ingrepen

**ONDERZOEKSRAPPORT BETREFFENDE HET
 RESULTAAT VAN HET ONDERZOEK NAAR DE STAND
 VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar
 de stand van de techniek
NL 2007671

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
WO 2008055690	A1	15-05-2008	
		AT 454814 T	15-01-2010
		AU 2007316899 A1	15-05-2008
		CA 2670679 A1	15-05-2008
		CN 101573028 A	04-11-2009
		DK 1920651 T3	10-05-2010
		EA 200970427 A1	30-12-2009
		EP 1920651 A1	14-05-2008
		ES 2339271 T3	18-05-2010
		NZ 577324 A	22-12-2011
		US 2009326548 A1	31-12-2009
		WO 2008055690 A1	15-05-2008

US 2002137033	A1	26-09-2002	GEEN



Agentschap NL
Ministerie van Economische Zaken,
Landbouw en Innovatie

WRITTEN OPINION

File No. SN57657	Filing date (<i>day/month/year</i>) 28.10.2011	Priority date (<i>day/month/year</i>)	Application No. NL2007671
International Patent Classification (IPC) INV. A01K11/00			
Applicant Nehls			

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 with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the application
- Box No. VIII Certain observations on the application

	Examiner von Arx, Vik
--	--------------------------

WRITTEN OPINION

Application number
NL2007671

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - on paper
 - in electronic form
 - c. time of filing/furnishing:
 - contained in the application as filed.
 - filed together with the application in electronic form.
 - furnished subsequently for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION

Application number
NL2007671

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of

the entire application

claims Nos. 18

because:

the said application, or the said claims Nos. 18 relate to the following subject matter which does not require a search (*specify*):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

no search report has been established for the whole application or for said claims Nos. 18

a meaningful opinion could not be formed as the sequence listing was either not available, or was not furnished in the international format (WIPO ST25).

a meaningful opinion could not be formed without the tables related to the sequence listings; or such tables were not available in electronic form.

See Supplemental Box for further details.

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes: Claims	1-17
	No: Claims	
Inventive step	Yes: Claims	1-17
	No: Claims	
Industrial applicability	Yes: Claims	1-17
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 18 is directed to a method for treatment of the human or animal body by surgery.

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 WO 2008/055690 A1 (NEHLS REINHARD [DE]; CAISLEY ROY [DE]; WINKELER HENRIK [DE]) 15 mei 2008 (2008-05-15) in de aanvraag genoemd
- D2 US 2002/137033 A1 (BREM GOTTFRIED [DE]) 26 september 2002 (2002-09-26)

Document D1 is regarded as being the prior art closest to the subject-matter of claim 1, and essentially discloses a system for marking a non-human biological object and removing a sample of the biological object according to the preamble of the independent claim 1.

The subject-matter of claim 1 therefore differs from this known system in that the second ear tag part is provided with a sample fixating spike member according to the characterizing part of claim 1 and is therefore new.

The problem to be solved by the present invention may be regarded as to reduce the sampling failure rate in the known system.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step for the following reasons:

Although D2, see the whole document and in particular the passages cited in the search report, hints at a protruding projection member 8 in a tissue receiving container of a similar system.

However, this projection is stationary and aims at crushing the sample and dividing it into two sample spaces 6 and 6a. D2 nor any other document cited in the description discloses or suggests sample fixating spike member spike fixating said sample to be removed and being movable away from an initial position into the sample container under the load of the sample when the cutter is pressed onto the opposite side of the

object.

The person skilled in the art would hence not be able to combine all the features of claim 1 and as such arrive at the claimed system without an inventive activity.

Claims 2 to 17 are dependent on claim 1 and as such also meet the requirements of novelty and inventive step.