United States District Court,
D. Delaware.

C.R. BARD, INC., and Davol Inc,
Plaintiffs.
v.
UNITED STATES SURGICAL CORPORATION,
Defendant.

Civil Action No. 99-286-RRM

June 15, 2000.

Owner of patent for surgical mesh plug used for hernia repairs sued competitor for infringement. The District Court, McKelvie, J., construed patent claims.

Claims construed.

5,356,432. Construed.

Jack B. Blumenfeld, and Maryellen Noreika, Morris, Nichols, Arsht & Tunnell, Wilmington, DE; Peter B. Ellis, Claire Laporte, Sarah Cooleybeck and John Nilsson, Foley, Hoag & Eliot, LLP, Boston, MA; counsel for plaintiffs.

Andre G. Bouchard and Joel Friedlander, Bouchard Margules & Friedlander, Wilmington, DE; Eric J. Lobenfeld, Drew M. Wintringham and Michael R. Graif, Chadbourne & Parke LLP, New York City; counsel for defendant.

OPINION

McKELVIE**, District Judge.**

This is a patent case. Plaintiff C.R. Bard, Inc. is a New Jersey corporation with its principal place of business in Murray Hill, New Jersey. Bard owns U.S. Patent No. 5,356,432, as reexamined ("the '432 patent"). Plaintiff Davol Inc., a wholly owned subsidiary of Bard, is a Delaware corporation with its principal place of business in Cranston, Rhode Island. Davol markets and sells products that practice the '432 patent. Defendant United States Surgical Corp. is a Delaware corporation with its principal place of business in Norwalk, Connecticut.

On May 7, 1999, plaintiffs (collectively, "Bard") filed the complaint in this action, which it amended on May 28, 1999. Bard alleges that U.S. Surgical has infringed and continues to infringe one or more claims of the '432 patent.

On June 14, 1999, U.S. Surgical filed its answer and counterclaims, which it amended on July 30, 1999 and on November 8, 1999. U.S. Surgical denies infringement; asserts the affirmative defenses of invalidity, unenforceability, and equitable estoppel, and that the complaint fails to state a claim upon which relief can

be granted; and counterclaims for a declaratory judgment of invalidity, noninfringement, and unenforceability of the '432 patent.

This case is scheduled for a two-week jury trial beginning July 10, 2000.

On June 2, 2000, the court held a trial in accordance with Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), to construe disputed claims of the '432 patent. This is the court's construction of those disputed claims.

I. *FACTUAL AND PROCEDURAL BACKGROUND*

The court draws the following facts from the pleadings, the patent at issue, and the prosecution history of the patent. Bard has submitted a declaration by Keith Millikan, an associate professor of surgery at Rush Medical College, that contains an undisputed recitation of the background of the invention, and has submitted the notebook of the inventors of the patented device. The court will consider the Millikan declaration and the notebook for the limited purpose of describing the background of the invention.

A. *Background of the Invention*

The invention at issue in this case is an implantable prosthesis formed of surgical mesh used to repair groin hernias. A hernia is a relaxation or weakening of the muscle wall, usually in the lower abdomen, which permits tissue to protrude through the muscle wall defect. Left untreated, a hernia will continue to enlarge and potentially lead to serious complications.

The Millikan declaration describes that a traditional method of repairing a hernia was to replace the tissue and sew the weakened muscle together. This method, however, proved to be quite painful and led to an unacceptably high rate of hernia recurrence.

The Millikan declaration states that in the 1970s, Irving Lichtenstein and his colleagues began recommending the use of cylindrical mesh plugs for certain types of hernia repairs. In this method, flat mesh was rolled into a cigarette-like shape and inserted into the defect without stapling or suturing. The mesh plug retained and repaired the hernia, and gradually became fixed in place by the process of tissue "fibroblasting," wherein the muscle tissue attaches itself to the mesh. Hand rolled plugs, however, had the disadvantage that they were not readily conformable to the contours of a defect, particularly when the defect was irregularly shaped.

The Millikan declaration states that in the 1980s, Lichtenstein and his colleagues began repairing hernias by suturing flat mesh to the muscle tissue. The advantage of mesh was that it was flexible and pliable, so that it could be employed without immobilizing the muscle wall. Rather than relying on the tension of the sutured muscle wall to retain the hernia, a doctor could staple or suture mesh over the muscle wall defect. Using sections of flat mesh to patch hernias, however, had certain drawbacks. Because the patch was commonly placed behind the abdominal wall, some dissection of the muscle tissue was necessary to install the patch. Moreover, the dissection was typically done "blindly," i.e., without the surgeon's being able to see what he was doing, which increased the likelihood of errors in placement.

The Millikan declaration states that prior to 1992, Ira Rutkow and Alan Robbins, the inventors of the patent at issue, began to hand-form plugs in a conical shape. Making a plug in a conical shape consumed less time and material, and the plugs were more pliable than the cylindrical cigarette plugs. These plugs had certain disadvantages, however. Each had to be individually rolled to fit the shape of the defect. If it was too large, its stiffness or lack of filler material would cause it to double over on itself, creating a significant gap between the mesh and the margins of the defect, through which re-herniation could occur. If a plug was too

small, it could migrate or might not adequately fill the defect, again causing a risk of recurrence. Although conical plugs were more pliable than the tightly rolled cigarette plugs, they were generally made from more than one layer of mesh and could, thus, be stiff, particularly in the case of a small plug. When the plugs were rolled so that they were roughly the same size as the defect, they could not always conform to irregularly shaped hernia defects.

Prior to 1992, Ermanno Trabucco published a manuscript entitled "A New Preperitoneal Plug Technic for Recurrent Groin Hernioplasty," in which he discloses the use of a hand-made plug in a roughly conical shape, formed by suturing a square piece of mesh into a conical, four-lobed configuration. This configuration lacked some of the advantages of simple conical plugs. Because the lobes were sutured together, the implant had a limited ability to conform to the size and shape of a hernia defect.

On January 22, 1992, Rutkow and Robbins disclosed to Bard engineers and marketing personnel their ideas for a preformed, cone-shaped mesh hernia plug. Bard's project notebook shows that Rutkow and Robbins contemplated using a 3-layered design, comprising an exterior, pleated layer, and two interior layers for support. The notebook says "Pleats-Purpose Is To Reduce Gaps To Reduce Recurrence," and "Fluted or Pleated For Expandability (Cones)." The notebook states that the plugs should have "Multiple Pleats-(Coffee Filter Like)," but that "Large Pleats May Allow Recurrence."

B. ***The Prosecution History of*** the '432 Patent

1. ***The Patent Application***

On February 5, 1993, Bard filed a patent application on the plug developed by Rutkow and Robbins. The Summary of the Invention states that "[t]he implant includes a pleated surface which increases the pliability of the implant, allowing the prosthesis to conform to irregularities in the tissue or muscle wall surrounding the opening." The application describes that a filler body within the plug imparts bulk to the device, ensuring a snug fit when it is compressed into a rupture. The application continues, "[p]ortions of the filler material are easily removed allowing the surgeon to customize the stiffness of the implant during the operation without damaging the integrity of the prosthesis." Figures 2 and 3 of the patent application illustrate preferred embodiments of the invention.

Fig. 2

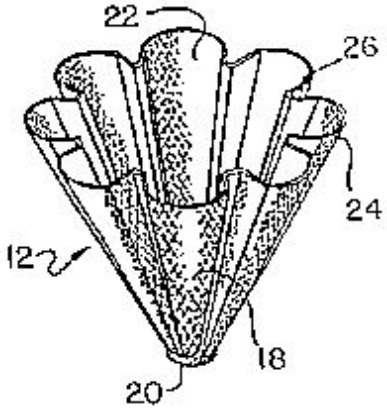

Fig.2

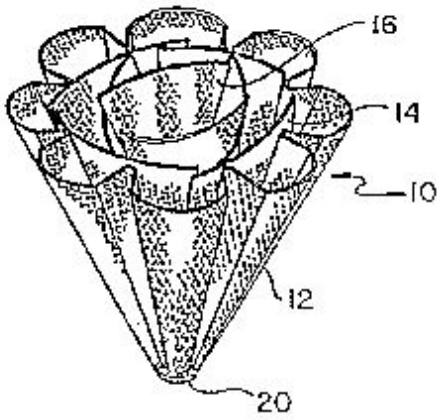

Fig.3

Fig. 3

The application states, as shown in Figures 2 and 3, that one embodiment of the invention includes "[l]ongitudinally running pleats [that] are hot molded into the mesh body which enhances the flexibility of the implant, allowing the implant to closely match the contour of the herniated opening when compressed within the defect."

The application describes, as shown in Figure 3, that "[i]n another embodiment of the invention, a filler body is positioned in a mesh cone and packs the implant when the plug is compressed by placement in the narrow hernia opening, providing the bulkiness believed to be essential for non-recurrent repair of abdominal wall hernias." The filler body contains a plurality of mesh petals which provide support to the device.

The application identifies a number of possible pleat configurations, which allow "the cone to conform to various irregularities in the contour of the defect." In some pleat configurations, the application discloses, "pleats may be provided on only that limited portion of the plug which is likely to encounter the irregular topography or which will require enhanced flexibility."

Figure 4 of the patent application illustrates the pleated plug conforming to an irregular defect. The application explains that "[t]he pleated conical plug is extremely pliable, allowing localized portions of the implant to adapt to the irregular contour 40 of the defect."

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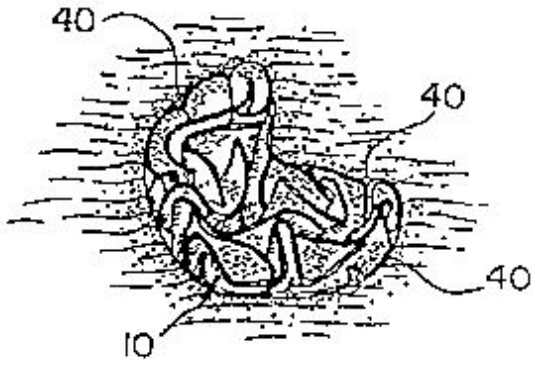

Fig. 4

Fig. 4

The patent application contains 22 claims, with claims 1, 5, 14, 19, 20, 21, and 22 drafted as independent claims. Claims 1-21 are apparatus claims, and claim 22 is a method claim. Independent claims 1, 14, and 19 recite the use of pleats in the claimed apparatus. Claim 5 does not contain a pleats limitation. Claim 20 of the application is written in means-plus-function language, claiming a "means for conforming to irregularities in the tissue." Claim 21 of the application, which subsequently issued as claim 20 of the '432

patent, reads as follows:

21. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

A hollow plug formed of a surgical mesh fabric and being compressible from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect so that said plug securely fits therein and occludes the defect, the surface of said plug being conformable to irregularities in the tissue or muscle wall defining the defect.

Claim 22 of the application, which subsequently issued as claim 21 of the '432 patent, reads as follows:

22. A method of repairing a tissue or muscle wall defect, comprising:

providing an implantable prosthesis including a plug formed of a surgical mesh fabric which is compressible from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect so that the plug securely fits therein and occludes the defect, the plug including an inner filler body formed of spaced petals of a surgical mesh fabric which stiffen the implantable prosthesis when the plug is compressed into the second configuration;

placing the plug in the defect so that the plug compresses into the second configuration; and

detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis.

2. *The First Office Action*

On June 4, 1993, the examiner issued his first Office Action, allowing claim 22 of the application on the grounds that the prior art did not disclose the method of removing petals to vary the stiffness of the implant. Claim 22 of the application subsequently issued as claim 21 of the '432 patent.

The examiner rejected claims 1-17, and 19-21, and objected to claim 18, under 35 U.S.C. s.s. 102 and 103. The examiner determined that U.S. Patent No. 5,147,374, which was issued to Alfredo Fernandez in 1992, disclosed a folded structure that anticipated or rendered obvious the pleats of Bard's application.

3. *Examiner Interview*

On November 9, 1993, the examiner held an interview with representatives of Bard. The examiner's Interview Summary Record states that "[a]pplicant argued that pleats helps it conform to an irregular opening."

4. *Proposed Amendment*

On December 6, 1993, Bard proposed amending the language of the claims that had been rejected, and proposed adding five new apparatus claims that recite the use of pleats. Bard proposed amending claim 21 of the application, which subsequently issued as claim 20 of the '432 patent, to read as follows (added language is underlined, and deleted language is bracketed):

21. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

a hollow plug, formed of a surgical mesh fabric *having openings therein for tissue ingrowth, constructed and arranged to securely fit within and occlude the tissue or muscle wall defect* and [being] *which is radially* compressible *upon insertion into the defect* from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect [so that said plug securely fits

therein and occludes the defect], the surface of said hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect.

Bard responded to the examiner's rejection by stating that Fernandez did not disclose the use of pleats, and that the folded structure previously identified by the examiner was the result of an otherwise flat portion of mesh that had been folded into a delivery device.

5. ***Notice of Allowability***

On May 18, 1994, the examiner allowed claims 1-5 and 7-27, as amended. The examiner limited claim 5 to a pleated structure by inserting the following language from claim 6 into claim 5: "a pleated surface which is conformable to irregularities in the tissue or muscle wall defining the defect." Modifying claim 5 in this manner limited all the apparatus claims, with the exception of allowed claims 19 and 20, to structures containing pleats. The examiner eliminated claim 6, and renumbered claims 7-27 of the application as claims 6-26, respectively.

The examiner stated that, in his prior rejection, he had interpreted the term "pleated" too broadly. The examiner found that "it would not have been obvious to pleat the materials of the prior art in the manner that facilitates radial compressibility because the prior art does not teach such a concept."

6. ***Issuance of*** the '432 Patent

The PTO issued the '432 patent on October 18, 1994.

7. ***Request for Reexamination***

On May 1, 1995, Bard filed a request for reexamination with the PTO, seeking review of three undated publications that it had previously disclosed to the examiner in the original patent application. The examiner had checked off all the prior art references listed on the Form PTO-1449 that Bard had submitted with its original application, with the exception of " 'Tension Free' Inguinal Herniorrhapy: The 'Mesh Plug' Technique," by Rutkow and Robbins; "Routine Sutureless Mesh and Primary Inguinal Hernioplasty" by Trabucco; and "A New Preperitoneal Plug Technique for Recurrent Groin Hernioplasty" by Trabucco.

Bard asserted that the reexamination references do not negatively affect the patentability of the claimed invention, because:

None of the reexamination references teach or suggest a plug which is radially compressible upon insertion into a defect opening, without kinking or buckling, so that the plug conforms to irregularities in the tissue or muscle wall defining the defect. This feature is an element of each claim, except method claim 21.

8. ***Office Action in Reexamination***

On October 13, 1995, the examiner allowed claims 1-18 and 21-26, and rejected claims 19 and 20 in light of the publication entitled "A New Preperitoneal Plug Technique for Recurrent Groin Hernioplasty" by Trabucco. In that publication, Trabucco discloses a hernia plug made by suturing a flat piece of surgical mesh into a four-lobed cone. The examiner stated that Trabucco discloses a "means to conform to the irregularities in the tissue defect in the form of sutures on the edges thereof to hold it into the shape of the defect."

9. ***Response to Reexamination Office Action***

On December 12, 1995, Bard responded to the PTO by proposing an amendment to claims 19 and 20. Bard

proposed amending claim 20 as follows:

20. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

a hollow plug, formed of a surgical mesh fabric having openings therein for tissue ingrowth, constructed and arranged to securely fit within and occlude the tissue or muscle wall defect and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect, the surface of said [of] hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect *upon insertion of said hollow plug into the defect*.

Bard asserted that the device disclosed by Trabucco did not provide "contour matching." Bard distinguished its invention from Trabucco's as follows:

As explained in the specification of the reexamination application, the surface of the inventive plug is pleated with [sic] enhances the flexibility and pliability of the implant, allowing the prosthesis to conform to irregularities in the shape of the hernia without kinking. Thus, it is the integrally formed pleats, and not additional fastening mechanisms (such as the sutures or clips disclosed by Trabucco), which allow the prosthesis to conform to the contours of the defect merely upon placement in the tissue or muscle wall opening.

10. *Final Office Action in Reexamination*

On April 22, 1996, the examiner issued a final rejection of claims 19 and 20. He reiterated his previous conclusions regarding the Trabucco reference, and added that Trabucco satisfies the amended limitation of conforming to irregularities "upon insertion of said hollow plug into the defect."

The examiner proposed a modification to the language of claims 19 and 20 to put them in allowable form. He suggested inserting the phrase "said means for conforming making the hollow plug extremely pliable and allowing localized portions of the hollow plug to adapt to the irregularities in the tissue or muscle wall defect" at the end of claims 19 and 20. In support of his suggested amendment, he referenced a section of the patent specification, which states:

The close fit of the implantable prosthesis 10 in an irregular opening 40 is illustrated in FIG. 4. The pleated conical plug is extremely pliable, allowing localized portions of the implant to adapt to the irregular contour 40 of the defect.

Col. 4, In. 44-48.

11. *Response to Reexamination Action*

On May 1, 1996, Bard responded to the rejection of its claims by proposing amended claim language for claims 19 and 20. Bard adopted the examiner's suggestion verbatim for claim 19. FN1 Bard proposed amending claim 20 as follows:

FN1. Claim 19 was amended as follows (added language is underlined and deleted language is bracketed):

19. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

a hollow plug, formed of a surgical mesh fabric having openings therein for tissue ingrowth, constructed

and arranged to securely fit within and occlude the tissue or muscle wall defect and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect, wherein [formed integral with] the surface of said hollow plug [are] *includes* means for conforming to irregularities in the tissue or muscle wall defining the defect upon insertion of said plug into the defect, *said means for conforming making the hollow plug extremely pliable and allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect*.

20. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

a hollow plug, formed of a surgical mesh fabric having openings therein for tissue ingrowth, constructed and arranged to securely fit within and occlude the tissue or muscle wall defect and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect, the surface of said hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect upon insertion of said hollow plug into the defect *and being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect*.

Bard stated that this amendment distinguished the claimed invention from Trabucco.

12. ***Reexamination Advisory Action***

On September 4, 1996, the examiner issued a Reexamination Advisory Action, stating that the amendments did not comply with 37 C.F.R. s. 1.121(f).

13. ***Response to Reexamination Advisory Action***

On September 25, 1996, the applicant amended claim 20 to read:

20. An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:

a hollow plug, formed of a surgical mesh fabric having openings therein for tissue ingrowth, constructed and arranged to securely fit within and occlude the tissue or muscle wall defect and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect, the surface of said [of] hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect *upon insertion of said hollow plug into the defect, said hollow plug being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect*.

14. ***Notice of Intent to Issue Reexamination Certificate***

On November 21, 1996, the examiner issued a Notice of Intent to Issue Reexamination Certificate. In explaining his allowance of claims 19 and 20, as amended, the examiner stated:

Claims 19 and 20 set forth a means for conforming which renders the hollow plug extremely pliable such that localized portions can adapt to irregularities in the tissue of muscle wall defect. The prior art of record, most relevantly the Trabucco article ... fails to teach hollow plugs with conformation to the extent now set forth in these claims as amended.

15. ***Issuance of Reexamination Certificate***

On February 4, 1997, the PTO issued a reexamination certificate to Bard for the '432 patent.

D. ***The Parties'*** Hernia ***Plugs***

Bard manufactures and sells a hernia plug, called the Perfix plug, which it acknowledges is an embodiment of the '432 patent. The plug has a pleated outer surface, and has several interior mesh petals that may be removed by a surgeon to vary the stiffness of the plug. When the Perfix plug is compressed into a small opening (such as the opening formed by the thumb and index finger of a loosely-clenched fist), the outer surface of the plug retains contact with the perimeter of the opening-i.e., the plug does not "kink or buckle."

U.S. Surgical manufactures and sells a hernia plug called the Hernia-Mate. The Hernia-Mate is a pre-formed mesh plug consisting of a semicircle of mesh joined at the seam. The Hernia-Mate has no pleats. The Hernia-Mate has petals that impart bulk to the plug. When the Hernia-Mate is compressed into a small opening, portions of the outer surface of the plug fold inwards-i.e., the plug "kinks and buckles."

Bard seeks to enjoin U.S. Surgical from producing the Hernia-Mate, and seeks to recover damages allegedly caused by U.S. Surgical's past and continuing sales of the Hernia-Mate.

E. ***Disputed Claims***

Plaintiffs allege that U.S. Surgical infringes claims 20 and 21 of the '432 patent. The parties dispute the proper construction of a number of elements of these two claims. The following charts summarize the claim terms in dispute. The parties have proposed the following construction of the elements of claim 20:

	Claim Term (Claim 20)	Plaintiffs' Construction	Defendant's Construction	
	An implantable prosthesis for repairing a tissue or muscle wall defect, comprising:	A surgical implant for repairing a defect, or hole, in a tissue or muscle wall, including:		
	a hollow plug,	a plug which is not solid, but has a cavity, gap, or space inside;		Lines
	formed of a surgical mesh fabric having openings therein for tissue ingrowth,	which is formed of surgical mesh;		
	constructed and arranged to securely fit within and occlude the tissue or muscle wall defect	which is constructed and arranged to securely fit within, and fill or close up, the hole in the tissue or muscle wall;		
	and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect,	and which can be radially compressed upon insertion into the hole from a configuration that is larger than the defect or hole into a second configuration that approximates the shape of the hole;	" radially compressible" means the capability of being compressible in a radial direction without "kinking or buckling"	
	the surface of said hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect upon insertion of said hollow plug into the defect, said hollow plug being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect.	and whose surface is capable of conforming to irregularities in the shape of the defect or hole when it is inserted into the hole; and which is extremely pliable, so that localized portions of the plug are able to adapt to irregularities in the shape of the defect or hole.	"surface of said hollow plug being conformable" requires pre-formed pleats which render the plug "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect"	

The parties have proposed the following construction of the elements of claim 21:

Claim Term (Claim 21)	Plaintiffs' Construction	Defendant's Construction	
A method of repairing a tissue or muscle wall defect, comprising:	A method of repairing a defect, or hole, in a tissue or muscle wall, including:		Lines
providing an implantable prosthesis including a plug formed of a surgical mesh fabric which is compressible from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect so that the plug securely fits therein and occludes the defect,	using a plug formed of surgical mesh that can be compressed from a configuration that is larger than the defect or hole into a second configuration that approximates the shape of the hole, so that the plug fits into and plugs up the hole;		
the plug including an inner filler body formed of spaced petals of a surgical mesh fabric which stiffen the implantable prosthesis when the plug is compressed into the second configuration;	the plug has inner mesh petals that stiffen the plug when it is compressed into the second configuration		
placing the plug in the defect so that the plug compresses into the second configuration; and	placing the plug in the hole, so that it compresses into the second, smaller configuration; and		
detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis	detaching one or more of the inner mesh petals so that the plug is less stiff.	"detaching" means "removing"and does not mean "trimming"	
		"detaching" means removing after implanting	
		"stiffness" does not mean "bulk"	

II. *DISCUSSION*

A. *Basic Principles of Claim Construction*

[1] [2] Claim construction is a matter for the court. Markman, 517 U.S. at 387, 116 S.Ct. 1384. The court will base the jury instructions in this case on the construction of the claims adopted herein. It is the province of the jury to determine whether the claims, as construed by the court, are valid and infringed. *Id*.

[3] [4] Claims are construed from the vantage point of a person of ordinary skill in the art at the time of the invention. Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed.Cir.1995). To define the scope of the invention, the court first looks to the words of the claims themselves. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). These words are to be given their ordinary meaning unless inconsistent with the specification and prosecution history. *See* Desper Products, Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1336 (Fed.Cir.1998); Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998).

[5] The court must then review the specification, of which the claims are a part. *See* Vitronics, 90 F.3d at 1582; Markman, 52 F.3d at 979. Claims should be interpreted consistently with the specification, which provides content for the proper construction of the claims because it explains the nature of the patentee's

invention. *See* Renishaw, 158 F.3d at 1250. As the Federal Circuit explained in *Renishaw,*

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.

Id. (citation omitted)

[6] The prosecution history should also be considered. The public has a right to rely on statements made by the patent applicant or his attorney during prosecution that define the scope of the claims. *See* Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed.Cir.1997).

The Federal Circuit has repeatedly cautioned against limiting the scope of a claim to the preferred embodiment or specific examples disclosed in the specification. *See, e.g.,* Ekchian, 104 F.3d at 1303; Intervet America, Inc. v. Kee-Vet Laboratories, Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989) ("[L]imitations appearing in the specification will not be read into claims, and ... interpreting what is meant by a word in a claim 'is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.' ") (citation omitted).

[7] Section 112 para. 1 of the Patent Act requires that a patent specification describe an invention and do so in sufficient detail that one skilled in the art can reasonably conclude that, as of the filing date, the inventors were in possession of the claimed invention. *See* Regents of University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed.Cir.1997). The written description requirement "is not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure.... Rather, it is a question whether the application necessarily discloses that particular device." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed.Cir.1997). The specification must sufficiently describe the claimed invention such that persons skilled in the art can discern that the inventor has in fact invented what has been claimed. Toro Co. v. Ariens Co., 2000 WL 504209, at (Fed.Cir. Apr.27, 2000).

The court will now consider the disputed terms of claims 20 and 21.

B. *Undisputed Claims*

As indicated in the above charts, U.S. Surgical has not opposed plaintiffs' construction of many of the claim terms. Claims 20 and 21 each recite the word "occlude" in one of their claim elements. Because the word "occlude" may not be understood by all prospective jurors, the court will adopt plaintiffs' proposed construction as to the claim elements reciting the word "occlude." As to the remainder of the claims for which U.S. Surgical has not proposed a construction, the court will adopt the existing claim language.

C. *Claim 20*

1. " *and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect* "
[8] The parties dispute the meaning of the claim limitation "and which is radially compressible upon insertion into the defect from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect."

Plaintiffs, adhering to the plain meaning of the claim language, propose that this limitation be construed to mean "and which can be radially compressed upon insertion into the hole from a configuration that is larger

than the defect or hole into a second configuration that approximates the shape of the hole."

U.S. Surgical contends that the term "radially compressible," as used in the above claim limitation, means the capability of being compressible in a radial direction without "kinking or buckling."

U.S. Surgical bases its proposed construction of this claim limitation on a statementmade by Bard to the examiner in its May 1, 1995 Request for Reexamination. As noted above, Bard attempted to distinguish its claimed invention from the reexamination references by noting that the prior art did not disclose a plug that is radially compressible without kinking or buckling. Bard stated that "[t]his feature is an element of each claim, except method claim 21." U.S. Surgical argues that this statement demonstrates that the phrase "radially compressible" should be not construed to cover a hernia plug that kinks and buckles when it is compressed. U.S. Surgical contends that Bard's statement to the examiner is consistent with the language of the specification, which states that the pleated surface of the implant allows the device to "conform to irregularities in the shape of the hernia without kinking." The specification, moreover, distinguishes the claimed invention from the prior art by stating that the prior art "may be susceptible to kinking and buckling during placement." U.S. Surgical contends that the specification and prosecution history dictate an interpretation of the term "radially compressible" in claim 20 as meaning compressible in a radial direction without kinking or buckling.

Bard notes that only eleven of the twenty-six claims of the '432 patent, as reexamined, expressly recite compression without kinking and buckling. Plaintiffs assert that the statement made by the prosecuting attorney in the Request for Reexamination was an erroneous remark about the number of claims containing the kinking and buckling limitation. Plaintiffs argue that the language of the claims, and not the statement of the attorney, should control. *See* Intervet, 887 F.2d at 1050 ("When it comes to the question of which should control, an erroneous remark by an attorney in the course of prosecution of an application or the claims of the patent ... we think the law allows for no choice. The claims themselves control"). Moreover, plaintiffs note, the attorney's comment was made as part of his initial request to the PTO to commence a reexamination proceeding, rather than in response to an office action. Plaintiffs contend that the comment should not be construed as an interpretative remark intended to import the kinking and buckling limitation into claim 20.

Only eleven of the twenty-six claims of the patent recite the kinking and buckling limitation. As such, the court finds that the remark by the prosecuting attorney that the kinking buckling limitation "is an element of each claim, except method claim 21" was an error. Because the erroneous statement was made in the context of an initial request for reexamination, rather than as a response to objections raised by the examiner, the court does not find that the claims, as allowed, should be construed in light of the attorney's statement. The court will adopt the existing language of this claim limitation.

2. " *the surface of said hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect upon insertion of said hollow plug into the defect, said hollow plug being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect*."

The parties dispute the meaning of the claim limitation "the surface of said hollow plug being conformable to irregularities in the tissue or muscle wall defining the defect upon insertion of said hollow plug into the defect, said hollow plug being extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect."

Bard argues that this limitation should be construed to mean "and whose surface is capable of conforming to irregularities in the shape of the defect or hole when it is inserted into the hole, and which is extremely pliable, so that localized portions of the plug are able to adapt to irregularities in the shape of the defect or hole."

Defendant argue that the phrase "surface of said hollow plug being conformable" requires pre-formed pleats which render the plug "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect."

a. *means-plus-function claims*

Defendant's proposed construction is based, in part, on an argument that claim 20 is written in means-plus-function language. Claims may be drafted in functional terms, as permitted by 35 U.S.C. s. 112 para. 6, which provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. s. 112 para. 6. Patent drafters typically invoke s. 112 para. 6 by including the words "means for," or the word "means," in the language of a claim. *See* Personalized Media Communications, LLC v. International Trade Commission, 161 F.3d 696, 703-04 (Fed.Cir.1998). The "means" term in a means-plus-function limitation is essentially a generic reference for the corresponding structure disclosed in the specification. *See* Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed.Cir.1998). If the drafter does not use the word "means" or "means for," there is a presumption that s. 112 para. 6 does not apply. *See* Personalized Media, 161 F.3d at 703-04.

[9] A claim may invoke s. 112 para. 6 even though it does not recite the words "means" or "means for." Section 112 paragraph 6 governs only claim elements that do not recite sufficient structural limitations. *See Al-* Site Corp. v. VSI International Inc., 174 F.3d 1308, 1318-19 (Fed.Cir.1999). When it is apparent that the element invokes purely functional terms, without the additional recital of a specific structure or material for performing that function, the claim element may be a means-plus-function element despite the lack of express means-plus-function language. *See id.; see also* Mas-Hamilton, 156 F.3d at 1214 (construing "lever moving element" in means-plus-function format).

b. *U.S. Surgical's position*

U.S. Surgical contends that claim 20 should be limited to a pleated implant. U.S. Surgical argues that claim 20, by itself, does not disclose any structure, material, or acts that would enable one skilled in the art to make a hollow plug that would perform all the claimed functions. Claim 20 recites that the implant should be "extremely pliable." U.S. Surgical asserts that this is a functional limitation, and that a person of ordinary skill in the art would have to consult the specification to determine what structures to use to make an "extremely pliable" implant. U.S. Surgical argues that it is necessary to invoke s. 112 para. 6 and construe the claim in light of the structures discussed in the specification. *See Al-* Site, 174 F.3d at 1318-19. U.S. Surgical contends that the specification repeatedly states that the use of pleats enhances the flexibility and pliability of the implant.

U.S. Surgical argues that the specification only discloses the use of a pleated structure, and that it would be inappropriate to broaden the scope of the claims beyond the scope of the invention. *See* Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed.Cir.1999). In *Wang,* Wang sued America Online and Netscape Communications for infringement of a 1984 patent directed to a system for providing users with textual and graphical information from computer-controlled databases via interactive two-way communications over a telephone network. The issue for claim construction and summary judgment was whether the claim term "frames of information" covered both character-based and bit-mapped-based

protocols, or whether the term should have been limited to character-based protocols. The preferred embodiment of the invention was directed to character-based protocol systems, although the specification acknowledged that bit-mapped protocols were part of the prior art. The Federal Circuit found that a person of ordinary skill in the art would understand the specification to refer only to character-based systems, and affirmed the trial court's construction that limited the claims to character-based systems.

U.S. Surgical argues that this case is analogous to *Wang*. U.S. Surgical argues that the specification of the '432 patent is directed only to a pleated implant. U.S. Surgical asserts that to construe claim 20 to cover unpleated implants would grant coverage to embodiments not disclosed by the patent.

U.S. Surgical argues that the prosecution history demonstrates that claim 20 should be construed in means-plus-function format. U.S. Surgical contends that during the reexamination proceedings, the examiner specifically suggested putting claim 20 in means-plus-function format, such that the suggested "means for conforming" language would refer to the portion of the specification discussing pleats. U.S. Surgical asserts that after Bard amended its claims, the examiner granted the claims under the belief that the claims set forth a "means for conforming," as stated in his Notice of Intent to Issue Reexamination Certificate. U.S. Surgical argues that the examiner would not have granted the claim had he not interpreted the claim to be in means-plus-function format.

U.S. Surgical argues that, regardless if claim 20 is construed in means-plus-function format, the prosecution history nevertheless limits the claim's construction to a plug which has pre-formed pleats. U.S. Surgical contends that Bard distinguished its invention from Trabucco through reference to its "integrally formed pleats," and that the examiner would not have allowed the claims but for this statement.

U.S. Surgical argues, moreover, that statements made by Bard during the prosecution of Canadian and European counterpart patents of the '432 patent demonstrate that the scope of claim 20 should be limited to a pleated implant. After the Canadian examiner rejected all the claims in the application on the grounds that a plug "having a pleated surface is known and described in the prior art cited," Bard argued that the prior art devices "do not have a pleated surface and are, therefore, unable to completely fill the opening formed by an irregularly shaped defect." Bard amended its claims by substituting verbatim the claims of the United States '432 patent. U.S. Surgical argues that this amendment constitutes an admission by Bard that claim 20 of the '432 patent is limited to a plug with a pre-formed pleated surface.

U.S. Surgical further states that the European examiner rejected the only independent claim of Bard's application on the grounds that the prior art disclosed pleated plugs. In response to the rejection, Bard stated that its plug "is preferably formed by hot molding, which indicates beyond a doubt that the pleats are permanent and are inherent in the plug." According to U.S. Surgical, this statement is an admission that the invention of the '432 patent includes a pre-formed pleated surface.

c. *Bard's position*

Bard argues that, under the ordinary meaning of the words used in claim 20, the claim should not be construed to refer to pleats. Claim 20 refers to a structure that is "conformable" and "extremely pliable." Bard asserts that the ordinary meaning of the terms "conformable" and "extremely pliable" should control. Bard contends that additional structural limitations may be read into a claim only when the language of the claim invites reference to the remainder of the specification or the prosecution history. *See* Johnson Worldwide Associates, Inc. v. Zebco Corp., 175 F.3d 985, 989-90 (Fed.Cir.1999).

In *Johnson Worldwide,* the patentee sought to enforce its claims to a steering control used with trolling motors. The patent at issue claimed a "heading lock coupled to a trolling motor." The defendant, Zebco, argued that statements made by the patentee during the prosecution history served to limit this claim to a

directional indicator "physically attached" to the trolling motor. The Federal Circuit stated that there is a "heavy presumption" against importing additional limitations into claim language. *See id*. at 989. There are two situations, the court stated, in which a claim term should be accorded other than its ordinary and accustomed meaning. The first arises if the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term. *Id*. at 990. The second is where the term or terms chosen by the patentee so deprive the claim of clarity that there is no means by which the scope of the claim may be ascertained from the language used. *Id*. The court found that the claim language was sufficiently clear that there was no need to import additional limitations from the specification and the prosecution history.

In this case, Bard contends that the limitations "conformable" and "extremely pliable" are sufficiently clear that it would be improper to import additional limitations from the specification and the prosecution history. Plaintiffs insist that neither term should be construed to refer to pleats, but rather that these are structural terms whose plain meaning should control.

Bard notes that the original patent application included a number of claims specifically reciting pleats, and other claims, including claim 20, that did not recite the use of pleats. Plaintiffs assert that the specification provides a written description of an embodiment of the invention that is not limited to pleats. The specification states: "[i]n another embodiment of the invention, a filler body is positioned in a mesh cone and packs the implant when the plug is compressed by placement in the narrow hernia opening, providing the bulkiness believed to be essential for non-recurrent repair of abdominal wall hernias." Plaintiffs argue that this embodiment is not limited to pleats, and that it provides support for a construction of claim 20 without reference to pleats.

Plaintiffs further contend that the prosecution history demonstrates that Bard never intended to refer to pleats in claim 20. When the examiner inserted a pleat limitation into claim 5, the examiner did not require the addition of language into claim 20 to refer to pleats. In the reexamination proceedings, after the examiner suggested adding a "means for conforming" limitation to claim 20, Bard declined to adopt this language, and instead added the limitation "said hollow plug being extremely pliable ...." This additional language, plaintiffs contend, is a structural limitation that does not refer to pleats, and that does not invoke s. 112 para. 6. Plaintiffs assert that claim 20 was allowed, not because it disclosed pleats, nor because it was limited to a plug that did not kink or buckle, but rather because it defined a plug whose extreme pliability allowed it to conform to a defect to a degree not achieved by the prior art. This reason for allowance is entirely consistent with the plain language of claim 20, plaintiffs state.

Moreover, Bard contends that it would be improper to invoke s. 112 para. 6 to construe claim 20. Bard argues that it never intended to draft the claim in means-plus-function language. *See* Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1582 (Fed.Cir.1996) (declining to construe claim in means-plus-function format when there was no evidence that the patentee intended to claim its invention in that fashion). Plaintiffs argue that claim 20 does not contain the words "means" or "means for," and so a presumption should apply that the claim is not written in means-plus-function language. Plaintiffs contend that the use of adjectives like "conformable" and "extremely pliable" to limit the structure is insufficient to trigger s. 112 para. 6. *See Personalized* Media, 161 F.3d at 705 ("[A]n adjectival qualification ... placed upon otherwise definite structure ... does not make the sufficiency of that structure any less sufficient for purposes of s. 112, para. 6. Instead, it further narrows the scope of those structures covered by the claim and makes the term more definite."); *see also Al-* Site, 174 F.3d at 1317-19 (reversing trial court's determination that the claim limitation "attaching portion attachable to a portion of said frame of said pair of eyeglasses" was a means-plus-function element, because the limitation is not written in traditional means-plus-function format and because the claim supplies structural, not functional, terms).

Plaintiffs argue, moreover, that it would be improper under the doctrine of claim differentiation to construe

claim 20 in means-plus-function format, because, under such a claim interpretation, the distinction between claims 19 and 20 disappears. Under the doctrine of claim differentiation, it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims. Clearstream Wastewater Systems, Inc. v. Hydro-Action, Inc., 206 F.3d 1440, 1446 (Fed.Cir.2000). This doctrine cannot be used to make a claim broader than what is contained in the written description, but it prevents the narrowing of broad claims by reading into them the limitations of narrower claims. *Id*. The doctrine of claim differentiation is a guide to claim construction, not a rigid rule. IMS Technology, Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1432 (Fed.Cir.2000).

Bard argues that the court should not interpret claim 20 in light of the statements it made during the prosecution of counterpart patents in Canada and Europe, as these statements were made in different factual and legal contexts. Bard contends that, in the Canadian application, it overcame the examiner's rejection by stating that "[t]he flexible nature of the plug further allows it to compress radially upon insertion into the defect." And, Bard contends that the European application is irrelevant to the present proceedings, because the examiner had required Bard to use a single independent claim, and Bard complied with this requirement by choosing to claim only a pleated structure.

d. *the court's construction*

[10] Two competing principles of claim construction are at issue in this case. One principle, advanced by plaintiffs, is that the court should not import additional limitations from the specification or the prosecution history unless the language of the claims, themselves, invites such analysis. *See* Johnson Worldwide, 175 F.3d at 989-90. As discussed above, *Johnson Worldwide* teaches that it is proper to introduce additional limitations into the plain meaning of claim terms only when the patentee is acting as its own lexicographer, or when the claim terms chosen by the patentee deprive the claim of clarity and provide no means for determining the scope of the claims. *Id*.

On the other hand, patent claims should not be construed to cover embodiments that are not supported by the specification. *See* Wang, 197 F.3d at 1383. Although it is generally improper to limit the scope of the claims to a preferred embodiment, *see* Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1303 (Fed.Cir.1997), claims should not be construed to encompass embodiments beyond those that are described and enabled in the specification. *See* Wang, 197 F.3d at 1382; *see also* Modine Manufacturing Co. v. U.S. International Trade Commission, 75 F.3d 1545, 1551 (Fed.Cir.1996) ("[W]hen the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment"). To determine whether the claims encompass art that is not supported by the specification, it is proper to look to the specification and the prosecution history to determine the scope of the invention. *See* Wang, 197 F.3d at 1383 ("Whether an invention is fairly claimed more broadly than the 'preferred embodiment' in the specification is a question specific to the content of the specification, the context in which the embodiment is described, the prosecution history, and if appropriate, the prior art, for claims should be construed, when feasible, to sustain their validity").

The crux of the present dispute is whether the specification describes an unpleated implant which is "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect." Plaintiffs note that the specification states that "[i]n another embodiment of the invention, a filler body is positioned in a mesh cone and packs the implant when the plug is compressed by placement in the narrow hernia opening, providing the bulkiness believed to be essential for non-recurrent repair of abdominal wall hernias." Although the quoted embodiment is not limited to a pleated implant, this embodiment does not describe that the implant should be "extremely pliable." The specification does use the term "extremely pliable," as it states on two occasions that "[t]he pleated surface is extremely pliable." While the specification describes plugs that are extremely pliable, it does so only in the context of pleated plugs. Thus, the specification does not provide support for an unpleated plug that is "extremely pliable,

allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect."

Bard amended claim 20 to include the limitation "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect" in order to distinguish the present invention from Trabucco. Bard amended claim 20 in this fashion after the examiner had rejected claim 20 in light of Trabucco, and after the examiner suggested adding the claim term "means for conforming." In support of his suggestion, the examiner referred to Col. 4, lines 44-48 of the specification, which specifies pleats as the structure that renders the implant "extremely pliable." After Bard made its final amendment to claim 20, the examiner appeared satisfied that Bard had added a "means for conforming" limitation, as he stated in his Notice of Intent to Issue Reexamination Certificate that "[c]laims 19 and 20 set forth a means for conforming which renders the hollow plug extremely pliable."

Bard argues that the added limitation, "said hollow plug being extremely pliable," is a structural limitation that, by itself, served to distinguish the claimed invention from Trabucco. However, as noted above, the specification does not describe how to make a plug that is extremely pliable, other than to say that the plug should be pleated. There is no basis to conclude that the term "extremely pliable" is a distinct structural limitation that is supported by the specification. The court finds that it is unlikely that the examiner found the "extremely pliable" language to be a structural limitation that distinguished Bard's invention from Trabucco.

The court finds that the best reading of the prosecution history is that the examiner found Bard's "extremely pliable" limitation to represent a "means for conforming." The court finds that the examiner would not have allowed claim 20 but for his conclusion that the claim sets forth "a means for conforming which renders the hollow plug extremely pliable such that localized portions can adapt to irregularities in the tissue of muscle wall defect," as he stated in his Notice of Intent to Issue Reexamination Certificate. Because the examiner accompanied his suggested amendment with a reference to Col. 4, lines 44-48 of the specification, which recites pleats as rendering the plug "extremely pliable," the court finds that the "means for conforming" refers to pleats.

Although claim 20 is not written in traditional means-plus-function format, the court finds that the claim language is sufficiently lacking in structural elements that it is proper to invoke s. 112 para. 6. As described above, the term "extremely pliable" is not a structural term that is supportedby the specification. When this term is disregarded, claim 20 has no additional structure beyond that of claim 19, which the parties acknowledge is written in functional language.

The court does not find that the doctrine of claim differentiation, as advocated by plaintiffs, bars interpretation of claim 20 in means-plus-function format. It appears that, when claim 20 is read in a means-plus-function format, claims 19 and 20 refer to the same structure. While claim differentiation is a useful canon of claim construction, the court finds that the language of the claims and the prosecution history provide adequate justification for interpreting claim 20 under s. 112 para. 6.

The court recognizes that the Federal Circuit has cautioned against reading examiners' statements into the scope of claims. *See* Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1556 (Fed.Cir.1997), *abrogated on other grounds,* Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1454-55 (Fed.Cir.1998). In *Eastman Kodak,* the patent examiner during a Reexamination Proceedings Interview Summary wrote that a set of conditions recited in a crystallization procedure referred to "further crystallization" as opposed to "initial crystallization." The Federal Circuit affirmed the trial court's decision to exclude the "further crystallization" limitation from the claims, as to do so would improperly use prosecution history statements to vary the meaning of the claims. The present case is distinguishable from *Eastman Kodak* because the examiner's statements in this case were made in his Notice of Intent to Issue Reexamination Certificate, wherein he gave his interpretation as to why claim 20 was allowable. There is no

indication in *Eastman Kodak* that the examiner's remarks were determinative of the meaning of the disputed claim.

Because the court is satisfied that the prosecution history of the '432 patent in the United States demonstrates that claim 20 should be limited to a pleated structure, the court will not consider the arguments raised by U.S. Surgical concerning Bard's foreign patent filings.

The court finds that the claim term "surface of said hollow plug being conformable" requires pre-formed pleats which render the plug "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect."

D. ***Claim 21***

1. " ***detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis*** **"**

The parties dispute the proper construction of one element of claim 21, which recites "detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis." Plaintiffs propose a plain meaning construction of the term, arguing that it should be construed as "detaching one or more of the inner mesh petals so that the plug is less stiff." U.S. Surgical makes three arguments regarding the construction of this claim limitation. First, it argues that "detaching" the petals means "removing" the petals, and does not mean "trimming" the petals. Second, it argues that "detaching" means removing after implanting. Third, it argues that "stiffness" does not mean "bulk."

a. ***removing or trimming***

[11] U.S. Surgical argues that "detaching" the petals does not mean trimming or snipping a portion of the petals. U.S. Surgical notes that the claim language recites detaching "one or more" petals. Moreover, the specification recites that the stiffness of the compressed plug "may be adjusted by snipping off individual leaves of the filler body if the surgeon determines that the implant otherwise will become too tightly packed." U.S. Surgical argues that the specification and the claim language show that the recited "detaching" is of the individual, full petals, and does not mean merely trimming or snipping a portion of those petals.

Plaintiffs do not advance a particular construction of the term "detaching." In oral argument, plaintiffs stated that, in practice, surgeons snip all or substantially all of the petal from near its base.

The language of claim 21 is explicitly directed to the "detaching of one or more petals." The written description of the invention, similarly, refers to "snipping off individual leaves of the filler body." Because the examiner allowed claim 21 (claim 22 of the application) as it appeared in the initial application, the prosecution history gives no additional context for the meaning of this claim term. The court finds that the claim language and specification, on their face, limit the literal scope of the claim to the detaching of one or more entire petals. The court finds that trimming a portion of the petals is not covered by the literal scope of claim 21. Trimming the petals may raise issues under the doctrine of equivalents. Because claim 21 already contains the language, "detaching one or more petals," the court will adopt the existing claim language as the court's construction of this claim.

b. ***sequence of events***

[12] U.S. Surgical argues that claim 21 covers only those surgical methods that involve performing the claimed steps in the order in which they are listed in the claim. *See* MHB Industries Corp. v. Dennis Garberg & Associates, Inc., 1996 WL 461592, at (D.Mass. July 25, 1996) ("Ordinarily, the recitation of steps in sequence suggests strongly that the steps are to be taken chronologically in the order described").

U.S. Surgical notes that claim 21 recites the step of detaching the petals after reciting the step of "placing the plug in the defect so that the plug compresses into the second configuration." U.S. Surgical also points out that the specification teaches that "[t]he stiffness of the *compressed* plug may be adjusted by snipping off individual leaves [i.e., petals] of the inner filler body if the surgeon determines that the implant otherwise will become too tightly packed" (emphasis added).

Plaintiffs contend that the order of the steps listed in the claim has no particular significance. Plaintiffs argue that only when the nature of the invention, or the language of the claims, dictates that the steps be practiced in order should the scope of the claim be restricted to the stated sequence. *See* Depuy Orthopaedics Inc. v. Androphy, 53 U.S.P.Q.2d 1941, 1957 (N.D.Ill.2000) ("The general rule is that unless the literal language or physical constraints of the process claim dictate otherwise, the steps of the claim have no required order of performance"). Plaintiffs state that a surgeon might elect to snip the petals from the implant once it has been inserted into the patient, or might choose to remove the petals prior to implanting it. Plaintiffs argue that either procedure should be covered by the patent.

The court finds that there is no particular significance to the order in which the implanting and detaching steps appear in claim 21. The specification states that "the stiffness of the compressed plug *may* be adjusted" by snipping the leaves after insertion. (emphasis added). The specification does not require that the detaching step follow the insertion step. The court declines to find that "detaching" refers to removing the petals after implantation of the device.

c. *stiffness or bulk*

[13] U.S. Surgical contends that the limitation "detaching one or more petals from the inner filler body to vary the stiffness of the implantable prosthesis" should not be construed to read on a procedure wherein the petals are removed to vary the bulk of the implant. U.S. Surgical contends that, throughout the specification, Bard ascribed distinct meanings to the terms "stiffness" and "bulk." The specification states:

A filler body contained within the plug imparts bulk to the device, improving its handling characteristics. The filler also stiffens the implant when it is compressed within the rupture, ensuring a snug fit of the implant against the tissue or wall structure defining the defect.

U.S. Surgical argues that stiffness means resistance to deformation, and does not mean bulk.

Plaintiffs argue that the specification shows that stiffness and bulk are directly and inherently related. The specification states that "[t]he stiffness and bulkiness believed to be important for a secure repair is provided by the inner filler bodies," and that "additional filler bodies may be provided for applications requiring increased stiffness and bulkiness of the implant." Plaintiffs contend that detaching one or more of the petals not only reduces the total bulk of the prosthesis, but also reduces its resistance to compression, i.e., its stiffness.

U.S. Surgical does not indicate how a surgeon could remove petals without varying both the bulk and the stiffness of the device. For this reason, the court declines to adopt U.S. Surgical's limitation of the "stiffness" term of claim 21.

III. *CONCLUSION*

In summary, the court will adopt the existing wording of the claims, except that the following constructions shall apply:

In claim 20, the limitation "constructed and arranged to securely fit within and occlude the tissue or muscle

wall defect" shall be construed to mean "which is constructed and arranged to securely fit within, and fill or close up, the hole in the tissue or muscle wall."

In claim 20, the claim term "surface of said hollow plug being conformable" requires pre-formed pleats which render the plug "extremely pliable, allowing localized portions of the hollow plug to adapt to irregularities in the tissue or muscle wall defect."

In claim 21, the limitation "providing an implantable prosthesis including a plug formed of a surgical mesh fabric which is compressible from a first configuration which is larger than the defect into a second configuration which approximates the shape of the defect so that the plug securely fits therein and occludes the defect" shall be construed to mean "using a plug formed of surgical mesh that can be compressed from a configuration that is larger than the defect or hole into a second configuration that approximates the shape of the hole, so that the plug fits into and plugs up the hole."

D.Del.,2000.
C.R. Bard, Inc. v. United States Surgical Corp.