PATENT COURT
THE FIRST DEPARTMENT
DECISION

Case No. 2008Heo8150 Invalidation of Registration (Patent)

Plaintiff (Released): Medtronic Spine LLC
Counsel/attorneys-at-law: Sanggeun KIM, Kwanseok OH, Minseo HWANG
Counsel/patent attorneys: Younghwan YANG, Yoonkee KIM, Jooho LEE

Plaintiff's Successor: Kyphon SARL
Counsel/attorneys-at-law: Sang Geun KIM, Kwanseok OH, Minseo HWANG
Counsel/patent attorneys: Younghwan YANG, Yoonkee KIM, Jooho LEE

Defendant: Yong-chol Ahn
Counsel/attorney-at-law: Dongse KANG
Counsel: Myungmoon Patent Law firm
Patent attorney in charge: Gunwoo PARK

Closure of Hearing: February 24, 2010

Date of Decision: March 19, 2010

Order

1. Plaintiff's Successor's claims are dismissed
2. The trial costs shall be borne by the Plaintiff's Successor

Tenor of Claim

The Korea Intellectual Property Tribunal's decision dated May 27, 2008 in Case No. 2007Dang3289 is hereby reversed.

Reasoning

1. Basic Facts

[Grounds for Recognizing Facts] Undisputed Facts, Plaintiff's Exhibits 1 through 5, Defendant's Exhibit 1, and the entire content of the hearings and the results obtained by evidence being taken.

A. Subject Patent

1) Title of Invention: Improved inflatable device for use in surgical protocol relating to fixation of bone

2) Filing Date (PCT Filing Date)/Priority Date: July 25, 1996 (Jan. 24, 1995)/Jan. 26, 1994

3) Registration Date/Registration No.: Sept. 23, 2002/No. 0355207

4) Patentee: Plaintiff's Successor
(After this lawsuit was initiated, all rights to the Subject Patent were transferred to the Plaintiff's Successor on May 7, 2009, and the Plaintiff's Successor joined this lawsuit on July 23, 2009. The original Plaintiff was released from this lawsuit on the same day with the consent from the Defendant.)

5) Scope of Patent Claims
Claim 1. A device for insertion in to a bone, that can apply pressure to the cancellous bone and move the fractured cortical bone (Element

1), comprising a catheter, and a distal end having a predetermined shape and size for insertion into a bone through a cannula, wherein said catheter supports near said distal end an inflatable body which has a wall and in its deflated state has a size and shape that can be inserted into a bone through the passage inside the cannula ("Element 2"), and, further, said wall has a size and shape configured to apply strength in response to the enlargement of the inflatable body inside the bone, and structured to change the thickness of the inflatable body so that it can restrain the enlargement inside the cancellous bone. ("Element 3") ("claim 1 of the Subject Patent")

Claims 2 through 24 (descriptions omitted)

6) Figures: Main figures are shown in Annex 1.

B. Prior Arts

1) Prior Art 1 (Prior Art 1 in the KIPT Decision)

Prior Art 1 relates to "a surgical procedure for fixation of bone using an inflatable device" described in US Patent No. 5,108,404 published on April 28, 1992, the main details and figures of which are provided in Annex 2, Technical Details and Main Figures of Prior Art 1.

2) Prior Art 2 (Prior Art 4 in the KIPT Decision)

Prior Art 2 relates to a "surgical device" described in US Patent No. 4,082,369 published on April 11, 1978, the main details and figures of which are provided in Annex 3, Technical Details and Main Figures of Prior Art 2.

3) Prior Art 3

Prior Art 3 relates to "low profile balloon catheter and method for making the same," described in US Patent No. 5,254,091 (Defendant's Exhibit 1) published on October 19, 1993, the main details and figures of which are provided in Annex 4, Technical Details and Main Figures

of Prior Art 3.

C. Procedural Background

1) The Defendant filed an invalidation trial with the Korea Intellectual Property Tribunal (the "KIPT") against the Plaintiff on November 27, 2007, on the grounds that the invention according to claim 1 of the Subject Patent could have been easily derived by a person having ordinary skill in the art ("PHOSITA") from Prior Art 1, 2 and 3, which were publicly disclosed before the filing date of the Subject Patent, and therefore lacked inventiveness.

2) The KIPT reviewed this invalidation trial Case No. 2007Dang3289, and rendered its decision on May 27, 2008, accepting the Defendant's claim on the ground that the Subject Patent lacked inventiveness over Prior Art 1 and 2.

2. Issues

The parties are in dispute over the issue of whether PHOSITA could have easily invented the invention according to claim 1 of the Subject Patent based on Prior Art 1, 2 and 3. Accordingly, the issue is whether the Subject Patent lacks inventiveness over Prior Art 1, 2 and 3. (The Defendant also argued that claim 1 of the Subject Patent failed to meet the description requirement, but withdrew the same on the date of the first hearing.)

3. Inventive Step of claim 1 of the Subject Patent

A. Technical Field and Objective

1) Technical Field

The invention according to claim 1 of the Subject Patent relates to

a device for stabilizing and treating broken bones, having an inflatable body (balloon) that can be inserted into the broken bone and form or expand a cavity (Plaintiff's Exhibit 3, Page 2). Prior Art 1 relates to an inflatable device that is inserted into the bone to form or expand the cavity, to stabilize and treat broken bones (Plaintiff's Exhibit 4, "Abstract"). Prior Art 2 relates to a surgical device having an inflatable balloon-like element used in the field of gynecology, such as hysterectomy (Plaintiff's Exhibit 5, "Abstract" and column 1). The invention according to claim 1 of the Subject Patent and Prior Art 1, 2 and 3 all belong to the same technical field, as they all relate to surgical devices having an inflatable structure (balloon) that are inserted into the human body and expand certain parts.

In this regard, the Plaintiff's Successor asserted that: the Subject Patent relates to the field of kyphoplasty; spinal orthopedics, gynecology and cardiology are each categorized as a separate specialized medical field; accordingly, PHOSITA should be limited to "spinal orthopedic surgeons" with ample clinical experience; as the inventors of the Subject Patent were the only ones in the field of kyphoplasty at the time of the filing date of the Subject Patent, balloon catheter devices for kyphoplastic use were not well known even in the field of orthopedics; further, there was not much communication between different medical fields, i.e., among the departments of spinal orthopedics, gynecology and cardiology; accordingly, inventions relating to devices used in specialized medical fields other than spinal orthopedics, such as Prior Art 2 and 3, should not be used as Prior Art in determining the inventive step of claim 1 of the Subject Patent.

We note that the "relevant technical field" in Article 29, Paragraph 2, of the Patent Law refers an industrial area in which the claimed invention is used and should be objectively determined by comprehensively considering the purpose, technical constitution and operational effects of the invention. (Supreme Court Decision dated April 25, 2003, No. 2002Hu987, etc.), and "a person having ordinary skill in the art" refers to a hypothetical natural person who would have been able to obtain

and understand all information at the technical level in the relevant technical field and freely exercise any ordinary means and abilities necessary for research and development, available at home and abroad at the time of the filing.

In this case, (i) the "abstract" section in the specification of the Subject Patent states that the main purpose of the balloon in the Subject Patent is the forming or enlarging of a passage or a cavity inside a bone, especially in, but not limited to, the vertebral bodies. The "examples" section describes "balloons for long bones including distal radius, proximal tibial plateau, proximal humerus and proximal femoral head," etc., in addition to the "balloon for vertebral bodies." (ii) One of the inventors for the Subject Patent, Karen Talmadge, is a "biochemist," not a "spinal orthopedic surgeon." (iii) The "technical background" section in the specification of the Subject Patent as prior art numerous angioplasty catheters. (iv) Claim 1 of the Subject Patent and Prior Arts 1, 2 and 3 may relate to different specific conditions to be treated but all commonly relate to a surgical device having an inflatable structure (balloon) that is inserted into the human body to enlarge certain parts. Descriptions in Plaintiff's Exhibit 3, some descriptions in Plaintiff's Exhibits 12 and 20 support the foregoing. In light of the above, it would be reasonable to conclude that the inventors for the Subject Patent, instead of limiting themselves to the field of orthopedics, invented the invention of the Subject Patent which can be used to form or enlarge a passage or a cavity inside a bone such as the vertebral bodies, distal radius, proximal tibial plateau, proximal humerus and proximal femoral head, etc., after research and development based on prior art encompassing a variety of surgical devices having an inflatable device (balloon) that were inserted into the human body and enlarged certain parts thereof. As such, it does not seem reasonable to limit the scope of the person having ordinary art to "spinal orthopedic surgeons" or to exclude inventions of medical devices in other specialized medical fields, such as Prior Art 2 and 3, as inappropriate to be used as Prior Art in determining the inventive

step of the invention according to claim 1 of the Subject Patent, which relates to a medical device in the field of spinal orthopedics. Descriptions in Plaintiff's Exhibits 7 through 11, 13 through 19 (including sub-numbered exhibits), some of the descriptions in Plaintiff's Exhibits 12 and 20, witness statement by Hak Sun KIM and the results of this court's inquiries with the Korean Orthopaedic Association, the Ministry of Food and Drug Safety, and the Health Insurance Review & Assessment Service fall short of negating the conclusion above, without anything else that suggests otherwise.

2) Purpose

Claim 1 of the Subject Patent and Prior Art 1 have the identical purpose, i.e., providing a device having an inflatable structure (balloon) which is inserted into a fractured bone and forms or enlarges a cavity to treat the fractured bone.

Nextly, while the purpose of claim 1 of the Subject Patent and that of Prior Art 2 and 3 are common in that they aim to provide a device having an inflatable structure (balloon) which is inserted into a human body and enlarges a certain part of the human body, the invention of claim 1 of the Subject Patent is used to restore a fractured bone, Prior Art 2 is used for surgical instruments in the field of gynecology to perform hysterectomy, etc., and Prior Art 3 is used for enlarging body conduits such as blood vessels and urethra, so the specific purposes of the inventions vary.

B. Comparison of the Constitution and Effects

1) Comparison of Element 1

Element 1 of claim 1 of the Subject Patent refers to "a device for insertion in to a bone, applying pressure to the cancellous bone and moving the fractured cortical bone." This element corresponds to "an inflatable device that is used to enlarge a cavity inside a fractured bone by inserting it into a fractured bone and inflating it to cause the

cancellous bone or the bone marrow to compress the inside (cortical bone) of the outer wall of the bone" in Prior Art 1 (Plaintiff's Exhibit 4, the "Abstract" section, Fig. 28).

The two elements are identical in terms of the constitution and the effect in that both are related to devices inserted into a fractured bone, which then compress the cancellous bone or the bone marrow, thereby moving the corticoid bone to restore the fractured bone to the original form or location and form a cavity inside the cancellous bone.

2) Comparison of Element 2

Element 2 of claim 1 of the Subject Patent is "comprising: a catheter, a distal end having a predetermined shape and size for insertion into a bone through a cannula, said catheter supports near said distal end an inflatable body which has a wall and in its deflated state has a size and shape that can be inserted into a bone through the passage inside the cannula" and corresponds to the "inflatable device inserted into a bone through a passage in the cannula (30) wherein a neck (77) is formed and supports a checker-shaped balloon (76) at the distal end of the neck (77)" in Prior Art 1. (Plaintiff's Exhibit 4, Figs. 21 to 24)

The two elements are identical in terms of the constitution and the effect in that both comprise a catheter [neck (77)] support an inflatable body [balloon (76)] that is inserted into a bone in its deflated state near the distal end of the catheter [neck (77)].

3) Comparison of Element 3

a) Interpreting Element 3

Element 3 of the Subject Patent refers to "said wall has a size and shape configured to apply strength in response to the enlargement of the inflatable body inside the bone, and structured to change the thickness of the inflatable body so that it can restrain the enlargement inside the cancellous bone." In this Element 3, however, descriptions such as "size and shape configured to apply strength in response to

the enlargement of the inflatable body inside the bone," "restrain the enlargement inside the cancellous bone" or "structured to change the thickness of the inflatable body" are abstract. It is thus difficult to specify the structure of the inflatable body based solely on the descriptions in the claims, and it is necessary to refer to the detailed description of the invention, etc., to confirm the technical details.

As for the descriptions "size and shape configured to apply strength in response to the enlargement of the inflatable body inside the bone" and "restrain the enlargement inside the cancellous bone," the detailed description of the invention section states that "in particular, the present invention is directed to a balloon for use in treating a bone that is fractured or predisposed to fracture. The balloon comprises a body that is inflatable so that it can be inserted into a bone yet non-expandable. The balloon has a predetermined shape and size so that it can be sufficiently inflated to compress the inner cancellous bone and create a cavity inside the cancellous bone and to restore the original position of the outer cortical bone. The balloon body is restrained to create said predetermined shape and size, and as a result, the fully inflated balloon body would not apply substantial pressure to the inner surface of the outer cortical bone if said bone is unfractured or uncollapsed. ··· These balloons approximate the inner shape of the bone they are inside of in order to maximally compress the cancellous bone. Preferably, they have additional design elements to achieve specific clinical goals. Preferably, they are made of inelastic materials and kept in their defined configurations by various restraining elements when inflated." (Plaintiff's Exhibit 3, Pages 4 and 5) In light of the entire description in the specification, it is reasonable to conclude that the descriptions "size and shape configured to apply strength in response to the enlargement of the inflatable body inside the bone" and "restrain the enlargement inside the cancellous bone" in Element 3 mean "an inflatable body (balloon) that, when inflated, has a size sufficient to form a cavity inside the cancellous bone while the outer cortical bone is being restored, and a shape approximating the inner

shape of the bone they are inside of, but when fully inflated, it is non-expandable so that it can keep the defined configuration (restrain enlargement) without applying substantial pressure to the inner surface of the outer cortical bone."

As for "structured to change the thickness of the inflatable body," we refer to the detailed description of the invention which states "in addition to the shape of the inflatable device itself, another aspect of importance is the construction of the wall or walls of the balloon such that proper inflation of the balloon body is achieved to provide for optimum compression of all the bone marrow" (Plaintiff's Exhibit 3, Page 4), "the fully inflated size and shape of the balloon is restrained by additional materials placed on the separate pieces of the balloon body, and the added thickness works as the restraining element. Further, the maximally inflated size and the shape of the walls of the balloon are restricted by restraints formed on the interior or the exterior of the device, such as meshwork, rolled on the substances melted and attached to the balloon body parts, continuous or discontinuous strings extending across the inside and glued at one place, connected to the exterior and sealing two balloon bodies, attaching two surfaces of the body using glue or heat. The spherical surface of the balloon body can be restricted by the use of inelastic materials in assembling the balloon body or by additional restraints described above." (Plaintiff's Exhibit 3, Page 5) In light of the entire description in the specification, it is reasonable to construe "structured to change the thickness of the inflatable body" as "a structure with varying thickness in different parts of the inflatable body (balloon)."

In sum, in light of the overall descriptions in the specification, Element 3 of claim 1 of the Subject Patent can be specified as "a structure with varying thickness in different parts of the balloon so that the walls of the inflatable body (balloon) can maintain a predetermined size and shape without further enlarging, when it is fully inflated inside a bone."

b) Specifying the corresponding element

① Corresponding element of Prior Art 1

Prior Art 1 states in the specification that "the intention of the present invention [is] to provide in each case of a fracture of osteoporotic or non-osteoporotic bone, an inflatable device that has a shape of or the ability to conform to the internal surface configuration of the cortical bone in which the device is used. For example, the inner surface configuration of the cortical bone of a vertebral body is disk-shaped or checker-shaped, the cortical bone of distal radius is gourd-shaped and the cortical bone of the proximal humerus is also gourd-shaped." (Plaintiff's Exhibit 4, column 2) "The outer configuration of the balloon (76) is substantially the same as that of the inner surface of the cortical wall of the vertebral body (66). The progress of balloon inflation is monitored fluoroscopically to ensure proper insertion of the balloon (76). In the case of an elliptical balloon, the balloon is injected gradually to maximum height. It is necessary to apply a pressure of about 300 psi to complete this task. The balloon's inflation should be monitored on the lateral fluoroscopic view of the spine. Posterior displacement of the bone into the spinal canal or full expansion of the balloon (76) signals the termination of the chamber preparation. Further, expansion at this point could result in spinal cord or root injury." (Plaintiff's Exhibit 4, column 7) "The balloon (95) has a configuration substantially the same as that of the inner surface of the cortical bone." (Plaintiff's Exhibit 4, column 8) In light of these descriptions, it is reasonable to construe the balloon in Prior Art 1 as "one having a configuration that is substantially the same as or is able to conform to the internal surface of the cortical bone, so that once fully inflated, it will have a determined shape and size that does not further expand" and this element corresponds to Element 3 of claim 1 of the Subject Patent.

In this regard, the Plaintiff's Successor argues that Prior Art 1 only discloses that the balloon's initial exterior configuration before inflation is made to be identical to the interior surface of the cortical

bone of the vertebral body (66), which does not mean that the balloon inflates to conform to the internal configuration of the cortical bone when it is inserted into a bone and inflated, and therefore, Prior Art 1 does not disclose Element 3 of claim 1 of the Subject Patent.

It seems that the specification of Prior Art 1 only states that "the exterior of the balloon has the same configuration as, or is able to conform to, the configuration of the interior surface of the vertebral bodies" and it is not expressly stated whether the exterior of the balloon refers to the exterior configuration of the balloon before or after inflation. There is no dispute between the parties on this point.

Other than the above-mentioned descriptions, however, Prior Art 1 also discloses that "the sagittal and coronal CAT-scan should be obtained before the performance of the method of the present invention. The coronal scan is also needed to determine the width of the vertebral body which is to be treated and ··· is needed to determine the height of the vertebral body to be treated." (Plaintiff's Exhibit 4, column 5) "The diameter of the balloon (76) is determined by the preoperative CAT-scan results. The diameter is in the range of 1.0 cm to 3.5 cm. The axial height (Fig. 23) of the balloon is determined by the intra-operative reduction height of the vertebral body fracture. The height is in the range of 0.5 cm to 4.0 cm. If the balloon placement is somewhat eccentric, a smaller balloon may be needed. The balloon (76) has a neck (77), and the outer configuration of the balloon (76) is substantially the same as that of the inner surface of the cortical wall of the vertebral body (66)." (Plaintiff's Exhibit 4, column 7) "Fig. 28A is a schematic side view of a vertebral body showing the initial insertion of an elliptical inflatable device in the vertebral body and before inflation of the device, Fig. 28B is a view similar to Fig. 28A but showing partial inflation of the inflatable device of Fig. 28A to initiate a cavity or passage in the bone marrow of the vertebral body, Fig. 28C is a view similar to Fig. 28B but showing a checker-shaped inflatable device in the vertebral body, Fig. 28D is a view similar to Fig. 28C but showing the initial injection stage in which liquid bone

or methyl methacrylate cement is injected into the vertebral body, [and] Fig. 28E is a view similar to Fig. 28D but showing the vertebral body after the liquid bone or methyl methacrylate cement has set to a hardened condition." (Plaintiff's Exhibit 4, column 3) "The purpose of the elliptical balloon (65) is to center a second, checker-shaped inflatable device or balloon (76) (Figs. 21-23) in the interior of vertebral body (66). After the elliptical balloon (65) is deflated and removed, checker-shaped or cylindrically shaped device or balloon (76) is inserted into the cannula and directed into the interior of the vertebral body (66) as shown in Fig. 21." (Plaintiff's Exhibit 4, column 6) It can be seen from these descriptions that in Prior Art 1 "the diameter and the axial height are determined by the width and the height of the vertebral body being treated, and the balloon which compresses the cancellous bone or the bone marrow to the internal surface of the cortical bone is a checker-shaped balloon having the same width and height." If the exterior configuration after inflation is not the same as the interior surface configuration of the cortical bone of the vertebral body, there is no reason to form the same initial pre-inflation exterior configuration that is the same as the interior surface configuration of the cortical bone. Accordingly, it is reasonable to conclude that the exterior configuration of the inflated balloon (76) in Prior Art 1 is substantially identical to the internal surface configuration of the vertebral bodies.

Therefore, as discussed above, the balloon (76) in Prior Art 1 "has a configuration that is the same as, or is able to conform to, the interior surface configuration of the cortical bone, and thus has a determined size and configuration that does not further expand," and corresponds to Element 3 of claim 1 of Prior Art 1. So the Plaintiff's Successor's argument explained above is inconsistent with this finding and cannot be accepted.

② Corresponding elements in Prior Art 2 and 3

The specification of Prior Art 2 further states that "the present invention contemplates an improved device ··· a balloon-like inflatable element in which the configuration of the balloon has been modified

to enable the same be used as a pneumatic packing and drainage device following a hysterectomy procedure. The improved device comprises an axially disposed rigid tube element and a balloon-like inflatable element ··· half of the inflatable element expands at a greater rate than the other, and is positioned to face the spine and pelvis of the patient, whereby the tube may be axially aligned with the vagina when the tube is positioned inside the cavity. ··· another embodiment of the improved trocar shield is provided with an inflatable element which assumes the contour of a torus whereby distending the cavity allowing adequate space in the distal side of the tubular member to perform surgical procedures. (said torus contour) can be accomplished by making the inflatable element in such manner that it includes three coaxially aligned portions, the outer two of which are relatively thicker in cross section than the centrally disposed portion." (Plaintiff's Exhibit 5, column 1) "According to the first embodiment of the invention, the device (10) comprises tubular element (11) and an inflatable element (12). ··· the inflatable element (12) has walls of different thicknesses with a relatively thin area (35) and relatively thick area (36). (Plaintiff's Exhibit 5, columns 1 to 2, Figs. 1 and 2) "In the second embodiment, ··· element (46) includes first, second and third bands (47)(48)(49) respectively, of annular configuration, the planes of which are disposed substantially perpendicular to that of the shield element (41). The first and third bands (47)(49), respectively, are formed of material which is substantially thicker than that of the second band (49) disposed therebetween. Thus, with inflation, the expanded element, because of the differential thickness of the bands (47)(48)(49) assumes a quasi-toroidal (doughnut) shape at equilibrium. ··· this quasi-toroidal shape causes the surgical cavity to be to be expanded for completion of a surgical procedure, and pushes the cavity in such manner that adequate space not occupied by the expandable element is available at the distal end of the tube, this configuration adding significant space availability as contrasted with the expandable element of uniform thickness ··· " (Plaintiff's Exhibit 5, columns 2 and 3, Fig. 3) The specification of

Prior Art 3 states that "balloon catheters are used to dilate or occlude various body conduits, cavities and openings such as blood vessels and the urethra. This is normally accomplished with a catheter formed from an elongate cannula and an inflatable balloon disposed circumferentially of the cannula near the distal end of the catheter. In accordance with a typical procedure, the catheter is provided with the balloon in a deflated or otherwise low profile state. With this configuration, the catheter is introduced into the body conduit and positioned with the balloon in the low profile state the point of desired dilation. At this point, the balloon in inflated or otherwise expanded to a high profile state thereby radially stretching the walls of the conduit. ··· These dilatation catheters are typically characterized by nondistensible balloons which are formed from materials such as polyethylene that are relatively inflexible and therefore do not expand significantly beyond a predetermined dimension. This characteristic of nondistensibility is of particular advantage in order to insure that the vessel or conduit is not injured by overextension. Unfortunately, however, the relatively inflexible materials which produce the nondistensible characteristics tend to inhibit the ability of the balloon to be rolled, compressed, deflated or otherwise formed into a low profile state." (Defendant's Exhibit 1, column 1) "In accordance with the present invention, a balloon catheter is provided wherein the balloon can be rolled on the catheter tube to a profile which is substantially constant in diameter along the length of the balloon. Furthermore, there are no sharp points associated with this low profile." (Defendant's Exhibit 1, column 2) "A dilatation catheter (10) is operatively disposed in a body conduit defined by walls (11) and includes an elongate cannula (12) having a distal end (14) and a proximal end. The catheter (10) also includes a balloon (16) having a distal end wall (18) and a proximal end wall (21) disposed in respective end regions (23)(25) of the balloon (16). ··· In accordance with the present invention, the thickness transition region (43) has a shorter axial dimension than does the height transition region (41). This occurs because the thickness of the end wall (21) thins to a dimension generally

equivalent to the thickness of the central wall (27) over a relatively short distance along the transition wall (32). ··· The balloons of the prior art have a thickness transition region (43) which is generally equivalent in axial length to the height transition region (41). In other words, the thickness of the transition wall (32) gradually decreases over the entire axial distance between the end region (25) and the central region (30). While this does not adversely affect the balloon in its inflated, high profile state, it has a dramatic effect on the rolled, low profile state of the balloon as illustrated in Fig. 2. With the relative thickness of the transition wall spaced even a short radial distance from the cannula (12) the balloon (10) in its rolled configuration tends to have an undesirable dog bone shape. ··· By thinning the wall (32) of the transition wall (36) and the wall (34) of the transition wall (38), the walls of the balloon (16) are either thick in proximity to the cannula (12) or thin at any substantial radial distance from the cannula (12). It is in this manner that the balloon of Fig. 1 in the rolled configuration achieves a low profile state as illustrated in Fig. 3." (Defendant's Exhibit 1, columns 4 to 6, Figs. 1, 2, 3 and 6) It can be seen from these descriptions that Prior Art 2 and 3 set the technical objective of providing a balloon that maintains a determined size and configuration when the balloon is inflated or deflated, and as a specific means of achieving the objective, adopted a balloon having walls of varying thickness. This structure corresponds to Element 3 of claim 1 of the Subject Patent.

c) Comparison

When Element 3 of claim 1 of the Subject Patent and the corresponding element of Prior Art 1 are compared, the corresponding element in Prior Art 1 is not substantially different from Element 3 of claim 1 of the Subject Patent having "a size and a configuration for applying pressure in response to the expansion of the walls of the inflatable body inside a bone," and "a structure restraining the expansion inside the cortical bone," in that the balloon has an exterior configuration that is substantially the same as the interior surface configuration of

the cortical bone. The corresponding element of Prior Art 1 does not include any express description of a specific means for maintaining the determined size and configuration of the balloon when fully inflated, i.e., "a balloon having walls of varying thickness."

As explained above, however, Prior Art 2 and 3 disclose the objective of maintaining the determined size and configuration when the balloon is inflated, as well as varying the thickness of the walls of the balloon as a means for achieving the same. In light of the following, it should not have been difficult to combine Prior Art 1 with Prior Art 2 or Prior Art 3. The effect achieved by the combination could also have been easily anticipated by PHOSITA from Prior Art 1, 2 and 3. In conclusion, Element 3 of claim 1 of the Subject Patent could have been easily derived by PHOSITA from Prior Art 1 combined with Prior Art 2 or 3. (Plaintiff's Successor argued that the level of ordinary skill in the art at the time of the priority date of the Subject Patent was very low and PHOSITA could not have easily combined Prior Art 1 and 2 or Prior Art 1 and 3, but such argument cannot be accepted in light of the factors set forth below.)

In other words, Prior Art 1, 2 and 3 all involve the same technical field and objective in that they all relate to balloon catheters that form or enlarge cavities by inserting a balloon into human body and compressing certain portions in an outward direction. Prior Art 1 discloses all of the basic/essential elements of the invention according to claim 1 of the Subject Patent except for the specific means for maintaining a determined size and configuration that does not further enlarge when the balloon is fully inflated. Accordingly, PHOSITA could have derived all of the elements of claim 1 of the Subject Patent by simply applying the element of varying the thickness of the walls in Prior Art 2 or 3 to the balloon described in Prior Art 1, without modifying another essential element of Prior Art 1, applying a new technical idea, etc.

C. Conclusion

Claim 1 of the Subject Patent and Prior Art 1, 2 and 3 involve the same technical field. Further, the objective of claim 1 of the Subject Patent is identical to that of Prior Art 1 and share generally common aspects with those of Prior Art 2 and 3, so the objective of the Subject Patent is not regarded as unique. Further, the constitution of the invention according to claim 1 of the Subject Patent can all be derived from the combination of Prior Art 1 with Prior Art 2 or 3. The combination would not have been difficult for PHOSITA, and the effect achieved by such combination could have been predicted without difficulty by PHOSITA from Prior Art 1, 2 and 3. We do not recognize any difficulty in the constitution or the superiority of the effect of the Subject Patent.

Therefore, the invention according to claim 1 of the Subject Patent could have been easily derived by PHOSITA from the combination Prior Art 1 and Prior Art 2 or 3.

D. Plaintiff's Successor's other arguments

In this regard, the Plaintiff's Successor asserts that the medical/ commercial success of products embodying the Subject Patent demonstrates the superior effect of the Subject Patent and thus the inventive step of claim 1 of the Subject Patent should not be denied.

Factors, such as commercial success, and long-term failure by others before the filing date of the Subject Patent, may be considered in determining inventive step, but such circumstances without more would not establish inventiveness. The inventive step of a patented invention is determined primarily based on the disclosures in the specification, i.e., the objective, constitution and effect of the invention, by determining whether PHOSITA could have easily derived the invention from prior art. (Supreme Court May 29, 2008, Case No. 2006Hu3052) It is difficult to conclude that the medical/commercial success of the products

according to claim 1 of the Subject Patent is a factor sufficient to override the comparison of the Subject Patent with the Prior Art. Further, considering that the Subject Patent contains 24 claims, it is difficult to conclude that the commercial success of the products was solely attributable to claim 1 of the Subject Patent, based only on the evidence submitted by the Plaintiff and the Plaintiff's Successor. No other supporting evidence has been submitted. So the Plaintiff's Successor's argument is rejected.

4. Conclusion

Therefore, the inventive step of claim 1 of the Subject Patent is denied based on Prior Art 1 and 2 or Prior Art 1 and 3, and its registration should thus be invalidated. The KIPT's decision is consistent with this conclusion and is thus proper. The Plaintiff's Successor's request for cancellation of the decision is thus dismissed.

Presiding	Judge	Yongsup KIM
	Judge	Sanggyoon LEE
	Judge	Taeil PARK

[Annex 1]

Main Figures of the Subject Patent

Fig. 1: Perspective view of an embodiment

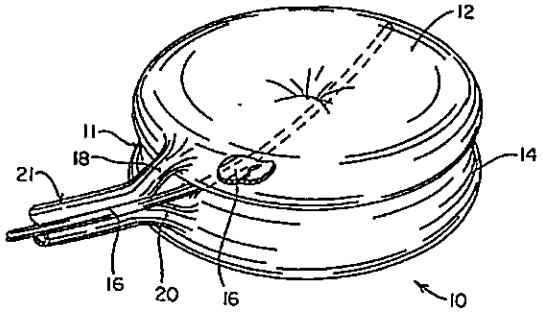


Fig. 3: Schematic view of another embodiment

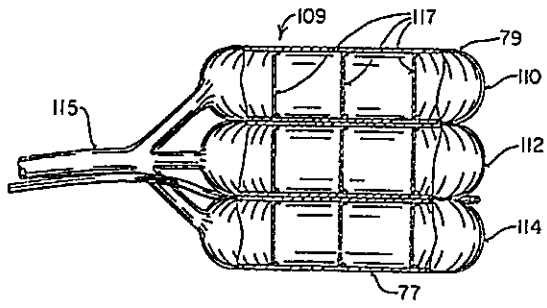
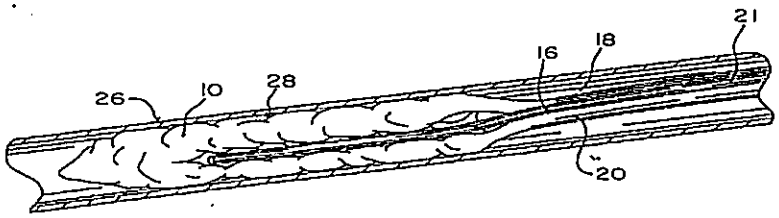


Fig. 8: Vertical section through the balloon being inserted into the vertebral body



[Numeral Indices]

10: balloon,
11: balloon body,
12, 14: balloon units,
16: suction tube,
18, 20: tube,
21: catheter,
26: cannula,
28: passage,
77, 79: inflatable surfaces,
109: inflatable device,
110, 112, 114: balloon units,
115: tube system,
117: restraints. The End.

[Annex 2]

Technical Details and Main Figures of Prior Art 1

1. Technical Details

A surgical method for fixation of bones using an inflatable device, the method comprising the following steps:

penetrating the bone having the fracture with a device having a guide pin and a cannula;

drilling the bone marrow of the bone to be treated to enlarge the cavity or passage;

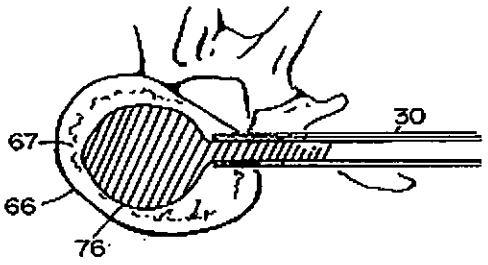
inserting an inflatable device like a balloon into the cavity and inflating it to compact the bone marrow against the inner surface of the outer wall of the bone and further enlarge the cavity;

injecting a flowable synthetic bone material or methyl methacrylate cement into the cavity and allowing it to harden; and removing the device,

Wherein said inflatable device has a configuration that is identical or conforming to the inner surface of the cortical bone (examples: the configuration of the inner surface of the vertebral bodies is disk-shaped or checker-shaped, and the cortical bone of the distal radius and the proximal humerus are gourd-shaped.) (Plaintiff's Exhibit 4, column 2).

2. Main Figures

Fig. 1: Top plan view of a checker-shaped inflatable device expanding the bone marrow



Figs. 2, 3: Top plan view and a side view of a checker-shaped inflatable device

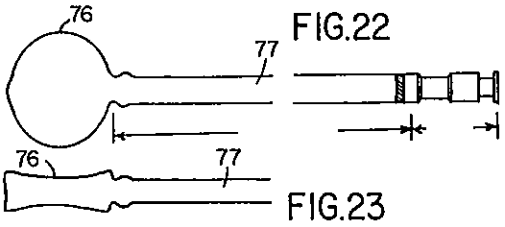


Fig. 4: Top plan view of the checker-shaped inflatable devices inserted into the vertebral body

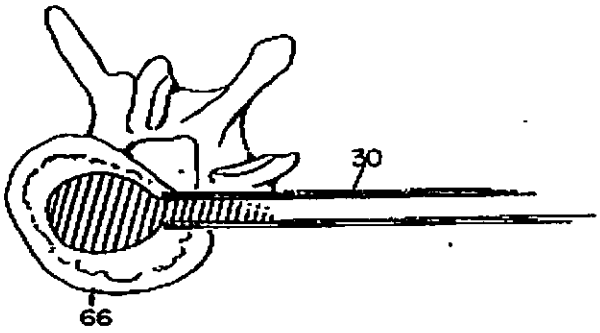
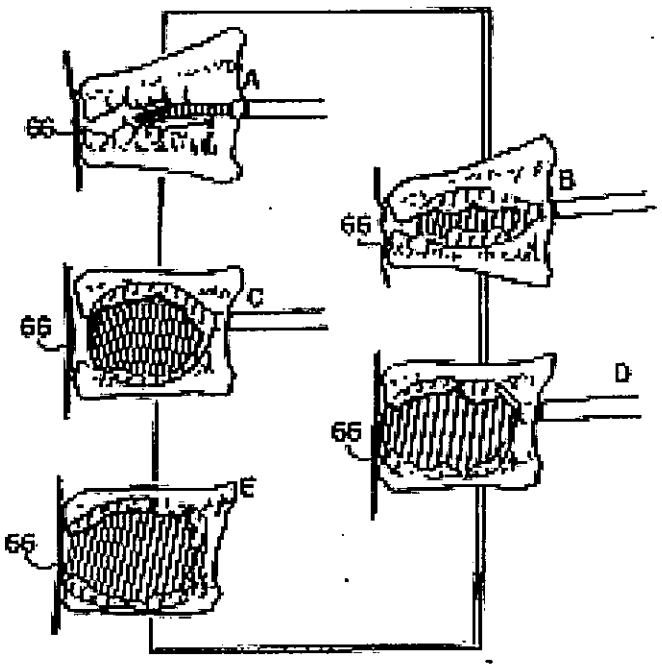


Fig. 5: Side view of treatment steps



[Annex 3]

Technical Details and Main Figures of Prior Art 2

1. Technical Details

The invention relates to surgical instrument used in the field of gynecology, such as hysterectomy. The technical elements comprising a balloon element of differential thickness whereby the configuration attained at equilibrium may be predetermined, and a tube element. The first embodiment includes an asymmetric hollow tubular inflatable element (12) having a relatively thin wall area (35) and a relatively thick wall area (36). The second embodiment includes a quasi-toroidal shaped inflatable element (46) wherein the first and third bands (47 and 49) are form of material that is thicker than that of the second band (48). (Plaintiff's Exhibit 5, "Abstract," columns 2 and 3)

2. Main Figures

Fig. 1: Schematic view of a first embodiment

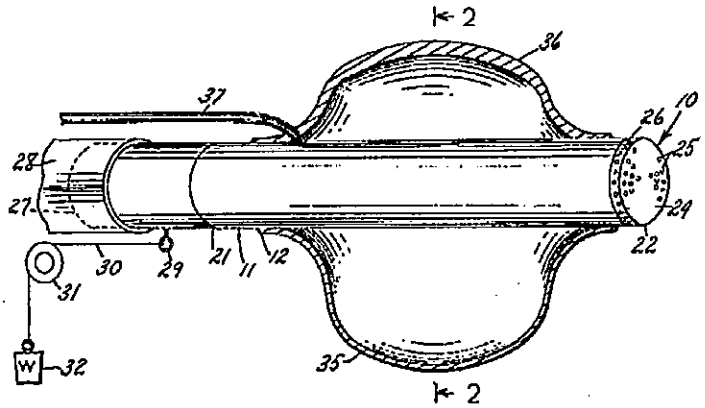


Fig. 2: Sectional view of the 'plane 2-2' in Fig. 1

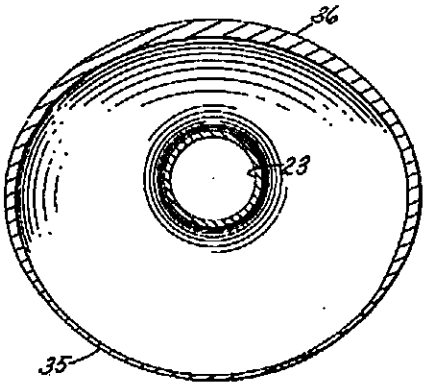
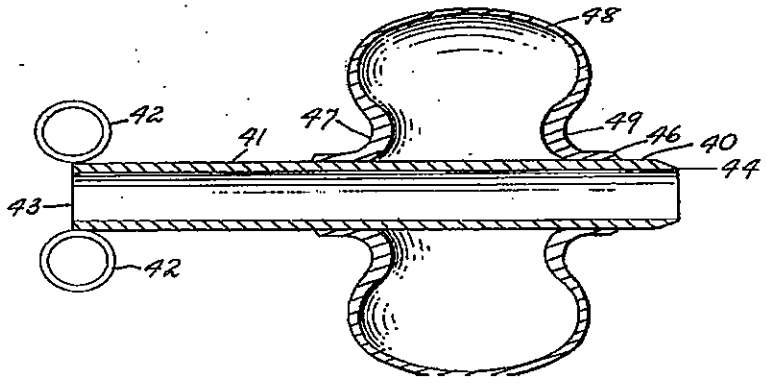


Fig. 3: Schematic view of the second embodiment



[Annex 4]

Technical Details and Main Figures of Prior Art 3

1. Technical Details

This invention relates to a low profile balloon catheter used for dilating various body conduits such as blood vessels and the urethra, and a method for making the same, wherein the balloon (16) has end walls (18 and 21) that are thicker than the central wall (27). (Plaintiff's Exhibit 6, column 5)

2. Main Figures

Fig. 1: Axial cross-section view of balloon catheter

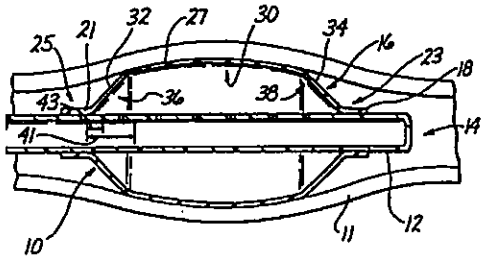


Fig. 2: Low profile top plan view of prior art balloon catheter

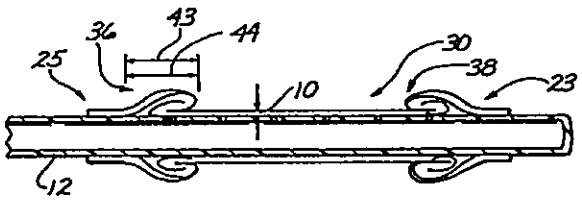


Fig. 3: Low profile top plan view of present invention

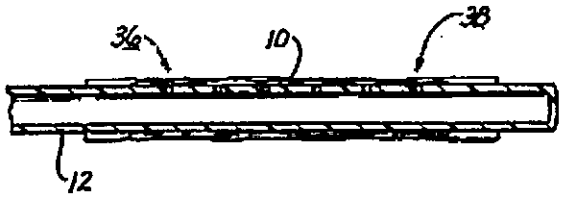


Fig. 6: Cross-section view of one quadrant of Fig. 1