

(19)



(11)

EP 2 529 720 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
05.12.2012 Bulletin 2012/49

(51) Int Cl.:
A61H 21/00 (2006.01)

(21) Application number: **12380027.8**

(22) Date of filing: **24.05.2012**

(84) Designated Contracting States:
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB
 GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO
 PL PT RO RS SE SI SK SM TR**
 Designated Extension States:
BA ME

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(30) Priority: **30.05.2011 ES 201100595**

(54) Inertial energy accumulating device for pelvic floor stimulation

(57) Inertial device (1) for the stimulation of the pelvic floor muscles, designed to be inserted into a user's vagina, comprising at least one hollow body (2) that contains at least one freely moving interior ball (3) that is able to move due to the force of gravity and the inertia of the user's movements and to impact against an inner surface (4) of the hollow body (2). The inner surface (4)

of the hollow body (2) comprises facets (5, 6) that form a certain angle with adjacent facets (5, 6) in a way that the interior ball (3) that is resting on a facet (5, 6) has to accumulate a certain amount of energy in order to move and hit an adjacent facet (5, 6). The device is effective and easy to manufacture, and it is also preferably symmetrical so that it is equally efficient irrespective of its positioning and the user's morphology.

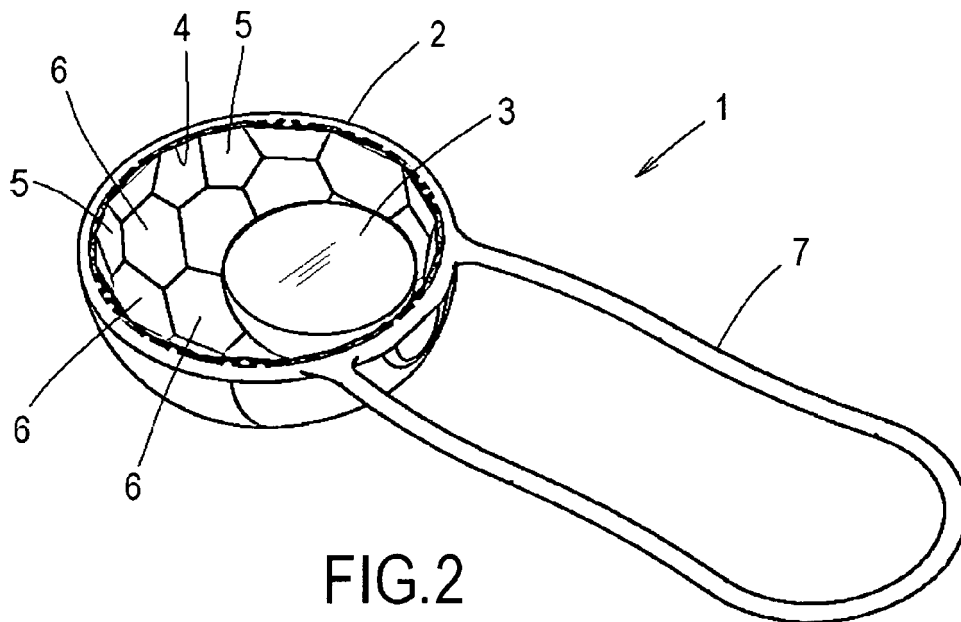


FIG.2

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Description

Technical field

[0001] The invention refers to an inertial device for the stimulation of a woman's pelvic floor muscles, of the kind that is inserted into the vagina and by using the inertia of a woman's movements is able to stimulate the muscle activity of the muscles adjacent to the device and thereby strengthen them.

Prior art

[0002] The pelvic floor is a set of muscles and fascia located in the minor pelvis that encloses the abdominal cavity from below and from the sides and whose functions are to provide visceral support (bladder, uterus, vagina and rectum), to absorb the abdominal pressure during straining, to intervene in the urinary and rectal continence and excretion, and to intervene in the sexual function. Also, it is considered to have obstetric functions. It is common that on account of various risk factors (pregnancy, vaginal deliveries, episiotomy, menopause, etc.) a woman's pelvic floor is weakened and loses its ability to contract, thus allowing the appearance of related medical conditions, such as the prolapse of the urinary bladder, the prolapse of the rectum and the prolapse of the uterus, causing in turn various dysfunctions such as the stress urinary incontinence. For this purpose, it is important to have the means to maintain the pelvic floor toned in order to avoid the appearance of these medical conditions that have such a negative impact on a woman's quality of life.

[0003] The use of devices of mechanical vibratory stimulation for toning the muscles that make up the pelvic floor has been known for some time now. Some devices take the form of one or various spherical bodies that are inserted into the vagina of the user in order to stimulate and induce a motor response from the smooth muscles of the vagina and a tonic response from the perineal striated muscles. If, in addition to that, the user performs a collaborative action by voluntarily contracting her pelvic floor muscles, said devices increase their toning capacity and the user gains strength in said muscles (i.e., the user's muscles increase their contractile capacity for closing the sphincters), as demonstrated in trials performed by the applicant of the present patent.

[0004] A type of device known as "inertial" is considered particularly useful, the spherical bodies of which are hollow and contain a ball of a certain weight that is able to move around, thus generating vibrations that stimulate the vibratory receptors of the vagina and cause the reflex (involuntary) contraction of the pelvic floor muscles.

[0005] Among the inertial devices, devices known as "passive" inertial devices are known. In these devices, the movement or displacement of the interior ball is caused by the motion of the user herself.

[0006] A very simple example of a passive inertial device is one that comprises spherical bodies containing a

ball of a certain weight that is able to freely roll around the inner smooth and spherical surface of the spherical bodies. Thus, when the user moves, the ball rolls around the interior of the hollow spherical body and is considered to generate a light vibration for stimulating the pelvic floor muscles.

[0007] A second example of a passive inertial device is described in patent ES2226590B1. Said inertial device comprises a hollow body that contains an interior ball, with the particularity of said ball being suspended in a pendulum-like manner from a cord that is connected to the inner surface of the hollow body. When the user moves, the interior ball oscillates and hits against the interior surface of the hollow body. Unlike the previous device, this one presents the particularity of having to be placed in a certain position inside the vagina (as the pendulum is operating under gravity) in order to function properly.

[0008] The fact that an inertial device must be placed in a certain position inside the vagina in order to properly function is inconvenient for several reasons. Firstly, the introduction and positioning of the device requires a lot of attention and precision, thus complicating the whole process; in fact, even if it is inserted and placed with great care and precision, the user does not always manage to place the device in a correct and exact position that guarantees its best possible function. Secondly, it must be taken into account that the position in which the device must be placed can vary according to the morphology of the tissue surrounding it. Thus, on the one hand, the case may occur that the morphology of a same user may vary for whatever reason, for example because of the success of the treatment; due to this variation, a device of the type that must be placed in a certain position may not always be correctly placed and could therefore decrease in effectiveness. On another hand, the fact that different users have different morphologies results in the unwanted effect that a device of the type that must be placed in a certain position is more efficient for some users than others.

[0009] A specific passive inertial device, also comprising a hollow body and a freely moving interior ball, is known and usually referred to as an inertial "energy-accumulating" device. The interior ball of this type of device must accumulate a certain amount of energy in order to move; as a consequence, the impact of the interior ball against the inner surface of the hollow body is generated with a certain amount of energy, above a certain threshold, thus increasing and improving the stimulation of the tissue adjacent to the device.

[0010] An example of a passive inertial device with energy accumulation is one in which the inner surface of the hollow body features protruding ribs running parallel to each other along a meridian. Said ribs serve as an obstacle to the interior ball, in a way that the ball has to accumulate a certain amount of energy for passing over one rib to another or for passing to the other side of the ribs and continue moving. This device presents the same

drawback as the device disclosed in ES2226590B1, i.e., it can only function when positioned correctly inside the vagina. If the device is not correctly positioned, it may happen among other things that the device stops acting as an energy accumulating device or even that the ball is not able to move.

[0011] The objective of the present invention is to offer an inertial device of mechanical vibratory stimulation of the pelvic floor, which is passive and energy-accumulating and features alternative energy-accumulating means to the already known ones. Also, the device should be easy to manufacture and work effectively.

[0012] In addition, the device according to the invention is aiming to guarantee, at least in its preferable embodiments, an optimum accumulation of energy and stimulation irrespective of the position or orientation of the device inside the vagina, thereby simplifying its placement in the vagina as it may be introduced in any kind of position. It will therefore also ensure that the efficiency of the device is not affected by possible changes in the morphological conditions of the user and that the device is equally effective for different users.

Brief description of the invention

[0013] The object of this invention is an inertial energy-accumulating device for the stimulation of the pelvic floor muscles that is designed to be introduced into the vagina of the user, which like other inertial devices comprises at least one hollow body, wherein at least one hollow body contains at least one freely moving interior ball that is able to move due to the force of gravity and the inertia of the user's movements and to impact against an inner surface of said hollow body. Additionally, the inertial device according to the invention features the particularity of the inner surface of the hollow body being provided with facets, wherein the facets form a certain angle with adjacent facets in a way that the interior ball that is resting on a facet must accumulate a certain amount of energy in order to move and hit an adjacent facet.

[0014] The advantage of using facets in order to partly prevent the moving of the interior ball(s) is that the hollow body manufacturing procedure is simplified and its cost is reduced, when compared to conventional energy accumulating devices in which the hollow body is provided with protruding ribs. In addition to that, there is a higher control over the moving energy of the interior ball(s) than in conventional devices, as it is possible to adjust the angle formed by the facets more precisely than it is to adjust the height and width of the internal ribs.

[0015] In one preferred embodiment of the invention the inner surface of the housing is completely faceted and the inner surface of the housing has a substantially spherical symmetry. This allows for a main body - and therefore an inertial device - that is equally effective no matter how it is positioned inside the vagina and the user's morphology. The ball(s), irrespective of the placement of the device or the user's morphology, will always

rest in the lowest position and be ready to accumulate and release the energy due to the inertia of the user's movements during the treatment, thus guaranteeing an optimum treatment in all practical cases.

[0016] In addition to that, the device ensures that the energy carried by the ball when switching from one facet to another exceeds a minimum threshold due to the shape of the facets' edges and the angle formed by the facets; then, the interior ball or balls remain in the facets until the angle of the vector sum of the weight and the inertia of the movement surpasses the angle of the facets, at which point the interior ball or balls begin to move in a controlled manner towards adjacent facets. This guarantees that the impact (involuntary and automatic response generated in the pelvic floor muscles as a consequence of the energy of the interior ball(s)) is also above a minimum threshold, in a way that the device provides a better, more stable and efficient stimulation of the nerve receptors of the tissue that is in contact with the device.

Brief description of the drawings

[0017] Details of the invention are depicted in the accompanying figures, which are intended to be illustrative and non-limiting:

- Figure 1 shows a perspective view of one embodiment of the device according to the invention.
- Figure 2 shows a perspective cross-section view of the device of the previous figure.

Detailed description of the invention

[0018]

Figure 1 shows one embodiment of the inertial device (1) for the stimulation of the pelvic floor with accumulation of energy according to the present invention. The represented embodiment is **characterised in that** it comprises a single hollow body (2), made of injected technical plastic for example, and an extraction means, which in this case takes the form of a closed-loop cord (7) made of an elastomer or injected silicone. The extraction means projects from the hollow body (2) and its end that is opposite to the hollow body (2) is designed to remain accessible outside the vagina when the device (1) is inserted in the vagina so that the user may extract the device (1) by simply pulling the cord (7).

Figure 2 shows a perspective cross-section view of the device (1) depicted in Figure 1. As can be seen, the hollow body (1) contains a freely moving interior ball (3) that is able to move due to the force of gravity and the inertia of the user's movements and to hit against an inner surface (4) of the hollow body (2). The inner surface (4) of the hollow body (2) compris-

es facets (5, 6), i.e., it is faceted at least partially. The facets (5, 6) form a specific angle with the adjacent facets (5, 6) in a way that the interior ball (3) that is resting on a facet (5, 6) has to accumulate a determined amount of energy in order to move and hit an adjacent facet (5, 6). In other words, the movement is not initiated until it is substantial enough, thus ensuring that the stimuli or impact is above a certain threshold.

[0019] The shape, geometry and edges of each facet (5, 6) can be configured so as to select the amount of energy to be accumulated before the interior ball (3) is able to move and until the forces resulting from gravity and inertia form a certain angle, which when exceeded, results in the interior ball (3) being allowed to move with the accumulated energy. It has been proven that the particular design of the edges of the facets (5, 6) has a significant influence on how the facets receive the impact of the interior ball (3) that has moved from the adjacent facets (5, 6).

[0020] Preferably, the inner surface (4) of the hollow body (2) is completely faceted. Thus, the accumulation of energy of the interior ball (3) may be produced in all areas of the inner surface (4); i.e., there are no areas in the inner surface (4) that allow for a free moving of the interior ball (3) without the accumulation of energy. It is preferable that the inner surface (4) have the form of an icosahedron or dodecahedron.

[0021] Preferably, the inner surface (4) of the hollow body (2) has a substantially spherical symmetry. This means that the behaviour of the interior ball (3) inside the hollow body (2) is independent of how the hollow body (2) is orientated inside the vagina. This guarantees optimum treatment for all users, and even for a single user experiencing morphological changes during her treatment.

[0022] It is preferable, as shown in Figure 2, that the faceted inner surface (4) comprises substantially pentagonal facets (5) and substantially hexagonal facets (6). The combination of these two types of facets is the most efficient for manufacturing the inner surface (4), especially if it is to be completely faceted and has a spherical symmetry.

[0023] If the previous technical characteristics are combined, that is to say, if the fact that the inner surface (4) is completely faceted and has a substantially spherical symmetry is combined with the fact that the inner faceted surface (4) comprises substantially pentagonal facets (5) and substantially hexagonal facets (6), then the inner surface (4) takes substantially the form of a truncated icosahedron. This embodiment is considered to simultaneously offer all the advantages: equal efficiency irrespective of the device's (1) orientation, cost-effective manufacturing, no areas without accumulation of energy, etc.

[0024] In the represented embodiment, all facets (5, 6) are substantially flat. This ensures that the equilibrium

point, where the interior ball(s) (3) will be resting, is at the edges of the facets (5, 6). If, on the contrary, the facets (5, 6) would present any type of concave curvature in their interior, the interior ball or balls (3) might rest within the facets (5, 6) resulting in a reduced accumulation of energy.

[0025] In one embodiment all the facets are not equal in size and geometry. The difference in size allows for the creation of certain particular effects. For example, if the difference in size between the facets is sufficient enough, some facets may act as receptors while others may become supports. The receptor facets are in charge of receiving the balls when only the force of gravity is acting (they would be smaller facets, solely responsible for detaining the interior ball but without providing resting support). The bigger sized supporting facets, on the other hand, serve to receive the energy of the interior ball after it has moved, and are therefore in charge of stimulating the exterior tissue.

[0026] Preferably, the interior ball (3) has a hard outer surface so that it does not absorb the impact of the interior ball (3) against the inner surface (4) of the hollow body (2). This way, the energy of the impact is kept to a maximum, which ultimately is the aim in order to produce a maximum stimulation of the surrounding tissue. However, it is also contemplated that the interior ball (3) be coated with a softer material, like rubber for example, if it were convenient to mitigate the noise produced when the interior ball (3) hits against the inner surface (4) of the hollow body (2).

[0027] The invention provides for various embodiments that are different to the one represented.

[0028] For example, the device (1) may comprise more than one hollow body (2), in which case the hollow bodies (2) would be interconnected by a connecting means, like a cord for example.

[0029] The form of the hollow body (2) may not only be spherical, as represented in the drawings, but it may also take any applicable form, such as an eccentric form that facilitates its introduction into and later extraction from the vagina. In any case, the exterior form of the hollow body (2) is not relevant for the present invention.

[0030] The hollow body (2) or hollow bodies (2) may contain more than one interior ball (3). If the device comprises several hollow bodies (2), each hollow body (2) may contain an equal or different number of interior balls (3). There is even the possibility that the invention is applied to only one or some of the hollow bodies (2) of the device (1).

[0031] In addition, the extraction means projecting from the hollow body (2) may be more than one cord (7), with or without closed loops, or even a different type of element that extends to the vagina's exterior and allows the user to pull it in order to extract the device (1).

[0032] In the represented embodiment, all the facets (5, 6) are flat. Alternatively, only one or more facets (5, 6), but not all, may be flat. If one or more facets (5, 6) are non-flat, the invention allows for one or more facets (5,

6) to be substantially curved (with concavities and/or convexities). With these or other variants the initiation of the movement of the interior ball(s) (3) and the reception of said ball(s) by the adjacent facets (5, 6) can be configured at will.

[0033] It is also possible, in combination with the previous or independently, that at least one facet (5, 6) presents an internal irregularity that serves as an additional obstacle to the interior ball(s).

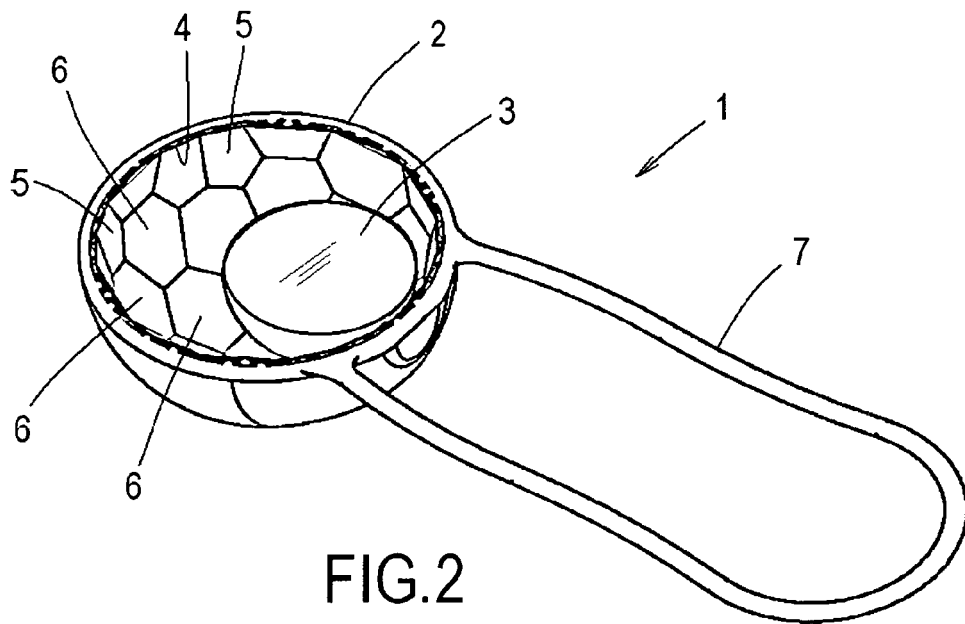
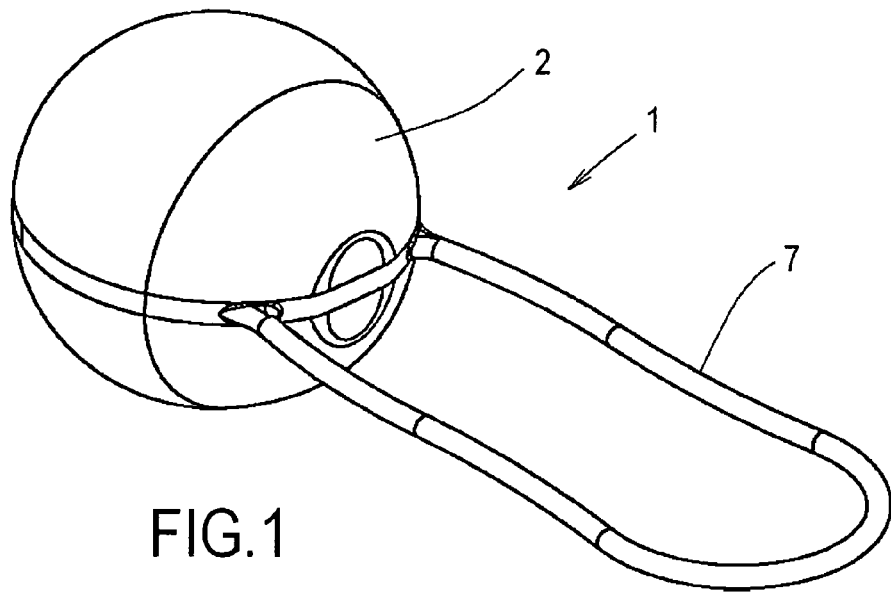
[0034] The invention also allows for the possibility that in between of at least two facets (5, 6) there is a ledge or protrusion. This would increase the threshold value of the energy that the interior ball (3) must accumulate at that point in order to pass to the adjacent facet (5, 6), thus increasing the impact on the pelvic floor muscles.

Claims

1. Inertial device (1) with accumulation of energy for the stimulation of the pelvic floor muscles, designed to be inserted into the vagina of the user, comprising at least one hollow body (2), wherein at least one hollow body (2) contains at least one freely moving interior ball (3) that is able to move due to the force of gravity and the inertia of the user's movements and to hit against an inner surface (4) of the hollow body (2), where the device (1) is **characterised in that**:
 - the inner surface (4) of the hollow body (2) is provided with facets (5, 6), where
 - the facets (5, 6) form a specific angle with the adjacent facets (5, 6) in a way that the interior ball (3) that is resting on a facet (5, 6) has to accumulate a determined amount of energy for moving and hitting an adjacent facet (5, 6).
2. Device (1), according to claim 1, **characterised in that** the inner surface (4) of the hollow body (2) is completely faceted.
3. Device (1), according to claim **Error! No se encuentra el origen de la referencia.**, **characterised in that** the inner surface (4) takes substantially the form of an icosahedron.
4. Device (1), according to claim **Error! No se encuentra el origen de la referencia.**, **characterised in that** the inner surface (4) takes substantially the form of a dodecahedron.
5. Device (1), according to claim 1. **characterised in that** the inner surface (4) of the hollow body (2) presents a substantially spherical symmetry.
6. Device (1), according to claim 1, **characterised in that** the inner faceted surface (4) comprises sub-

stantially pentagonal facets (5) and substantially hexagonal facets (6).

7. Device (1), according to claim 1, **characterised in that** at least one facet (5, 6) is substantially flat.
8. Device (1), according to claim **Error! No se encuentra el origen de la referencia.**, **characterised in that** all the facets (5, 6) are substantially flat.
9. Device (1), according to claim 1, **characterised in that** at least one facet (5, 6) is substantially non-flat.
10. Device (1), according to claim **Error! No se encuentra el origen de la referencia.**, **characterised in that** at least one facet (5, 6) is substantially curved.
11. Device (1), according to claim 1, **characterised in that** at least one facet (5, 6) presents an internal irregularity that serves as an additional obstacle to the interior ball(s).
12. Device (1), according to claim 1, **characterised in that** there is a ledge or protrusion in between of at least two facets (5, 6).





EUROPEAN SEARCH REPORT

Application Number
EP 12 38 0027

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	DE 20 2009 010633 U1 (WEFO TEC DEUTSCHLAND GMBH [DE]) 23 December 2010 (2010-12-23) * the whole document *	1-12	INV. A61H21/00
A	DE 201 13 738 U1 (FUNFACTORY GMBH [DE]) 10 January 2002 (2002-01-10) * figures *	1	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61H
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
The Hague		24 October 2012	Knoflacher, Nikolaus
CATEGORY OF CITED DOCUMENTS		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			

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EPO FORM 1503 03.82 (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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24-10-2012

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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