

United States Court of Appeals for the Federal Circuit

REGENTS OF THE UNIVERSITY OF MINNESOTA,
Plaintiff-Appellant,

v.

AGA MEDICAL CORPORATION,
Defendant-Appellee.

2012-1167

Appeal from the United States District Court for the
District of Minnesota in No. 07-CV-4732, Judge Patrick J.
Schiltz.

Decided: June 3, 2013

KEVIN D. CONNEELY, Leonard, Street and Deinard
Professional Association, of Minneapolis, Minnesota,
argued for the plaintiff-appellant. With him on the brief
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MOERKE.

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nesota, argued for defendant-appellee. With him on the
brief were ALAN G. CARLSON, R.J. ZAYED, and TARA C.
NORGARD.

Before RADER, *Chief Judge*, and DYK and WALLACH,
Circuit Judges.

DYK, *Circuit Judge*.

Appellant Regents of the University of Minnesota (“the University”) owns U.S. Patent No. 6,077,281 (“the ’281 patent”) and U.S. Patent No. 6,077,291 (“the ’291 patent”), which are directed to medical devices for repairing heart defects. The University accused AGA Medical Corporation (“AGA”) of infringing both patents. After claim construction, the district court granted summary judgment that the ’291 patent was not infringed and that the asserted claims of the ’281 patent were invalid as anticipated. The University appeals, arguing that the district court erred in its construction of the claims of the ’291 patent, and in finding the ’281 patent anticipated by a prior art device. We affirm.

BACKGROUND

The ’291 and ’281 patents are directed toward “septal occluders,” which are medical devices used to block holes in a thin wall of muscle and tissue (a “septum”) dividing two chambers of the heart. “Transcatheter” septal occluders can be delivered to the heart and positioned in a septal defect using a catheter threaded through a vein. In 1975, King and Mills received a patent on the first transcatheter septal occluder (“the King device”). U.S. Pat. No. 3,874,388 (filed Feb. 12, 1973).

In 1992, the University filed Patent Application No. 07/822,951 (“the ’951 application”) claiming a transcatheter septal occluder invented by Dr. Gladwin Das. Four patents eventually issued from successive divisions of the ’951 application, including U.S. Patent No. 5,334,217 (“the ’217 patent”), issued in April 1994, another patent not at issue here, and the ’291 and ’281 patents, which were both issued in June 2000. The patents have different claims,

but generally share the same specification. The “Summary of the Invention” explains that the claimed device has “first and second occluding disks which are attached to one another” centrally. ’291 patent col. 3 ll. 7–8; ’281 patent col. 3 ll. 11–12. Each disk comprises a membrane and a frame, and can be “collapsed” to fit in a catheter. ’291 patent col. 3 ll. 8–12. The device is delivered through the catheter to the heart, where it is positioned with one disk on each side of the defective septum. As the catheter is withdrawn, the disks expand, covering both sides of the defective septum and blocking the hole. *See id.* at col. 3 ll. 10–14. The patents’ shared specification acknowledges prior art septal occluders with expandable membranes, including the patented King device and a device described in an article by Dr. James Lock (“the Lock device”). The Lock and King devices both have “umbrella-like” structures mounted on radial frames. The specification of the patents-in-suit disparages prior art radial frame devices as “mechanically complex and requir[ing] a great deal of remote manipulation for deployment,” ’291 patent col. 2 ll. 44–45; ’281 patent col. 2 ll. 48–49, and because the “single point or pivot” connecting the two umbrella structures can drift within the septal defect, allowing the device to become decentered. ’291 patent col. 2 ll. 52–56; ’281 patent col. 2 ll. 56–60.

In 2007, the University filed suit against AGA, alleging infringement of the ’291 and ’281 patents. AGA’s accused septal occluders are one-piece devices made from tubes of wire mesh. The mesh is molded into a preset shape with two large flat regions separated by a narrow waist. The device can be compressed into an elongated shape to fit in a catheter. Upon deployment from the catheter inside the heart, the device spontaneously springs back to the preset shape and blocks the septal defect.

At the parties’ request, the district court held a *Markman* hearing and construed various disputed terms

in the '291 and '281 patents. *See Regents of the Univ. of Minn. v. AGA Med. Corp.*, 660 F. Supp. 2d 1037 (D. Minn. 2009). In January 2011, the court partially granted AGA's motion for summary judgment of non-infringement, ruling that no reasonable jury could find that AGA's one-piece mesh device infringed the '291 patent. *Regents of the Univ. of Minn. v. AGA Med. Corp.*, No. 07-CV-4732, 2011 WL 13943, at *9, *15–16 (D. Minn. Jan. 4, 2011). In December 2011, the court granted AGA's motion for summary judgment of invalidity with respect to asserted claims 1, 4, and 5 of the '281 patent, *Regents of the Univ. of Minn. v. AGA Med. Corp.*, 835 F. Supp. 2d 711 (D. Minn. 2011), finding that all three claims were anticipated by the prior art Lock device, *id.* at 723–26.¹ The district court dismissed AGA's remaining counter-claims as moot. *Id.* at 713–14.² The University timely appealed, and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1). Although the patents in this case are relat-

¹ AGA had also requested ex parte reexamination of claims 1, 4 and 5 of the '281 patent. In 2011, the Patent and Trademark Office ("PTO") examiner issued a final office action rejecting all three claims as anticipated by King and Lock. *See Office Action in Ex Parte Reexamination*, No. 90/011,290 (PTO June 27, 2011). An appeal of the final office action is pending before the Patent Trial and Appeal Board. *See Order Withdrawing Remand and Re-Docketing Appeal*, PTAB Appeal No. 2012-010628 (PTAB Dec. 7, 2012).

² The district court also determined that the '281 patent was invalid because claim 1, the only independent claim, was indefinite. *Regents*, 835 F. Supp. 2d at 730–31. Because we agree that the asserted claims of the '281 patent are invalid as anticipated, we do not reach the question of indefiniteness.

ed, they present distinct legal issues on appeal, so we discuss them separately.

DISCUSSION

I. The '291 Patent

A. Claim construction

The dispute as to the '291 patent turns almost entirely on claim construction. Claim construction is a question of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996), which we review without deference, *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454–55 (Fed. Cir. 1998) (en banc).

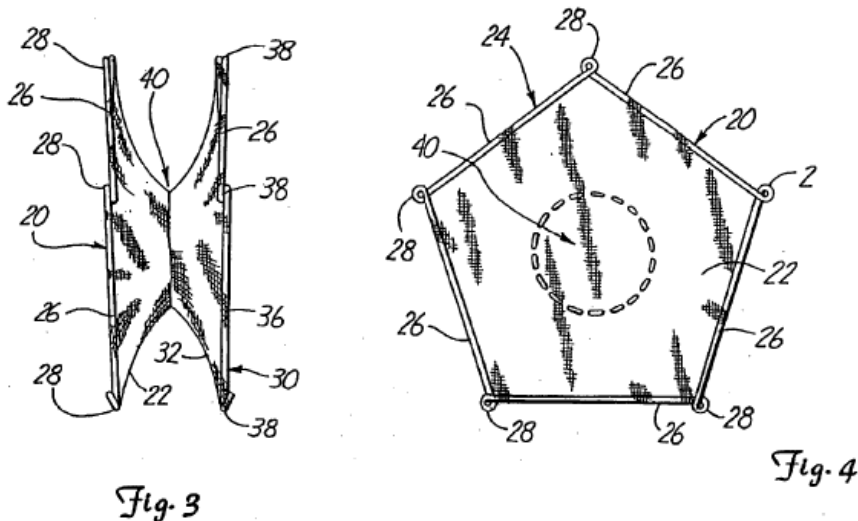
Representative claim 1 of the '291 patent describes a septal occluder with two occluding disks “affixed” to one another at their centers, to “define a conjoint disk”:

1. A septal defect closure device *comprising first and second occluding disks*, each disk comprising a flexible, biologically compatible membrane capable of being collapsed for passage through a catheter and elastically returning to a predetermined shape for tautly holding a portion of the membrane against a septum; *a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a conjoint disk*

'291 patent col. 17 ll. 54–61 (emphases added).

As shown in Figures 3 and 4, a preferred embodiment of the claimed invention comprises two membrane disks (20, 30), each having a jointed pentagonal frame (24) “attached to and desirably extend[ing] substantially around the periphery of the membrane.” '291 patent col. 5 ll. 5–6. The flexible frames can be compressed to allow the device to pass through a catheter for delivery to the heart. As the catheter is withdrawn and the device is

released, the frames expand to pull the membrane disks taut. Figure 3 depicts a side view of the device with the two membrane disks fully expanded (22, 32) and the smaller “conjoint disk” (40) between them:



'291 patent figs. 3,4. Figure 4 illustrates how, in this preferred embodiment, the two membrane disks are “sewn to one another . . . with the stitching defining the shape and size of the conjoint disk” (40). '291 patent col. 7 ll. 55–57. An appropriately sized conjoint disk is positioned inside the septal defect, while the expanded frames (which are larger than the defect) rest against either side of the septum to hold the device in place.

With respect to the '291 patent, one issue of claim construction is disputed on appeal: whether the district court correctly construed the patent to require two discrete disks. All independent claims of the '291 patent relate to a device with “first and second disks” or “first and second occluding disks.” *Regents*, 660 F. Supp. 2d at 1042. The two disks are described as “affixed” (claims 1,

4, 23, 24, 30), “joined” (claims 17, 24, 25), or “connected” (claim 28) to one another, forming a “conjoint” structure (claims 1–5, 9, 11, 12, 14, 15, 23, 25–27). As the district court noted, “[t]he parties . . . agreed to treat the terms ‘affixed,’ ‘joined,’ and ‘connected’ as essentially synonymous.” *Id.* at 1041. Nor does either party dispute that throughout the ’291 patent, the term “conjoint” is used to denote the affixed, joined, or connected portions of the disks. The district court concluded that “a person of ordinary skill in the art . . . would read the ’291 patent as covering only a device made up of two physically separate disks that are attached to one another,” and therefore construed the phrase “first and second [occluding] disks” to mean “physically distinct and separate disks.” *Id.* at 1045. The court reasoned that “one does not ordinarily speak of the parts of a unitary structure as being ‘affixed’ or ‘joined’ or ‘connected’ to each other,” *id.* at 1044, and concluded that this “clear implication . . . should be made explicit” in its claim construction by requiring that the disks had been originally separate, *id.* at 1043. The court “reached this decision in part based on how the phrase ‘conjoint disk’ is used throughout the patent,” that is, to describe a structure formed by affixing, joining, or connecting the two disks. *Id.* at 1044; *see also id.* at 1056. A subsequent order elaborated that “[t]he word ‘disks’ in the phrases ‘first and second occluding disks’ and ‘first and second disks’ means ‘disks that, before being affixed, joined, or connected, exist separately as individual, physically distinct disks.’” *Regents*, 2011 WL 13943, at *2. It is undisputed that this construction excludes AGA’s device, which is molded from a single tubular piece of mesh.

On appeal, the University argues that the district court’s construction improperly imported limitations from outside the claims, and is unsupported by the specification or prosecution history. We disagree.

The claim language fully supports a requirement of separateness. Independent claim 1 explains that the

“conjoint disk” is formed by “affix[ing]” the membranes of the “first and second occluding disks” to one another. ’291 patent col. 17 ll. 54–64. Dependent method claim 23 describes the occluder as having “a central portion of the flexible structure of the first disk being affixed directly to a central portion of the flexible structure of the second disk to define [a] conjoint disk.” *Id.* at col. 19 ll. 16–19. Both dependent claims 11 and 12 describe a “conjoint disk” “compris[ing] a piece of another material *disposed between* the first and second disks,” further supporting the conclusion that the two disks must be discrete structures.³ *Id.* at col. 18 ll. 23–29.

The separateness requirement is also fully supported by the specification, which is “the single best guide to the meaning of a disputed term.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). The ’291 specification never teaches an embodiment constructed as a single piece. Quite the opposite: “every single embodiment disclosed in the ’291 patent’s drawings and its written description is made up of two separate disks.” *Regents*, 660 F. Supp. 2d at 1044. The ’291 patent explains that

[t]he present invention provides a simple, reliable device for effectively occluding a septal defect. The instant closure device includes first and second occluding disks which are attached to one another. . . . A central portion of the membrane of each disk is affixed to a corresponding portion of the mem-

³ Although the University suggests that language in unasserted claims is not relevant, our precedent establishes that “both asserted and unasserted” claims are valuable to “illuminate the meaning of the same term in other claims.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc).

brane of the other disk, thereby attaching the two disks directly to one another at their centers. The affixed central portion of the two membranes define[] a central “conjoint disk” of the device

'291 patent col. 3 ll. 5–20. “When a patent thus describes the features of the ‘present invention’ as a whole, this description limits the scope of the invention.” *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007); *see also TiVo, Inc. v. EchoStar Commc’ns Corp.*, 516 F.3d 1290, 1300 (Fed. Cir. 2008).

The specification discloses various methods of affixing the two disks to one another, including gluing, bonding, fusing, and sewing. It warns that “[t]he adhesion between the two central membrane portions should be strong enough to ensure that the two disks will not become separated from one another,” ’291 patent col. 7 ll. 50–53, indicating that the membrane disks forming the conjoint disk are structurally distinct (and thus prone to “separate,” rather than “tear”). All conjoint disks described or pictured in the specification are structurally consistent with two discrete surfaces adhered together in various ways. *See, e.g.*, ’291 patent fig.12; col. 9 ll. 15–20; col. 7 ll. 62–66; col. 8 ll. 60–63. Moreover, the specification discloses that “the conjoint disk may include another piece of material” that is “desirably disposed between the two membranes and sewn or otherwise bonded to the two membranes in defining the conjoint disk”—a configuration that can only make sense if the disk membranes are separate, physically distinct structures. ’291 patent col. 7 ll. 62–67. In other words, a device formed by attaching two disks together “is not just the preferred embodiment of the invention; it is the *only* one described.” *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed. Cir. 1996).

The district court’s construction is further buttressed by the prosecution history. During the prosecution of the

'951 application, the predecessor to the '291 patent,⁴ the PTO examiner rejected the relevant claims as anticipated by King's prior art septal occluder, which also possessed two flexible occluding disks. The King device comprised two membranes supported by umbrella-like radial frames, which were individually delivered through a catheter. Once inside the heart, they were connected at a central "hub," and the umbrellas were opened to block the septal defect. J.A. 1671. The University, in its response to the PTO's office action, argued that King's umbrella-like structures had to be "attached to one another after they are deployed in a patient's beating heart" using a "complex multi-component hub," while the "two disks" of the University's device, "each formed of a membrane and a frame," were advantageously assembled prior to insertion in the catheter, and the assembly was simplified by "attach[ing] the membranes of the two disks essentially directly to one another" to form a "conjoint disk." J.A. 1706–08.

Although the '951 application was abandoned, a division of that application produced the predecessor '217 patent. Like the '951 application, the '217 patent requires "a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a central conjoint disk," '217 patent col. 18 ll. 37–39; J.A. 5227, which is claim language substantially identical to that of the '291 patent. The Examiner's Supplemental Notice of Allowability indicated that "[t]he

⁴ The '291 patent issued from Application No. 08/756,776 (filed Nov. 26, 1996), which is a division of Application No. 08/284,766 (filed Aug. 2, 1994) (issued as U.S. Pat. No. 5,578,045), which is a division of Application No. 08/062,095 (filed May 14, 1993) (issued as U.S. Pat. No. 5,334,217), which is a division of Application No. 07/822,951 (filed Jan. 21, 1992) ("the '951 application"). The '951 application was abandoned.

primary reason for the allowance of the [’217 patent’s] claims [wa]s the inclusion, in all the claims, of the limitation that . . . *a first membrane is connected to a central portion of a second membrane* to form a conjoint disk.” J.A. 5274 (emphasis added).⁵ Thus, the prosecution history supports the district court’s construction of the claims.

Finally, the district court’s construction is faithful to the ordinary meaning of the language of claim 1. According to dictionaries predating the 1996 filing of the ’291 patent, the word “affix” means:

1. to fasten, join or attach (usually fol. by to): *to affix stamps to a letter.*
2. to put or add on; append: *to affix a signature to a contract.*
3. to impress (a seal or stamp).
4. to attach (blame, reproach, ridicule, etc.).

⁵ During prosecution of the European counterpart to the patents-in-suit, the University distinguished a prior art Russian device by asserting that a device “made in one piece with a *tubular* part . . . does not comprise two disks with a central portion of a first disk being affixed to a central portion of the second disk.” *Regents*, 660 F. Supp. 2d at 1045. The University contends that its position on appeal is not inconsistent with those representations, because “[i]t was the absence of occluding disks joined (i.e., affixed) in the area of their respective central portions—not the unitary or non-unitary construction . . . that was being discussed.” Appellant’s Br. 29. While we do not find it necessary to rely on the European proceedings, the position taken by the University in those proceedings only supports the conclusion that, as a matter of common sense, a device defined as two disks affixed together to form a conjoint disk cannot also be a one-piece, tubular structure.

Random House Unabridged Dictionary 34 (2d ed. 1993),
or:

1: to attach physically (as by nails or glue):
FASTEN . . . 2: to attach in any way: connect
with: ADD, SUBJOIN . . . 3: IMPRESS

Webster's Third New International Dictionary 36 (1993).
The ordinary meaning of "conjoint" is "joined together;
united; combined; associated," or "pertaining to or *formed
by two or more in combination; joint,*" *Random House
Unabridged Dictionary* 430 (emphasis added), and accord-
ing to the note on synonyms of "join" in Webster's Third,
"CONJOIN usu[ally] emphasizes both the togetherness of
a joining *and the separateness of the things joined.*"
Webster's Third New International Dictionary 1219 (em-
phasis added). As further explained by Webster's Third,

[a]lthough they are used to signify a more specific
union, LINK, CONNECT, JOIN, and CONJOIN
in their nonphysical application may suggest a
bringing or coming together as general and un-
specified as that implied by RELATE or
ASSOCIATE but tend more, *esp[ecially] in physi-
cal application, to signify a junction of some kind,*
often an inseparable junction as by a chain or by
bonding. CONNECT is the most general of these
four and suggests a loose attachment, *esp[ecially]
one that preserves the identity of the elements and
the evidence of the connection . . .* LINK suggests a
slightly closer coupling[,] *esp[ecially] in the physi-
cal application of the word in which is implied in-
separability but of still clearly identifiably
separate elements . . .* JOIN usu[ally] suggests
strongly the idea of physical or moral contact or
junction or the making of *a continuity of two or
more things*

Id. (emphases added). The dictionary definitions support
the conclusion that when a physical object is described as

having been “affixed,” “joined,” “connected,” or “conjoin[ed]” to another object, it means that those objects were previously separate.

The University argues that the district court improperly imported process limitations into the construed claims. We disagree. Words like “affixed” or “conjoint,” which when “read in context, describe[] the product more by its structure than by the process used to obtain it,” are product limitations, not process limitations, *see, e.g., Hazani v. U.S. Int’l Trade Comm’n*, 126 F.3d 1473, 1479 (Fed. Cir. 1997) (citing *In re Moore*, 439 F.2d 1232, 1236 (CCPA 1971)), and are “commonly and by default interpreted in their structural sense,” *3M Innovative Prods. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003); *see also In re Garner*, 412 F.2d 276, 278–79 (CCPA 1969) (“[I]ntermixed,’ ‘ground in place,’ ‘press fitted,’ ‘etched,’ and ‘welded,’ all . . . at one time or another have been separately held capable of construction as structural, rather than process, limitations.”). When a patentee chooses to use these words, they should be given their ordinary meanings with respect to the claimed product’s structure. *See, e.g., Vanguard Prods. Corp. v. Parker Hannefin Corp.*, 234 F.3d 1370, 1372–73 (Fed. Cir. 2000); *Hazani*, 126 F.3d at 1479. In *Miken Composites, L.L.C. v. Wilson Sporting Goods Co.*, 515 F.3d 1331, 1337 (Fed. Cir. 2008), we rejected the patentee’s contention that the district court impermissibly imported a process limitation into a product claim, concluding that the ordinary meaning of the word “insert” required a particular relationship between the “insert” and a surrounding frame:

To contend . . . that it does not matter whether an insert is placed into a pre-existing frame or whether a frame is built around it ignores that ordinary and customary meaning. . . . As for [the patentee’s] contention that the district court impermissibly imported a process limitation into a

product claim, we disagree. As we have discussed, the district court merely adopted an ordinary meaning of the term ‘insert.’

Id. Similarly, in *Vanguard*, we “agree[d] with the district court that the word ‘integral’ describes the relationship between the elastomeric layers, not the means of joining them,” and held that “‘integral’ is used here in its ordinary sense to mean formed as a unit with another part,” because “the term was used to describe the product, and not as a designation of a specific manufacturing process.” 234 F.3d at 1371–72. Our reading of the ’291 patent is fully consistent with the approach used in our previous cases.

In sum, the ’291 patent’s claims “consistently use the term[s]” affixed and conjoint “in the sense of [their] ordinary meaning[s],” *Miken*, 515 F.3d at 1337, indicating that the disks are discrete structures. The specification, “the single best guide to the meaning of a disputed term,” *Vitronics*, 90 F.3d at 1582, “comports with the plain language of the claims, fully supporting the conclusion” that the disks are separate, *see Becton, Dickinson & Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1255 (Fed. Cir. 2010). Finally, the prosecution history shows that the University described the innovative aspect of the claimed device as an improved way of connecting the two disks. We conclude that the district court properly construed the ’291 patent as requiring two physically separate disks.

B. Infringement

On appeal, the University argues that AGA’s mesh tube devices infringe even under the district court’s claim construction, because AGA’s sales literature describes them as having two “disks.” However, AGA’s sales descriptions neither expand the ’291 patent nor bring AGA’s device within its scope. It is undisputed that AGA’s accused occluders are not constructed from two physically separate disks. *Regents*, 2011 WL 13943, at *9. AGA’s

devices are made from lengths of mesh tubing; the tubing is molded into two flattened end portions separated by a narrow waist. The wires of the mesh run continuously from one end of the device to the other. At no point are two halves of the tube “affixed” to one another, and no structure resembling a “conjoint disk” is present between them. The district court thus correctly determined that no reasonable jury could find that AGA’s devices infringe the ’291 patent. *Id.* We therefore affirm the district court’s grant of summary judgment of non-infringement to AGA with respect to the ’291 patent.

II. The ’281 Patent

Like the ’291 patent, the ’281 patent is directed to a transcatheter septal occluder device. Claim 1 of the ’281 patent describes the device as comprising two “members,” each having a “self-expanding structure”:

1. A septal defect closure device *comprising a first member and a second member each comprising a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation for passage through a medical instrument having an inner diameter and an expanded orientation having an enlarged diameter for tautly holding at least a portion of the closure device against a septum, the enlarged diameter of the member being greater than the inner diameter of the medical instrument; each of the first and second members also including a central portion, at least a substantial portion of the central portion of the second member being in communication with at least a substantial portion of the central portion of the first member.*

’281 patent col. 18 ll. 11–24 (emphases added). The specifications of the two patents are generally the same, including the description of the preferred embodiment

with a jointed wire frame, which was discussed above. See '281 patent figs. 3, 4.

The district court held that the '281 claims' reference to "members" did not require separateness, and thus a reasonable jury could conclude the claims were infringed by AGA's devices. *Regents*, 2011 WL 13943, at *9. However, the court held that the asserted claims of the '281 patent were anticipated. *Regents*, 835 F. Supp. 2d at 723–26. Like an infringement analysis, an anticipation analysis has two parts: first, the disputed claim terms are construed, then the construed claims are compared to the prior art. *In re Aoyama*, 656 F.3d 1293, 1296 (Fed. Cir. 2011). A patented invention is anticipated by a prior art reference if that reference discloses all elements of the claimed invention, including means-plus-function structures or their equivalents. See, e.g., *Kegel Co. v. AMF Bowling*, 127 F.3d 1420, 1430 (Fed. Cir. 1997). "While anticipation is a question of fact, 'it may be decided on summary judgment if the record reveals no genuine dispute of material fact,'" a decision that we review de novo. *Leggett & Platt, Inc. v. VUTEk, Inc.*, 537 F.3d 1349, 1352 (Fed. Cir. 2008) (quoting *Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1321 (Fed. Cir. 2008)). Whether the prosecution history imposes a limitation on the range of equivalents is a legal determination reviewed de novo. *J&M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1366 (Fed. Cir. 2001).

In this case, the question is whether the prior art device described in the Lock article anticipated claims 1, 4, and 5 of the '281 patent. Independent claim 1, set forth in full above, states in relevant part:

1. A septal defect closure device *comprising a first member and a second member each comprising a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation . . . and an ex-*

panded orientation . . . , at least a substantial portion of the central portion of the second member being in communication with at least a substantial portion of the central portion of the first member.

'281 patent col. 18 ll. 11–24 (emphasis added). Dependent claim 4 states:

4. The device of claim 1, wherein the first member in its compressed orientation extends primarily distally from the second member and the second member in its compressed orientation extends primarily proximally from the first member, each member in its expanded orientation extending primarily radially outward from its central portion.

Id. at col. 18 ll. 31–36. Dependent claim 5 states:

5. The device of claim 1, wherein each of the first and second members comprises a flexible fabric disk.

Id. at col. 18 ll. 37–38. The district court determined that although the prior art King device anticipated claims 1 and 5, King did not satisfy claim 4, because of the orientation of its umbrella-like radial frames. *Regents*, 835 F. Supp. 2d at 717–22. However, the district court determined that all three claims were anticipated by the Lock device, which, like King, used umbrella-like radial frames. *Id.* at 723–26. The University agrees that the Lock device has all the limitations of the three asserted claims, with the exception of the following two elements: (1) a structure satisfying the means-plus-function limitation, and (2) structures “in communication with” each other, and having “at least substantial portions of the[ir] central portion[s]” in communication with one another.

A. The means-plus-function limitation

Although claim 1 of the '281 patent was not drafted in standard means-plus-function language, the court determined, and the parties now agree, that the portion reading:

a self-expanding structure exhibiting a spring-like behavioural component for moving the member between a compressed orientation . . . and an expanded orientation

is a means-plus-function element, '281 patent col. 18 ll. 11–16, with the function of “moving the member from a compressed orientation to an expanded orientation,” *Regents*, 660 F. Supp. 2d at 1051. Under section 112 ¶ 6, now recodified as 35 U.S.C. section 112(f), a means-plus-function claim limitation includes both the corresponding structures disclosed by the specification as means of performing the function, and the equivalents of those structures. *See Mettler-Toledo, Inc. v. B-Tek Scales, LLC*, 671 F.3d 1291, 1296 (Fed. Cir. 2012). Here, the district court concluded that the specification disclosed two corresponding structures: “a frameless membrane made of a thin piece of a superelastic material,” and “a flexible, elastically deformable frame carried around the periphery of the member” (the “peripheral frame structure”). *Regents*, 660 F. Supp. 2d at 1050–52. The parties do not dispute the identification of these structures.

Neither party argues that the Lock device has a frameless superelastic membrane or a peripheral frame. However, the district court concluded that Lock’s radial, umbrella-like frame was an equivalent of the peripheral frame structure in the claimed device. For purposes of section 112(f), an equivalent of the disclosed structure performs the same function as the disclosed structure, in substantially the same way, with substantially the same result. *See, e.g., JWV Enters. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1333 (Fed. Cir. 2005). AGA presented

expert evidence, accepted by the district court, that Lock’s “springy” radial frame performed the same function as the peripheral frame structure—“mov[ing] [the device] from a compressed to an expanded orientation”—in substantially the same way, with substantially the same result. *Regents*, 835 F. Supp. 2d at 720.

The University argues that the district court was wrong to treat this issue as undisputed, because there was conflicting expert testimony as to equivalence. The district court disagreed, determining that there was no conflicting expert testimony, because “on the question of equivalence, [the University’s expert] O’Laughlin . . . fail[ed] to offer any evidence or analysis.” *Id.* at 725. The district court correctly found O’Laughlin’s testimony on equivalence to be “a conclusion supported by no explanation or reasoning,” and therefore inadequate. *Id.* at 720. “Conclusory expert assertions cannot raise triable issues of material fact on summary judgment.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1001 (Fed. Cir. 2008) (citing *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1278 (Fed. Cir. 2004)).

This leads us to the University’s primary argument: that during prosecution it disclaimed the use of a radial frame as an equivalent of the peripheral frame. The University argues that this disclaimer took place during prosecution of the ’951 application, which was the predecessor to the patents-in-suit. Independent claim 1 of the ’951 application stated:

1. A septal defect closure device comprising first and second occluding disks, each disk comprising a flexible, biologically compatible membrane having a periphery, and *an elastically deformable frame carried about the periphery of the membrane. . . .*

J.A. 1625 (emphasis added). The claim did not include a means-plus-function element. The PTO examiner rejected

the claim as anticipated by King, explaining that King disclosed features including “occluding disks” and “frames carried about the periphery of the disks by sutures.” J.A. 1671.

The University criticized and distinguished King, arguing, *inter alia*, that unlike King, the claimed device did not have an umbrella-like radial frame, but rather a frame “extend[ing] along the periphery of the membrane” of each disk. J.A. 1706–08. The University also submitted an amendment which it described as expressly limiting the claim language to “a frame which extends along the periphery of the disk, something which King’s radial arms simply do not do.” J.A. 1707. The amendment replaced “carried about” with “extending along and attached adjacent to.” J.A. 1698, 1707. After the amendment, the ’951 claim language read:

1. A septal defect closure device comprising first and second occluding disks, each disk comprising a flexible, biologically compatible membrane having a periphery and *an elastically deformable frame extending along and attached adjacent to the periphery of the membrane . . .*

See J.A. 1625 (original language); J.A. 1698, 1707 (explaining the relevant substitution in language) (emphasis added). (The University and examiner apparently never discussed the Lock device in connection with any of the patents in the family, although Lock was mentioned in the specification, and at least one article describing the Lock device was before the examiner). Claim 1 was subsequently allowed.⁶

⁶ The prosecution history establishes unequivocally that the University understood the amendment to claim 1 to have effectively traversed the rejection over King. In response to the next Office Action, which rejected claims

When an applicant tells the PTO that a prior art reference lies outside the scope of his claim, he is bound by that argument. *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579–80 (Fed. Cir. 1995). In this case, no one disputes that the University effected a clear and unambiguous disclaimer of King’s radial frame with respect to the language describing the “elastically deformable frame” in amended claim 1 of the ’951 application. Nor is there any apparent dispute that the University’s disclaimer of King’s radial frame is also applicable to the similar radial frame disclosed by Lock. The question is whether the University’s disclaimer carries forward to the means-plus-function language used in claim 1 of the ’281 patent.

18 and 27 as anticipated by King, the University amended those claims in the same way as it had amended claim 1:

As noted above, applicant has . . . amended claims 18 and 27 to replace the phrase “carried about the periphery” with “extending along and attached adjacent to the periphery”. Aside from a myriad of other distinctions in the use and structure of these devices, applicant respectfully submits that the radially extending arms employed by King do not extend about the periphery of the “membrane” taught therein. Accordingly, applicant respectfully submits that these claims are readily distinguishable from King’s teachings and therefore are not anticipated by this reference.

Applicant’s Oct. 20, 1992 Response to July 20, 1992 Office Action at 25, *Regents of the Univ. of Minn. v. AGA Med. Corp.*, No. 07-CV-4732 (D. Minn. Mar. 6, 2009), ECF No. 70-25. The ’951 application was eventually abandoned, but amended claim 1 eventually issued from a division of that application as claim 1 of the ’217 patent. *See* ’217 patent col. 18 ll. 29–34.

Our law makes clear that “[j]ust as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under § 112, ¶ 6.” *Alpex Computer Corp. v. Nintendo Co.*, 102 F.3d 1214, 1221 (Fed. Cir. 1996). Thus, prosecution history disclaimer may limit the range of equivalent structures that fall within the scope of a means-plus-function limitation. *See, e.g., J&M*, 269 F.3d at 1367. We have also held that a disclaimer made during the prosecution of a patent application may operate as a disclaimer with respect to later patents of the same family. *Verizon*, 503 F.3d at 1306.

The problem for the University is that this limitation of the ’951 application was not carried forward to the ’281 patent. After the ’951 application was abandoned in 1993, successive divisions produced the ’281 patent, which issued in 2000.⁷ Over the course of four divisional applications (and seven years of prosecution) the amended claim limitations disappeared from the ’281 patent, to be replaced with the means-plus-function limitation:

1. A septal defect closure device comprising a first member and a second member each comprising *a self-expanding structure exhibiting a spring-like behavioural component for moving the member be-*

⁷ The ’281 patent issued from Application No. 09/271,762 (filed Apr. 22, 1999), which is a division of Application No. 08/756,776 (filed Nov. 26, 1996), which is a division of Application No. 08/284,766 (filed Aug. 2, 1994) (issued as U.S. Pat. No. 5,578,045), which is a division of Application No. 08/062,095 (filed May 14, 1993) (issued as U.S. Pat. No. 5,334,217), which is a division of the ’951 application (filed Jan. 21, 1992).

tween a compressed orientation . . . and an expanded orientation

'281 patent col. 18 ll. 11–24 (emphasis added). There is no mention of a frame, peripheral or otherwise, in any claim of the '281 patent.

We have explained that “[w]hen the purported disclaimers [made during prosecution] are directed to specific claim terms that have been omitted or materially altered in subsequent applications (rather than to the invention itself), those disclaimers do not apply.” *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007). In general, a prosecution disclaimer will only apply to a subsequent patent if that patent contains the same claim limitation as its predecessor. *See, e.g., Ventana Med. Sys. v. Biogenix Labs., Inc.*, 473 F.3d 1173, 1182 (Fed. Cir. 2006) (“[P]rosecution disclaimer generally does not apply when the claim term in the descendent patent uses different language.”); *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005) (“[T]he prosecution of one claim term in a parent application will generally not limit different claim language in a continuation application.”); *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1383 (Fed. Cir. 2003) (“Prosecution history is irrelevant to the meaning of [a] limitation [if] the two patents do not share the same claim language.”); *Biogen, Inc. v. Berlex Labs., Inc.*, 318 F.3d 1132, 1141 (Fed. Cir. 2003) (“When the applicant is seeking different claims in a divisional application, estoppel generally does not arise from the prosecution of the parent.”).⁸

⁸ The sole exception is when the disclaimer is directed to the scope of the invention as a whole, not a particular claim. *See, e.g., Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314–15 (Fed. Cir. 2007) (the patentee’s statements “w[ere] not associated with particular language from [the] claims” but were instead directed to

Thus, our cases establish that the two patents must have the same or closely related claim limitation language. If the language of the later limitation is significantly different, the disclaimer will not apply. For example, this court recently concluded in *Digital-Vending* that an inventor's arguments with respect to certain claim limitations in a parent should not apply to significantly different claim limitations in a divisional application. *Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1277 (Fed. Cir. 2012). The court explained that "in light of the language of the later issued claims," and the fact that "the inventors never argued" that the disclaimer applied "when pursuing the divisional application that gave rise to the [patent-in-suit]," application of the disclaimer to the divisional's claims would be improper. *Id.*

Although the '281 patent's claims do not include a peripheral frame limitation, the University argues that the peripheral frame structure described in the specification satisfies the same language requirement. As amended, claim 1 of the '951 application required "an elastically deformable frame *extending along and attached adjacent to* the periphery of the membrane." See J.A. 1698 (em-

the "present invention" and the "overall method" claimed). In circumstances closely analogous to this case, this court has held that "the alleged disclaimer distinguishing the prior art focused on a particular claim limitation . . . and was not directed to the invention as a whole." *Saunders Grp.*, 492 F.3d at 1333. In this case, the University's statements and amendments were directed to specific claims pertaining to the framed embodiments, not to the overall invention. The University does not contend that its representations restricted the scope of its invention "as a whole."

phasis added). The structure corresponding to the means-plus-function limitation in claim 1 of the '281 patent has “[a] frame . . . [that] *is attached to and desirably extends substantially around* the periphery of the membrane.” ’281 patent col. 5 ll. 7–8 (emphasis added).

The University is mistaken. The proper inquiry is whether the scope of the claim limitation is substantially the same in the subsequent application as it was in the earlier application. *See, e.g., Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305 (Fed. Cir. 2001) (prosecution history may be relevant if “it addresses a limitation in common with the patent in suit”); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (“[T]he prosecution history regarding a claim limitation . . . applies with equal force to subsequently issued patents that contain the same limitation.”). In disclaiming claim coverage in light of certain prior art, the applicant does not thereby act as a lexicographer, redefining individual words. The appropriate focus is on the scope of the claim element, not the meaning of particular words in isolation. This is why our cases evaluate the similarity between the earlier and later claim limitations, carrying disclaimer forward if there are only immaterial differences, *see, e.g., Elkay*, 192 F.3d at 979–80 (carrying disclaimer forward where “[t]he relevant portion of claim 1 of the [later] patent is identical to the above-quoted limitation in claim 1 of the [first] patent,” except for a single word); *see also Invitrogen*, 429 F.3d at 1078 (amendment “to a related limitation in the parent application” is relevant to “a later (though differently worded) limitation”), and declining to extend disclaimer to a subsequent limitation that contained “materially” different claim language, *see Saunders Grp.*, 492 F.3d at 1333; *see also Medtronic*, 248 F.3d at 1315 (“[N]one of the claims of the [earlier] patent contain the same limitation that we are construing from the [later] patent,” and “[a]ccordingly, we decline . . . to consider the [earlier] patent’s prosecution

history for the purpose of construing the limitation in question.”).

Our requirement that the patents share “limitations in common” is not a mere technicality: it is necessary to support the inference that the patentee’s earlier arguments are also applicable to the claim limitations of the patent-in-suit. *See, e.g., Digital-Vending*, 672 F.3d at 1277. Without claim language that makes that linkage clear, neither the PTO examiner nor the patentee’s competitors would be on notice as to the true scope of the later patent’s claims. We have held that it is permissible for a patentee to take a different approach to claiming an invention in subsequent patents, either by adding limitations or by altering the claims’ format. When the patentee does so, however, we cannot rely on the dubious argument that dissimilar claims present equivalent issues of validity, or that the applicant’s disclaimer with respect to one claim would be equally applicable to another claim.

Here, the basis for distinguishing prior art in the second application is not the same as in the first. The amended ’951 claim language, “[a] septal defect closure device comprising first and second occluding disks, each disk comprising . . . an elastically deformable frame extending along and attached adjacent to the periphery of the membrane,” *see* J.A. 1625, 1698, 1707, was not carried over to the later application which gave rise to the ’281 patent. The later application instead used the language “[a] septal defect closure device comprising a first member and a second member each comprising a self-expanding structure,” ’281 patent col. 18 ll. 11–24, and disclosed two corresponding structures in the specification, one of which contained a peripheral frame structure. The scope of claim 1 in the second application is plainly not the same as it was in the first application, and it would be inappropriate to import the first application’s limitations into the different context of the second application. “Although statements in a file history may of course be used to

explain and potentially limit the meaning of claim limitations,” they “cannot be used to add an entirely new limitation to the claim.” *Serrano v. Telular Corp.*, 111 F.3d 1578, 1584 (Fed. Cir. 1997); *see also Markman*, 52 F.3d at 980 (“Although the prosecution history can and should be used to understand the language used in the claims, it . . . cannot ‘enlarge, diminish, or vary’ the limitations in the claims.”). It is likewise inappropriate to apply a narrowing disclaimer to limitations that are materially different from the limitation to which it originally applied.

In other words, claim 1 of the ’281 patent contains a different claim limitation than its predecessors and captures different subject matter. From the examiner’s perspective, prior art devices like King and Lock are relevant in different ways to the ’951 application’s literal “frame carried about the periphery” requirement, and the ’281 claim’s functional “self-expanding structure” requirement. During the prosecution of the first application, the University never told the PTO examiner that a radial frame was ineffective at expanding a device’s occluding disks; instead, the University criticized the King device as being too difficult to assemble and keep in position. It does not follow that the University found the radial frame unacceptable for use in performing the claimed expanding function in the redrafted ’281 patent. Thus, the original disclaimer does not carry over to limit the range of equivalents here, and does not negate the district court’s anticipation finding.⁹

⁹ The University also argues that the specification of the ’281 patent disclaims Lock’s radial frame. But the ’281 specification only expresses concern about using radial arms to hold the expanded device in place against the septum of the beating heart. It does not disavow the use of a radial frame to move the device from a compressed orientation to an expanded orientation upon deployment.

B. “In communication with” and “at least a substantial portion”

The University’s remaining two challenges to the district court’s anticipation analysis pertain to the requirement that “at least a substantial portion of the central portion of the first member” be “in communication with at least a substantial portion of the second member.” *See Regents*, 835 F. Supp. 2d at 716. The district court construed this claim to require that substantial portions of the central portions of the members communicated “movement.” *See id.* at 721. The University styles its arguments as challenges to the district court’s application of this claim construction, but they are essentially indirect objections to the claim construction itself, which the University did not raise to the district court.

First, the University contends that the district court wrongly allowed translational movement communicated between Lock’s members to satisfy the claim limitation. The University argues that the members are required to communicate expansion or contraction movement, not translational movement. But the district court correctly stated that its claim construction placed no restriction whatsoever on the type of movement required by the claim. *Id.* (“[T]he Court’s claim construction says nothing about ‘expansion or contraction movement’; it refers to ‘movement,’ plain and simple.”). We agree with the district court that the University’s interpretation of the claim limitation is inconsistent with the district court’s construction. If the University objected to that construction, it should have presented its objection and its alternative construction to the district court. But the University’s claim construction briefs, including supplemental briefs directed specifically to the phrase “in communication with,” never argued that the correct construction required a particular type of movement. The University has therefore waived any objection to this aspect of the district court’s construction, and cannot

advance a new reading of the claim language indirectly on appeal. *See, e.g., Digital-Vending*, 672 F.3d at 1273.

The University's second argument fares no better. The University's argument appears to be that the "central portion" of each member must fill the septal defect, and that Lock's hub does not satisfy this requirement. However, the plain language of the asserted claims does not support this reading, and the district court's claim construction does not require it. Despite multiple opportunities to offer briefing on this limitation, the University never objected to this aspect of the district court's construction or argued for an alternative construction including this requirement; it is therefore barred from making this argument on appeal.¹⁰ We conclude that the district court did not err in finding that the Lock device satisfied all limitations of the asserted claims.

Because the district court properly concluded that Lock anticipates the asserted claims 1, 4 and 5 of the '281 patent, we affirm the district court's grant of summary judgment of invalidity to AGA with respect to those claims.

AFFIRMED

¹⁰ The University also seems to suggest that in the Lock device, the area of attachment between the two members is too small to be a "substantial portion." But the district court rightly rejected this argument because the claim construction only requires that the members "transmit movement[]between a substantial portion of their central portions," and "a reasonable jury would have to find that [Lock's] umbrellas *communicate* (by way of their central attachment point) over a substantial portion of their central portions." *Regents*, 835 F. Supp. 2d at 726.