United States Court of Appeals for the Federal Circuit

BRUCE N. SAFFRAN, M.D., PH.D.,
Plaintiff-Appellee,

v.

JOHNSON & JOHNSON AND CORDIS CORPORATION,
Defendants-Appellants.

2012-1043

Appeal from the United States District Court for the Eastern District of Texas in No. 07-CV-0451, Judge T. John Ward.

Decided: April 4, 2013

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JENNIFER KUHN, Law Office of Jennifer Kuhn, of Austin, Texas, for amicus curiae Professor Lara A. Estroff.

Before LOURIE, MOORE, and O'MALLEY, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE, in which *Circuit Judge* MOORE joins except as to Parts II-A-2 and II-B-2, and in which *Circuit Judge* O'MALLEY joins except as to Parts II-A-1 and II-B-1.

Opinion concurring in part filed by *Circuit Judge* MOORE.

Opinion concurring in part filed by *Circuit Judge* O'MALLEY.

LOURIE, *Circuit Judge*.

Johnson & Johnson and Cordis Corporation (collectively, "Cordis") appeal from the final judgment of the

United States District Court for the Eastern District of Texas in favor of Dr. Bruce N. Saffran ("Saffran"), in which the district court held Cordis liable for infringing claims 1–3, 6, 8, 9, 11, 13, 15, and 17 of Saffran's U.S. Patent 5,653,760 (the "'760 patent"). *Saffran v. Johnson & Johnson*, No. 2:07-cv-451 (E.D. Tex. Mar. 31, 2011), ECF No. 326 ("*Final Judgment*"). We conclude that the district court erroneously construed the claims of the '760 patent and that, under the correct construction, Cordis is entitled to a judgment of noninfringement as a matter of law. Accordingly, we *reverse*.

I. BACKGROUND

Saffran is the owner and sole named inventor of the '760 patent, which is entitled "Method and Apparatus for Managing Macromolecular Distribution" and concerns "the treatment of injured tissues within human or animal bodies, specifically . . . the way injured tissues are joined and the way macromolecules are directed to promote healing." '760 patent col. 1 ll. 21–24. In particular, the '760 patent discloses methods and devices for treating injured tissues by sequestering particles and macromolecules in a defined space using a selectively permeable barrier.

The specification primarily describes the invention in terms of a strategy for treating serious bone fractures, known as complex or comminuted fractures, where the bone has been shattered into numerous fragments. In such cases, standard treatment may involve surgical intervention to align the bone fragments and affix a stabilizing device across the fracture site in order to enable new bone to form between, and eventually unite, the fragments during healing. The specification teaches that such complex fractures often heal poorly, requiring repeated operations and leading to permanent disability. *See id.* col. 1 l. 43 – col. 2 l. 16.

The specification describes several cellular and molecular processes that may influence clinical outcomes following a complex fracture. For one, cells at the site of injury secrete growth-promoting proteins (growth factors) into the interfragmentary spaces, where those proteins can, in sufficient concentrations, stimulate cellular proliferation and the assembly of a "scaffolding" matrix between fragments that serves as a prelude to new bone formation. If the local concentration of growth factors is too low, the scaffolding process does not occur—small bone fragments instead remain isolated and are eventually absorbed by the body, leaving persistent and ever-larger gaps between the major fragments. In addition, when bone growth factors diffuse away from the fracture site and into adjacent soft tissues, they can spur calcification and heterotopic bone growth within the muscles, which can permanently limit the patient's range of motion. *Id.* col. 2 ll. 17–64.

To improve the treatment of such injuries, the '760 patent discloses "a unique method of fracture stabilization and a means to restrain interfragmentary macromolecules using a single, flexible minimally porous sheet." *Id.* col. 7 ll. 34–36. For purposes of the '760 patent, substances larger than about 500 daltons[1] (*e.g.*, proteins and many drugs) are considered macromolecules. *Id.* col. 8 ll. 3–6. The single-layered sheet serves as a selective barrier that blocks macromolecules and larger particles, such as tissue fragments and cells, yet contains micropores sized to allow free passage for small molecules (*e.g.*, water). *See id.* col. 13 ll. 39–57. Other sheets might be designed to screen molecules according to properties such as ionic charge or hydrophobicity rather than size. *Id.* col. 8

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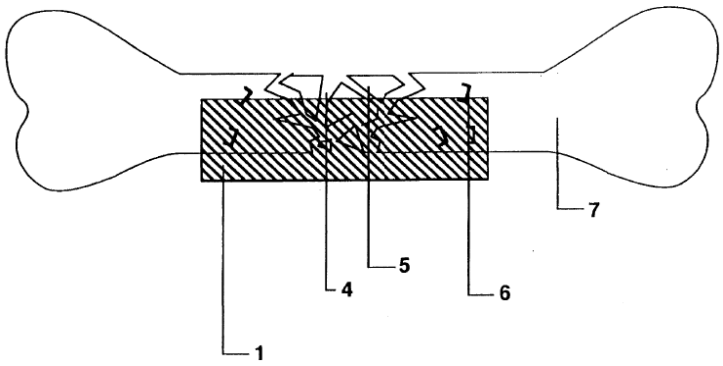
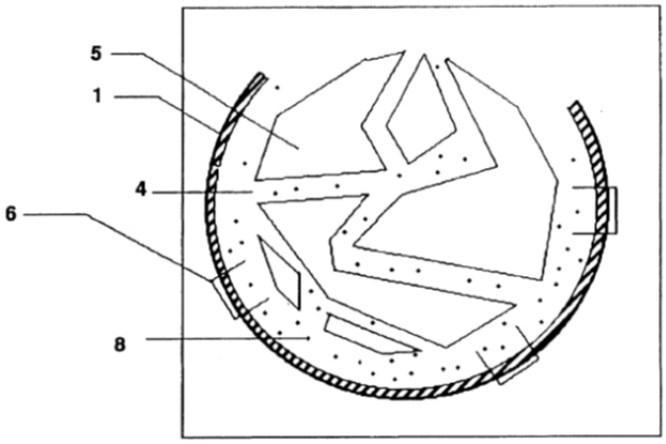
[1] The dalton is a standard unit of measure used for quantifying mass on a molecular scale. One dalton is approximately equal to the mass of one hydrogen atom.

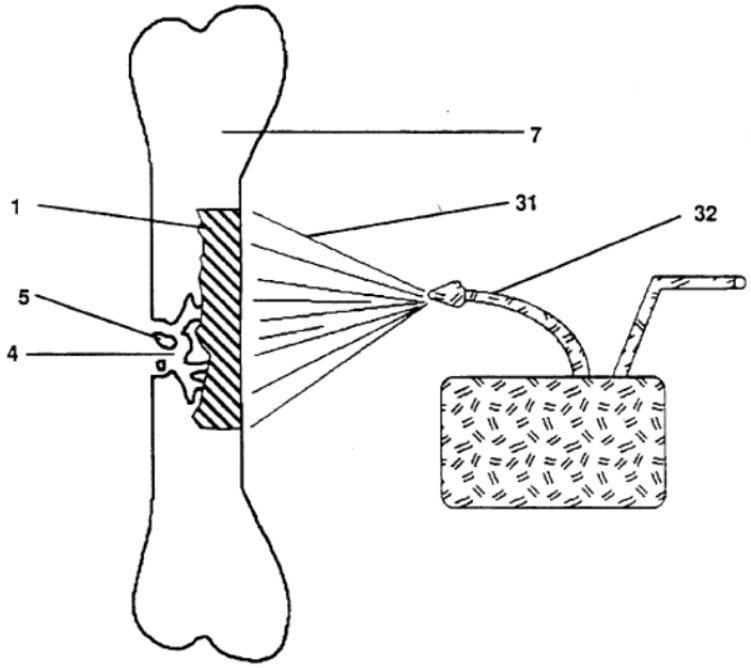
ll. 15–24. Once selected and cut to the desired size and shape, the sheet (1) is wrapped around or affixed to the fracture site, for example, with staples (6), as shown below.



'760 patent fig. 4a; *see also id.* col. 16 ll. 13–47. Because of the invention's barrier properties, the growth factors and other macromolecules (8) produced by the injured tissues at the fracture site are restrained and concentrated within the interfragmentary spaces (4), as illustrated in a cross-sectional diagram of the device after implantation:



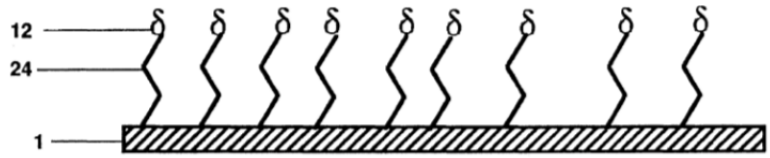
'760 patent fig. 4b. In addition to pre-formed sheets, the specification also discloses that "the invention can be applied to the site of injury as a spray . . . such that it is deposited as a thin film on the tissue . . . to maximize the surface area being treated while minimizing the need to dissect and staple." *Id.* col. 18 ll. 29–47.



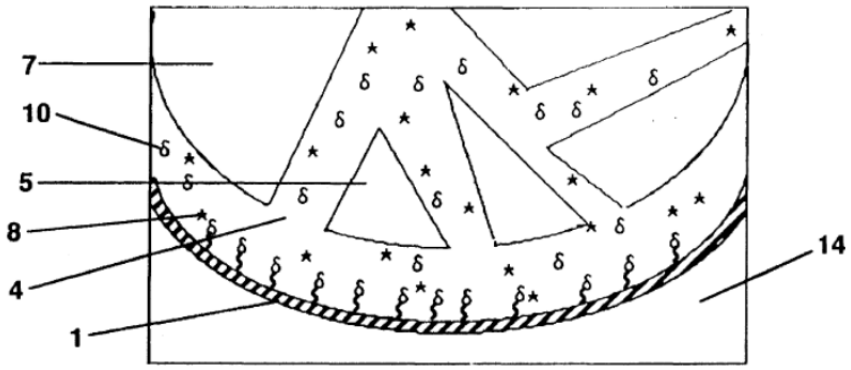
Id. fig. 6a; *see also id.* fig. 6b.

In addition to its above-described properties, the sheet can also be configured to deliver a drug or other therapeutic agent (a "treating material") to the treatment site. In such embodiments, the '760 patent teaches that the treating material "is affixed directly to one surface of the minimally-porous sheet." *Id.* col. 8 ll. 31–32. In particular, the '760 patent describes affixing a treating material (12) to one side of the sheet (1) through a hydrolyzable chemical bond (24), which in the preferred embodiment can be severed to release the treating material by means

of water molecules present at the treatment site.[2] *Id.* col. 14 ll. 65–67. Figure 3a of the '760 patent represents a sheet configured for drug delivery as described above:



'760 patent fig. 3a. Lysis of the bonds occurs at a constant rate, releasing a steady dose of treating material. *Id.* col. 14 l. 43 – col. 15 l. 20, col. 22 ll. 4–17. Moreover, because the released treating material (10) is too large to pass through the minimally porous sheet, the disclosed device can deliver such therapeutics in a spatially directed manner—generally, the treating material is delivered from and then maintained adjacent to the side of the sheet facing the injured tissue, as illustrated in the '760 patent:

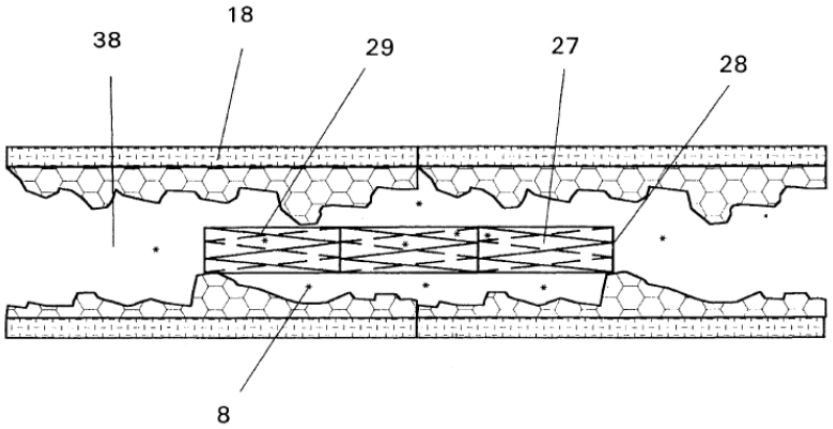


'760 patent fig. 3b.

As another use for the invention, the '760 patent also describes intravascular stents incorporating the disclosed technology. *See id.* col. 20 l. 9 – col. 21 l. 3. According to

[2] A hydrolyzable bond is one that can be broken by means of a chemical reaction with water.

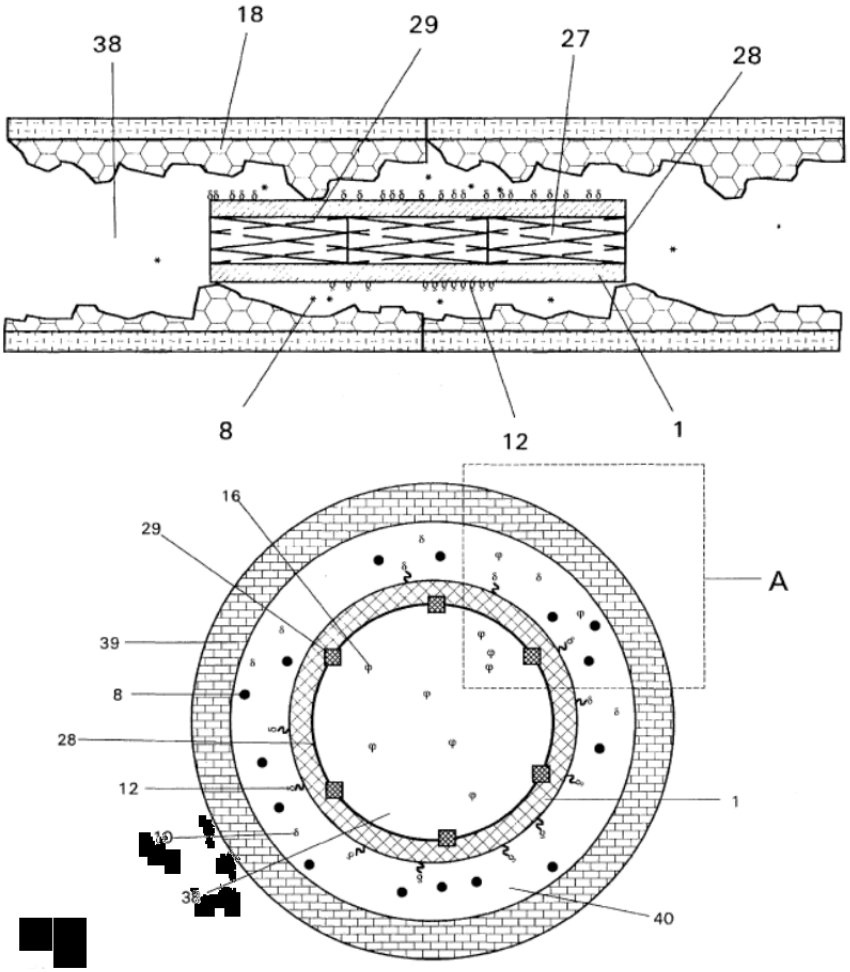
the specification, vascular plaques form in response to microscopic injuries to a blood vessel wall: "When the vessel attempts to heal, neighboring cells [secrete] a series of macromolecules to 'patch' the defect. If the macromolecules are not kept substantially in place, they will be swept away by moving blood. . . . [T]he sooner the injury is repaired, the smaller the resulting plaque will be." *Id.* col. 20 ll. 14–21. In this regard, the '760 patent criticizes prior art stents consisting of an open wire mesh because the holes (27) in the mesh between adjacent stent struts (29) are so large that "both cells and macromolecules [(8)] are free to move through them" and into the blood vessel lumen (38), *id.* col. 20 ll. 34–38, as illustrated below.



'760 patent fig. 8c. The specification notes prior art U.S. Patent 5,383,928 ("Scott") as an improvement to the traditional open mesh stent design, incorporating a "sheath that can cover the metallic mesh of a porous stent thereby somewhat limiting its porosity." '760 patent col. 20 ll. 38–45; *see also id.* fig. 8d. The '760 patent also observes that Scott described embedding a drug within the sheath for local delivery but explains that Scott "does not have means to restrain macromolecules between their sheath and the vessel wall" and therefore cannot provide "'directional drug delivery means' necessary to restrain

the medicine that their sheath delivers." *Id.* col. 20 ll. 42–58.

In contrast, the minimally porous sheet of the '760 patent "provides the means to restrain the macromolecules elaborated by the healing tissue, as well as the ability to restrain any number of medicines in the space adjacent to the injured blood vessel wall." *Id.* col. 20 ll. 59–62. The '760 patent provides several figures depicting the disclosed stents in operation:



'760 patent figs. 8e–f; *see also id.* figs. 8g–9e. The drawings show the disclosed minimally porous sheet (1) wrapped around a mesh stent and positioned inside a partly occluded blood vessel containing an atherosclerotic plaque (18). The sheet has treating material (12) bound to one side facing the blood vessel wall (39). Tissue-derived macromolecules (8) and released treating material (10) remain sequestered between the sheet and the vessel wall, while water and other small molecules (16) pass freely into the blood vessel lumen (38). *See id.* col. 11 ll. 28–53, col. 12 l. 21 – col. 13 l. 18.

The specification of the '760 patent concludes with 18 claims reciting devices and methods for treating damaged tissues using the disclosed minimally porous devices. Independent claims 1 and 8 are representative:

> 1. A flexible fixation *device* for implantation into human or animal tissue to promote healing of a damaged tissue comprising:
>
> a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface, the layer being capable of being shaped in three dimensions by manipulation by human hands,
>
> the first major surface of the layer being adapted to be placed adjacent to a damaged tissue,
>
> the second major surface of the layer being adapted to be placed opposite to the damaged tissue,
>
> the layer having material release *means for release of an at least one treating material in a directional manner* when said layer is placed adjacent to a damaged tissue,
>
> the *device* being flexible in three dimensions by manipulation by human hands,

the *device* being capable of substantially restricting the through passage of at least one type of macromolecule therethrough.

. . . .

8. A method of treating a damaged tissue to promote repair comprising:

a) providing a *device* including, a layer of flexible material that is minimally porous to macromolecules, said layer having a first and second major surface, the layer being capable of shaping in three dimensions by manipulation by human hands,

the first major surface of the layer being adapted to be placed adjacent to the damaged tissue,

the second major surface of the layer being adapted to be placed opposite to the damaged tissue,

the layer having material release *means for release of an at least one treating material in a unidirectional manner* when said layer is placed adjacent to the damaged tissue,

the *device* being flexible in three dimensions by manipulation by human hands,

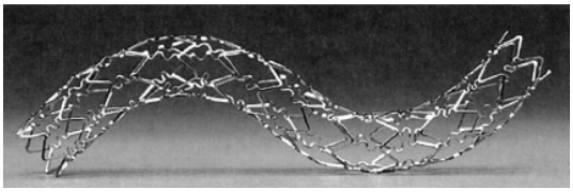
the *device* being capable of restricting the through passage of at least one type of macromolecule therethrough,

b) placing the *device* adjacent to a damaged tissue,

c) whereby the placed *device* results in directional presentation of the at least one treating material.

Id. col. 22 ll. 29–47, col. 23 ll. 14–37 (emphases added).

On October 9, 2007, Saffran filed suit against Cordis alleging infringement of the '760 patent. According to the complaint, Cordis infringed by making, using, and selling drug-eluting stents marketed under the brand name Cypher®. Briefly, the accused stents comprise a metallic mesh with a microscopic layer of polymer that coats the surface of each strut. The coating applied to the Cordis stents contains two polymers mixed with the macromolecular drug sirolimus,[3] which diffuses out of the device in a controlled fashion after implantation, gradually escaping through gaps in the polymer matrix over a 90-day period. The holes between the coated struts remain open, as shown in images of the accused products:



The district court conducted *Markman* proceedings to construe several disputed claim limitations. *Saffran v. Johnson & Johnson*, 740 F. Supp. 2d 899 (E.D. Tex. 2010) ("*Claim Construction Order*"). The district court first addressed the term "device," which it viewed as non-limiting preamble language that "merely gives a descriptive name to the set of limitations in the body of the claim." *Id.* at 911. Accordingly, the district court construed "device," as used in the claims of the '760 patent, to mean "a device having the limitations called out by the body of the claim." *Id.* The district court also interpreted the language "minimally porous to macromolecules" as

[3] Sirolimus, also known as rapamycin, is an immunosuppressive drug that has a molecular weight of approximately 914 daltons.

meaning "substantially impermeable to macromolecules," in view of the phrase's ordinary meaning and the '760 patent's specification. *Id.* at 913–14. Finally, the district court concluded that the language "means for release of at least one treating material in a directional manner" is a means-plus-function limitation governed by 35 U.S.C. § 112, ¶ 6.[4] Accordingly, the district court held that the function of the claimed "means for release" is "to release a drug preferentially toward the damaged tissue" and defined the corresponding structures disclosed in the '760 patent's specification as "chemical bonds and linkages." *Id.* at 914–19.

The case proceeded to trial and the jury returned a verdict in favor of Saffran on January 28, 2011. Specifically, the jury found that the '760 patent was not proven invalid; that Cordis had willfully infringed the '760 patent through the manufacture, use, and sale of its accused stent products; and that Saffran was entitled to damages totaling $482,000,000. *Saffran v. Johnson & Johnson*, No. 2:07-cv-451, 2011 WL 1299607, at *1 (E.D. Tex. Mar. 31, 2011). After the verdict, Cordis moved for judgment as a matter of law on invalidity, infringement, willfulness, and damages. The district court held that sufficient evidence supported the jury's conclusions as to invalidity, infringement, and damages, denying Cordis's motions on those grounds. *Id.* at *2–8, *10–11. Regarding willfulness, however, the district court determined that Saffran had not satisfied the objective prong of the willfulness test and therefore granted Cordis's motion for judgment as a matter of law on that issue. *Id.* at *8–9. Having upheld

[4] Paragraph 6 of 35 U.S.C. § 112 was replaced with newly designated § 112(f) when § 4(c)(6) of the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, took effect on September 16, 2012. Because this case was filed before that date, we will refer to the pre-AIA version of § 112.

the jury's calculation of damages, the district court awarded an additional $111,364,281 in prejudgment interest, bringing the total award to $593,364,281. *Final Judgment*, slip op. at 1–2. Cordis now appeals; we have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

Claim construction is an issue "exclusively within the province of the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). We apply regional circuit law in assessing the grant or denial of a motion for judgment as a matter of law. *Summit Tech., Inc. v. Nidek Co.*, 363 F.3d 1219, 1223 (Fed. Cir. 2004). The Fifth Circuit reviews orders granting or denying a motion for judgment as a matter of law without deference, applying "the same standard to review the verdict that the district court used in first passing on the motion." *Hiltgen v. Sumrall*, 47 F.3d 695, 699 (5th Cir. 1995). Accordingly, judgment as a matter of law is appropriate if "the facts and inferences point so strongly and overwhelmingly in favor of one party that the court concludes that reasonable jurors could not arrive at a contrary verdict." *Bellows v. Amoco Oil Co.*, 118 F.3d 268, 273 (5th Cir. 1997).

On appeal, Cordis disputes, *inter alia*, the district court's construction of the claim limitations "device" and "release means for release of an at least one treating material in a directional manner." Under the correct constructions, according to Cordis, its products cannot be found to infringe the '760 patent as a matter of law. We will consider those arguments as set forth below.

A. Claim Construction

1. Device

The term "device" appears in every claim of the '760 patent—in the preamble and body of independent claim 1, in the bodies of independent claims 8 and 15, and at least by reference in each of the dependent claims. In its *Claim*

Construction Order, the district court nonetheless concluded that, as used in the '760 patent, the term "device" serves only as non-limiting preamble language that does not require a sheet and "merely gives a descriptive name to the set of limitations in the body of the claim that set forth the invention." 740 F. Supp. 2d at 911.

Cordis argues that the term "device" should be construed to mean a continuous sheet. According to Cordis, the specification of the '760 patent consistently and exclusively describes the device of the invention as a sheet. Furthermore, Cordis asserts, the '760 patent highlights the sheet's ability to sequester macromolecules near an injury as a "critical" feature of the invention, while criticizing stents with uncovered mesh holes as unable to prevent tissue macromolecules from escaping. Cordis also contends that during prosecution of the '760 patent, Saffran defined the claimed "device" as a sheet in attempting to overcome cited prior art, and that he therefore cannot now assert a broader meaning in litigation. Finally, Cordis argues that the district court erroneously relied on certain embodiments described in the '760 patent as disclosing alternatives to, rather than forms of, a sheet.

Saffran responds that the district court correctly declined to limit the term "device" to require a sheet. Saffran accuses Cordis of limiting the claims to certain preferred embodiments while ignoring other disclosures. Furthermore, Saffran contends that Cordis misunderstands the invention's macromolecular restraint function, arguing that the disclosed device need not restrain all macromolecules from all injured tissue. Instead, according to Saffran, the device must simply be capable of restraining at least one type of macromolecule at locations where the stent strut contacts the blood vessel wall. Finally, Saffran asserts that the prosecution history of the '760 patent evinces no clear and unambiguous disavowal

of claim scope and instead supports a broad reading of the asserted claims.

We conclude that Saffran's statements during prosecution of the '760 patent limit "device" to a continuous sheet. On multiple occasions during prosecution, Saffran sought to distinguish prior art by representing to the examiner that "[t]he device used is a sheet rather than a pre formed chamber (Gaskill)." J.A. 1100, 1119, 1127. Saffran contends that his statements merely disclaimed the rigid pre-formed chambers disclosed in U.S. Patent 4,911,717 ("Gaskill") without further limiting the invention to a sheet. While Saffran surely disclaimed preformed chambers during prosecution, we disagree that his statements have such limited import.

Saffran's arguments to the examiner presented two bases for distinguishing Gaskill: (i) that his device is a sheet, and (ii) that his device is not a pre-formed chamber. Even if, as Saffran suggests, the examiner had relied only on the latter, that would not annul the remainder of his statement. "Rather, as we have made clear, an applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007). Furthermore, the record before us makes clear that the examiner shared Saffran's stated view of the claimed device as a continuous sheet. In recording his reasons for allowance, the examiner noted that "[t]he claimed invention embodies a unique method of [macromolecular restraint] using a single flexible minimally porous sheet layer." J.A. 530.

To be sure, a prosecution disclaimer requires "clear and unambiguous disavowal of claim scope," *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 833 (Fed. Cir. 2003), but applicants rarely submit affirmative disclaim-

ers along the lines of "I hereby disclaim the following . . ." during prosecution and need not do so to meet the applicable standard. In this case, Saffran's unqualified assertion that "the device used is a sheet" extends beyond illuminating "how the inventor understood the invention," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc), to provide an affirmative definition for the disputed term. Given such definitive statements during prosecution, the interested public was entitled to conclude that the "device" recited in the claims of the '760 patent is a continuous sheet.

Saffran's arguments alleging that the '760 patent contains contrary embodiments are not persuasive. Saffran first contends that the "spray" embodiment disclosed in the '760 patent does not yield an unbroken sheet but forms a layer only where it contacts bone or some other solid surface, such as the struts of a stent. But the record belies that assertion. The figures illustrating the spray embodiment show a spray nozzle depositing a continuous, unbroken sheet that spans open gaps between individual bone fragments. '760 patent figs. 6a–b; *see also id.* col. 12 ll. 21–22. More fundamentally, and as Saffran acknowledged during trial, the '760 patent never mentions spraying the device onto a stent or any other support substrate except the injured tissue itself. *See, e.g.*, *id.* col. 18 ll. 30–32 (explaining that the spray "is deposited in a thin film *on the tissue*") (emphasis added). On that very basis, in fact, Saffran attempted to distinguish his spray embodiment from a prior art vascular graft (disclosed in U.S. Patent 5,152,782 ("Kowligi")) that was subjected to spray coating before implantation: "The critical difference here is that Kowligi disclose[s] a way to *make* their device, while I disclose a way to *deploy* mine." J.A. 385. The '760 patent's spray embodiment thus concerns depositing a continuous sheet of material onto injured tissue, not preparing a support structure such as a stent for later implantation into a patient.

The specification supports this conclusion. Throughout its specification, the '760 patent consistently describes the disclosed "device" as a sheet, whether wrapped around a stent, affixed to a fractured bone, or applied as a spray. *See, e.g.*, '760 patent at [57] ("The device is composed of a single sheet of material . . . ."); *id.* col. 7 ll. 35–37 ("The invention is a unique method . . . to restrain interfragmentary macromolecules using a single, flexible minimally porous sheet."); *id.* col. 13 l. 39 (stating that "[t]he device, 1, is composed of a single sheet of material"); *id.* col. 14 ll. 34–42 ("Attachment of a treating material to the device of the invention: I have found unexpectedly that medicine or other treating materials can be attached directly to the flexible, minimally-porous sheet . . . ."); *see id.* col. 16 ll. 8–47 (using the terms "device," "sheet," and "the invention" interchangeably). In addition, every drawing in the '760 patent depicts the claimed device as a sheet. *E.g.*, *id.* figs. 4a, 5a, 8e; *see also id.* col. 12 ll. 21–22 (defining reference numeral 1, which appears in every figure depicting the invention,[5] as a "[s]ingle-layered, flexible, minimally-porous sheet having macromolecular restrainment means"). Extensive, consistent usage in the specification therefore suggests that the claimed "device" should be understood as a sheet, which, rather than confining the term to a single embodiment, would accord with *every* embodiment and description presented in the '760 patent, not to mention the prosecution history.

Furthermore, the '760 patent emphasizes macromolecular containment as a key feature of the invention, and, in the specific context of vascular stents, expressly relies on the sheet to distinguish the claimed device from

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[5] Fig. 2b lacks reference numeral 1 but contains a sheet labeled with reference numeral 21, which the specification defines as: "Positively-charged, single-layered, flexible, minimally-porous *sheet*." '760 patent col. 12 ll. 52–53 (emphasis added).

prior art open mesh stents. The specification describes the device's ability to restrain tissue macromolecules near the site of injury as a "cardinal" and "exceedingly important" feature of the invention. '760 patent col. 7 ll. 38–46, col. 20 ll. 49–51. The specification also criticizes prior art stents as unable to restrain macromolecules between the stent and the vessel wall; according to the '760 patent, prior art stents "are porous meshes" characterized by holes so large that "both cells and large macromolecules are free to move through them." *Id.* col. 20 ll. 22–48; *compare id.* fig. 8c (showing tissue macromolecules (8) passing through the holes (27) between the struts (29) of a prior art open-mesh stent and into the vessel lumen), *with id.* fig. 8e (showing sheet (1) covering holes (27) and containing tissue macromolecules (8) between the device and the vessel wall). In short, the specification makes clear that restraining tissue macromolecules is not only a key feature of the invention, but also one that open mesh stents cannot provide. Therefore, reading the claim term "device" to both require a sheet and exclude stents having open mesh holes "most naturally aligns with the patent's description of the invention." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1313 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1316).

Finally, Saffran relies on an alleged "stent coating" embodiment in the specification. But that "embodiment" is no more than an isolated phrase taken out of context; the cited passage occurs in a section summarizing potential uses of the previously described sheet-wrapped vascular stents within the biliary or digestive systems. *See id.* col. 21 ll. 5–37 ("The stent coating properties of this device are not limited to use within the vascular system."); *see also id.* figs. 9a–b. The cited passage is consistent with interpreting the device as a continuous sheet.

In summary, we reverse the district court's claim construction and construe the term "device," as used in the claims of the '760 patent, to mean a continuous sheet and

to exclude stents having open mesh holes. While the district court was clearly correct that the term "device" must possess all the "limitations in the body of the claim," the term itself requires construction beyond those limitations, as we have indicated above.

2. Release Means

Cordis also disputes the district court's construction of the "release means" limitation recited in each independent claim of the '760 patent. The claims require a "means for release of an at least one treating material in a directional manner," '760 patent col. 22 ll. 41–43,[6] and the district court construed that language as a means-plus-function limitation governed by 35 U.S.C. § 112, ¶ 6. The district court identified the claimed function as "to release a drug preferentially toward the damaged tissue" and the corresponding structure as "chemical bonds and linkages." *Claim Construction Order*, 740 F. Supp. 2d at 916–19. On appeal, Cordis and Saffran agree that the disputed claim language should be analyzed as a means-plus-function limitation pursuant to § 112, ¶ 6; neither side disputes the district court's definition of the claimed function. The parties differ, however, as to the district court's identification of corresponding structures disclosed to carry out that function.

Cordis argues that the district court erred in identifying the corresponding structures disclosed in the '760 patent. According to Cordis, the district court's generic

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[6] Independent claims 8 and 15 recite "means for release of an at least one treating material in a *unidirectional* manner" rather than a "*directional* manner" as recited in claim 1. *Compare* '760 patent col. 22 ll. 41–43, *with id.* col. 23 ll. 26–28, *and id.* col. 24 ll. 23–25. The parties have agreed, however, that the terms "directional" and "unidirectional" are equivalent. *Claim Construction Order*, 740 F. Supp. 2d at 915.

construction is overbroad, erroneously sweeping undisclosed types of "chemical bonds and linkages" into the scope of the claims. Cordis contends that the correct structure is a hydrolyzable bond—the only type of bond identified in the '760 patent for performing the claimed directional drug release function.

In contrast, Saffran defends the district court's construction as correct under § 112, ¶ 6, arguing that the '760 patent broadly discloses "chemical bonds and linkages" as a clear category of structures that would be readily understood by one of ordinary skill in the art as suitable for performing the claimed function.

We conclude that although the district court correctly identified the claimed function as "to release a drug preferentially toward the damaged tissue," it erred in identifying the corresponding structure disclosed in the specification. The claimed structure for the "release means" limitation is correctly construed as a hydrolyzable bond.

Under § 112, ¶ 6, a means-plus-function claim "shall be construed to cover the *corresponding structure*, material, or acts described in the specification or equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2006) (emphasis added). We have held that "structure disclosed in the specification is 'corresponding' structure *only* if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the *quid pro quo* for the convenience of employing § 112, ¶ 6." *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997).

Applying those standards, we agree with Cordis that the types of bonds set forth in the '760 patent as corresponding to the claimed release function are limited to hydrolyzable bonds. The specification repeatedly describes the linkage between treating materials and the sheet as a hydrolyzable bond. *E.g.*, '760 patent col. 8

ll. 37–43 ("[I]f one wishes to release medicine . . . at different rates, one simply has to manufacture the device with bonds that become hydrolyzed at a different rate."). Moreover, the specification distinguishes the invention over the prior art based on the use of hydrolyzable bonds:

> A surprising new feature of this device is the improvement in the medicine release kinetics compared to the prior art. Whereas [prior art devices] rely on the random diffusion of medicine from micropores, I have found that I can achieve a prolonged duration and much more stable rate of efflux from the device when medicine is attached using a hydrolyzable bond.

Id. col. 14 ll. 53–61. At a minimum, it is thus clear that the specification sets forth hydrolyzable bonds as at least one structure linked to the release function of the claims.

The '760 patent does not, however, link any additional structures to the release function with sufficient specificity to satisfy § 112, ¶ 6. In arguing otherwise, Saffran again relies on fragmentary statements taken out of context from the specification. For example, Saffran points to a statement in the '760 patent that "the linkages can be made of any suitable bond." But the full passage states: "In the preferred embodiment, these linkages are hydrolyzable by the water within the interfragmentary space; however the linkages can be made of any suitable bond, e.g., a bond that requires a particular enzyme for hydrolysis." *Id.* col. 14 l. 65 – col. 15 l. 2. Read in context, "suitable" bonds may thus include hydrolyzable bonds that, unlike the preferred embodiment, cannot be broken by water alone and may also require, for example, an enzyme to trigger hydrolysis. No non-hydrolyzable bonds are discussed or suggested. Similarly, Saffran stresses another isolated passage from the specification suggesting that one of the figures shows a medicine "affixed to the invention by means of a chemical bond." *Id.* col. 14 ll. 43–

45. Elsewhere in the specification, however, the specific description of that same figure clarifies that it depicts a *hydrolyzable* chemical bond: "This drawing shows an embodiment in which a treating material has been affixed to the invention. In this example, medicine is attached to the invention using a hydrolyzable chemical bond." *Id.* col. 10 ll. 10–13. In another instance, Saffran mischaracterizes the specification's disclosure that certain sheet materials may restrain macromolecules by physical properties such as charge or hydrophobicity rather than size; that portion of the specification relates to the sheet's ability to block macromolecules from passing and does not, as Saffran suggests, concern drug delivery, let alone affirmatively disclose ionic or so-called "hydrophobic" bonds between a treating material and the sheet as structures that correspond to the "release means" limitation. *See id.* col. 8 ll. 15–24. Accordingly, we are not persuaded that the specification's scattered use of the generic phrase "chemical bonds" conveys additional, specific corresponding structures separate and apart from hydrolyzable bonds.

In urging otherwise, Saffran has expended considerable effort arguing that given the claimed function, a person of ordinary skill would "understand the range of chemical bonds and linkages that could be used." Appellee's Br. 60, 2012 WL 2375038. As we have explained, however, "[a] patentee cannot avoid providing specificity as to structure simply because someone of ordinary skill in the art would be able to devise a means to perform the claimed function." *Blackboard, Inc. v. Desire2Learn, Inc.*, 574 F.3d 1371, 1385 (Fed. Cir. 2009). Under § 112, ¶ 6, the question is not what structures a person of ordinary skill in the art would know are capable of performing a given function, but what structures are specifically disclosed and tied to that function in the specification.

Saffran also argues that limiting the disclosed corresponding structures to hydrolyzable bonds would make

dependent claim 3—which specifies drug release "by lysis of a chemical bond"—broader than claim 1, citing *Wenger Manufacturing, Inc. v. Coating Machinery Systems, Inc.*, 239 F.3d 1225 (Fed. Cir. 2001). In *Wenger*, the district court had construed the means-plus-function term "air circulation means" in an independent claim to require structures for both circulating and recirculating air, even though the recirculation function was recited separately in a dependent claim and the specification disclosed distinct structures for performing the two functions. 239 F.3d at 1232–35. In that case, we held that claim differentiation supported the conclusion that "air circulation means" "should not be interpreted as requiring structure capable of performing *the additional function* of recirculation" that was entirely absent from the independent claim. *Id.* at 1234 (emphasis added). But that is not the case before us. Here, claims 1 and 3 concern the same function, and the only structure disclosed in the '760 patent for performing that function is a hydrolyzable bond. In such circumstances, we have long held that a patentee cannot rely on claim differentiation to broaden a means-plus-function limitation beyond those structures specifically disclosed in the specification. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991). Saffran's claim differentiation arguments are therefore unavailing, and we conclude that hydrolyzable bonds are the sole type of chemical bond linked to the claimed "release means" function in the specification.

In view of the foregoing, we conclude (i) that the "release means" limitation recited in the claims of the '760 patent is a means-plus-function limitation governed by § 112, ¶ 6; (ii) that the recited function is "to release a drug preferentially toward the damaged tissue"; and

(iii) that "hydrolyzable bonds" constitute the corresponding structures disclosed in the '760 patent's specification.[7]

B. Infringement

As described above, we agree with Cordis that the district court misconstrued the "device" and "release means" limitations of the asserted claims. Cordis further contends that, applying the correct constructions, it is entitled to a judgment of noninfringement as a matter of law. Specifically, Cordis argues that its accused stents both lack a sheet covering the open mesh holes between their struts and lack a drug affixed to their surfaces via hydrolyzable bonds and therefore cannot infringe the asserted claims. We agree.

1. Device

Under the correct construction of the term "device," Cordis cannot infringe the asserted apparatus or method claims unless its accused stent products include a continuous sheet and lack uncovered holes in the stent mesh. The accused Cordis stents all exhibit a metallic mesh structure, their struts coated with a thin layer comprising polymer and sirolimus. But that layer is akin to paint on a chain link fence, not a continuous sheet wrapped around the mesh, and open holes remain between the struts of the accused devices—as Saffran has acknowledged. Therefore, no reasonable jury could conclude that Cordis's accused stents infringe the asserted claims of the '760

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[7] While not controlling here, we also note that the United States Patent and Trademark Office ("PTO") arrived at a similar definition during an *ex parte* reexamination of the '760 patent (Reexamination Control No. 90/009,795), limiting even its broadest reasonable interpretation of the "release means" limitation to require hydrolyzable bonds. The PTO ultimately confirmed the patentability of each reexamined claim in that proceeding.

patent, and Cordis is entitled to a judgment of noninfringement as a matter of law.

2. Release Means

In addition, our construction of the "release means" limitation provides a separate and independent basis for a judgment of noninfringement. As construed, each of the asserted apparatus and method claims requires a treating material attached to the substantially impermeable sheet via hydrolyzable bonds or an equivalent thereof, 35 U.S.C. § 112, ¶ 6, but the sirolimus provided by the Cordis products is not attached by hydrolyzable bonds. It is instead embedded within the polymer layer and held in place by intermolecular "hydrophobic" interactions that facilitate its slow diffusion through the polymer matrix. Saffran has not argued otherwise. Moreover, Saffran stipulated before trial that he would not pursue any infringement arguments representing that so-called "hydrophobic" interactions are equivalent to hydrolyzable bonds, and he is therefore precluded from doing so now. *See Saffran v. Johnson & Johnson*, No. 2:07-cv-451 (E.D. Tex. Dec. 1, 2010) (Cordis motion in limine), ECF No. 185; *Saffran v. Johnson & Johnson*, No. 2:07-cv-451 (E.D. Tex. Jan. 13, 2011) (Order granting stipulated motion), ECF No. 269. Accordingly, Cordis is also entitled to a judgment of noninfringement because its accused products do not satisfy the properly construed "release means" limitation.

3. Remaining Arguments

Because we hold that Cordis does not infringe the asserted claims of the '760 patent as correctly construed, we need not reach Cordis's additional contention that its products are not "minimally porous to macromolecules" as further required by the claims.

III. CONCLUSION

The district court erred in construing the asserted claims of the '760 patent; because the accused products do

not satisfy those claims as correctly construed, Cordis is entitled to a judgment of noninfringement as a matter of law. We therefore *reverse* the judgment of the district court.

REVERSED

United States Court of Appeals for the Federal Circuit

BRUCE N. SAFFRAN, M.D., PH.D.,
Plaintiff-Appellee,

v.

JOHNSON & JOHNSON AND CORDIS CORPORATION,
Defendants-Appellants.

2012-1043

Appeal from the United States District Court for the Eastern District of Texas in No. 07-CV-0451, Judge T. John Ward.

MOORE, *Circuit Judge*, concurring-in-part.

I join Judge Lourie's opinion except for Parts II-A-2 and II-B-2. Respectfully, I conclude that the district court adopted the correct claim construction of "release means." The only issue in dispute is the identification of the corresponding structure for the release means. The district court concluded that the corresponding structure was "chemical bonds and linkages." I agree. The specification is clear: "[t]he rate of healing can be . . . accelerated by attachment of a treating material, either mechanically or by *chemical bond*, to the inner surface of

the device," which includes a "method of medicine release by chemical bond." '760 patent, col.22 l.4–7. This passage directly associates the claimed "release means" with the *chemical bond* structure, which is sufficiently specific to satisfy § 112 ¶ 6. *See, e.g.*, *Med. Inst. & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1213–14 (Fed. Cir. 2003) (explaining that § 112 ¶ 6 requires only "some link between a generic structural reference and a claimed function" understandable to a person of skill in the art). I simply cannot fathom what more the patentee must do "to link or associate structure to function" so as to provide "sufficient specificity." Op. at 21–22. By limiting the structure to "hydrolyzable bonds," my colleagues punish the patentee for providing a detailed description of his preferred embodiment.

My colleagues' erroneous construction of the "release means" limitation is all the more puzzling because it is unnecessary to resolve this case. As Parts II-A-1 and II-B-1 convincingly explain, the clear prosecution disclaimer of "devices" other than "sheets" mandates reversal of the infringement verdict. Parts II-A-2 and II-B-2 are thus entirely dicta. For these reasons, I decline to join Parts II-A-2 and II-B-2.

United States Court of Appeals for the Federal Circuit

BRUCE N. SAFFRAN, M.D., PH.D.,
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2012-1043

Appeal from the United States District Court for the Eastern District of Texas in No. 07-CV-0451, Judge T. John Ward.

O'MALLEY, *Circuit Judge*, concurring in part.

I concur in the result my colleagues reach today because I agree that, under the proper construction of the "release means" limitation, Cordis does not infringe the asserted claims of U.S. Patent No. 5,653,760 ("the '760 patent" or "the patent"). I disagree, however, with my colleagues' construction of the term "device." Accordingly, I do not join Parts II-A-1 or II-B-1 of the majority opinion.

I. CONSTRUCTION OF "DEVICE"

The majority construes "device" to mean a continuous sheet that excludes stents with open mesh holes. Majority Op. at 14-20. Upon review of the intrinsic record, I do

not agree. The claim language is broad and the written description, while focused on the treatment of fractured bones with a sheet, discloses a host of other embodiments and treatment applications. Several of those embodiments cannot fairly be characterized as sheets. And, I find no clear and unambiguous disclaimer of those embodiments in the prosecution history. Accordingly, I would affirm the district court's construction of "device" as something which comprises the limitations set out in the body of the claim.

Turning first to the claim language, it does not limit the claimed "device" to a "sheet." It only describes three characteristics of the "device:" it comprises a layer; it is "capable of being shaped in three dimensions by manipulation by hands;" and it is "capable of substantially restricting the through passage of at least one type of macromolecule therethrough." '760 patent col. 22 ll. 29-47. As my colleagues recognize, "device" is a generic term, Majority Op. at 15, that under its common usage is not limited to devices in the form of a sheet. Accordingly, the proper inquiry before us is whether the meaning of "device" as it appears in the asserted claims is narrowed by the written description or prosecution history. In my opinion, it is not.

To find a special definition mandated by the written description, a term must be "clearly" redefined, and an "express intent" to do so must be evident from the patent. *See Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc.*, 214 F.3d 1302, 1307 (Fed. Cir. 2000) ("While we have held many times that a patentee can act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning, the written description in such a case must clearly redefine a claim term so as to put a reasonable competitor or one reasonably skilled in the art on notice that the patentee intended to so redefine that claim term. Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning.")

(citations and internal quotation marks omitted); *see also Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009) ("Similarly, we will adopt a definition that is different from the ordinary meaning when the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.") (internal quotation marks omitted); *Cannon Rubber Ltd. v. The First Years, Inc.*, 163 F. App'x 870, 875 (Fed. Cir. 2005) ("These two cited instances, however, do not clearly indicate that the patentee intended to assign a more narrow definition to the phrase 'in the body' than it would otherwise possess."). In my view, the patent contains no clear definition of "device" or express intent to narrow its meaning.

Admittedly, in many instances, the patent includes descriptions of the invention being composed of a sheet,[1] accomplishing certain functionality using a sheet,[2] or being provided as a sheet.[3] Those statements, standing alone, could conceivably impart a special definition to "device" by implication.[4] When read as a whole, however,

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[1] *See* '760 patent col. 13 ll. 39-41 ("The device, **1**, is composed of a single sheet of material that in its principal embodiment is supplied as a thin, pliable, fabric that is flexible in three dimensions by human hands.").

[2] *See id.* col. 7 ll. 34-36 ("The invention is a unique method of fracture stabilization and way to restrain interfragmentary macromolecules using a single flexible minimally porous sheet.").

[3] *See id.* col. 16 ll. 9-10 ("The invention is to be provided as a sterile sheet.").

[4] *See, e.g.*, *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001) ("However, a claim term may be clearly redefined without

the written description detracts from the notion that "device" has a special meaning. Although it focuses on the treatment of fractured bones with a sheet, the written description discloses numerous other physical forms which the patented invention can take, some of which decidedly are not sheets. It describes a sheet as one possible embodiment. *See, e.g.*, '760 patent col. 7 ll. 57-60 ("According to one embodiment, a single sheet that is flexible in three dimensions and minimally porous to macromolecules, is wrapped around or affixed to a fractured tissue."); *id.* col. 13 l. 66 – col. 14 l. 2 ("The principal embodiment of the present invention is a sheet with the same characteristics as the malleable, minimally-porous anchoring component, **3**, of the Malleable Fracture Stabalization Device with Micropores."). It is almost unnecessary to restate that, "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc).

A close look at the written description reveals the breadth of its disclosure. The written description begins with a "Background of the Invention" section with a "Field of the Invention" subsection stating the "invention relates to the treatment of injured tissues within human or animal bodies, specifically to the way injured tissues are joined and the way macromolecules are directed to pro-

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an explicit statement of redefinition. Indeed, we have specifically held that the written description of the preferred embodiments can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format.") (citations and internal quotation marks omitted).

mote healing." '760 patent col. 1 ll. 21-24. This statement seemingly refers to embodiments relating to the treatment of fractured bones. But the Field of Invention section goes on to say that, "[a]lthough I [the inventor] will frame this invention initially in terms of traumatic injuries, I will also discuss this invention in the treatment of many other conditions including metastases, infections, metabolic conditions such as osteoporosis, primarily neoplasms, and vascular disease." *Id.* col. 1 ll. 27-32. This statement significantly broadens the scope of the disclosure, as does the text that follows.

The Background section proceeds to discuss the state of the art in the field of bone fracture fixation, in a subsection titled "Description of Prior Art." *Id.* col. 1 l. 33 – col. 6 l. 10. But the patent notes that other injuries are also implicated by the invention: "many tissues are commonly fractured in traumatic injury, e.g., the liver, the kidney, the bowel, the bladder, the spleen and the testicle, perhaps the most often injured tissues are the bones." *Id.* col. 1 ll. 39-42. Returning to bone fractures, the patent discusses techniques used to treat bone fractures, problems arising when bone fractures are treated, and different fixation devices used on bone fractures (including compressions plates, intramedullary rods, porous substrates, bone chips, implantable gels, injectable cements, polymer coated sheets, non-porous grafts, and Saffran's microporous device disclosed in U.S. Patent Application Ser. No. 08/11,745, which issued as U.S. Patent No. 5,466,262 ("the '262 patent")). *Id.* col. 2 l. 43 – col. 6 l. 10. Still within the Background of the Invention section, the patent describes the present invention, calling it an improvement of the device disclosed in the '262 patent and discussing it specifically in the context of bone fracture fixation. *Id.* col. 6 ll. 11-62. But, in a subsection entitled "Objectives of the Present Invention," the patent moves beyond bone fractures and discloses features of the invention touching upon other medical applications, i.e.,

the invention provides "a unique method and apparatus that can be deployed via endoscope, catheter, or open surgical procedure that can serve both to preferentially direct endogenous macromolecules and release treating materials while also providing structural support to hollow viscera, solid organs, or blood vessels." *Id*. col. 7 ll. 20-26.[5]

The next subsection, entitled "Summary of the Invention," focusing again on bone fractures, states that "[t]he invention is a unique method of fracture stabilization and way to restrain interfragmentary macromolecules using a single, flexible minimally porous sheet." *Id*. col. 7 ll. 34-36. It goes on to describe aspects of the patented invention, such as its one-layer construction, its ability to selectively restrain macromolecules, and the option of affixing treating material to its surface. *Id*. col. 7 l. 38 – col. 9 l. 11. Although, up to now, this section seems limited to bone fracture applications, the patent next states that the invention can "be introduced into the medullary cavity, blood vessel and hollow viscera using a percutaneous delivery system." *Id*. col. 9 ll. 12-14. It discusses embodiments in which the invention is rolled up and deployed via catheter or introducer needle, manufactured as a stent, or deployed via endoscope. *Id*. col. 9 ll. 15-30. These embodiments, the patent explains, can be used to treat the inner walls of bones, blood vessel walls, hollow viscera lumen, abscess cavities, medullary cavities, solid organs (e.g., the liver, biliary system), or hollow organs (e.g., the esophagus), allowing for the treatment of inflammatory conditions or metabolic conditions such as osteoporosis. *Id*.

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[5] The majority of the stated objectives, however, do relate to treatment of bone fractures. *See* '760 patent col. 6 l. 63 – col. 7 l. 31.

After sections describing the drawings and figures of the patent, a section entitled "Description of the Preferred Embodiments" elaborates on the numerous applications for the claimed invention. This section first describes the structure of the claimed device, the attachment of treating material to its surface via chemical bond, the construction material for the device, and the various treating materials that can be used. *Id.* col. 13 l. 48 – col. 16 l. 6. Regarding potential treating materials, the patent states that, "[a]lthough originally engineered to deliver bone growth factors, the device can deliver any of a number of treating materials including but not limited to bone morphogenetic proteins, nerve growth factors, extracellular matrix components, e.g., fibronectin and laminin, connective tissue growth factors such as fibroblast growth factors, antibiotics, vitamins, cofactors, a growth factor, a glycosaminoglycan, a bioactive ion, nuclear or ionic radiation, radiofrequency, a molecule produced by fractured tissue, a pharmaceutical, a hormone, and living cells—either wild-type or genetically engineered." *Id.* col. 15 l. 63 – col. 16 l. 6. Next, in a subsection entitled "Operation of the Invention," the patent returns to bone fracture applications. *Id.* col. 16 ll. 7-64. But the patent proceeds, in separate subsections, to discuss "several new and unexpected applications" of the inventions. *Id.* col. 17 ll. 2-3. The invention can be used, for example, "to treat metastases," *id.* col. 17 ll. 16-46, (by delivering chemotherapeutic medicines), "to treat osteomyelitis," *id.* col. 17 ll. 47-59, to treat herniated disks, *id.* col. 19 ll. 21-23, to treat osteoporosis, *id.* col. 19 ll. 27-37, to treat intra-abdominal abscesses resulting from diverticulitis and inflammatory bowel disease, *id.* col. 19 l. 46 – col. 20 l. 7, to treat cystic tumors and aneurysms, *id.* col. 19 ll. 7-8, "to treat vascular disease," *id.* col. 20 ll. 9-67, "to treat mycotic aneurysms," *id.* col. 21 ll. 1-3, to treat malignant biliary strictures cause by pancreatic head tumors, *id.* col. 21 l. 6-11, and to "deliver radiofrequency energy or radioactivity directed to the tumor," *id.* col. 21 ll. 38-47.

And, the invention can take many forms, being applied, for example, "within a fenestrated IM [intramedullary] rod," *id*. col. 17 l. 63, "as a thin film to the surface of a solid rod," *id*. col. 18 ll. 12-13, as a solid, rigid Krishner wire used to treat finger fractures, *id*. col. 18 ll. 21-29, as a spray "such that it is deposited in a thin film on the tissue," *id*. col. 18 ll. 31-32, as a rolled up sheet, *id*. col. 19 ll. 5-20, and as a coating for vascular and biliary stents, *id*. col. 20 l. 9 – col. 21 l. 47. Most pertinently, when discussing the use of the invention as a coating for stents, the written description states that the "device can be manufactured with any stent," *id*. col. 20 l. 65, and has "stent coating properties," and the stents are described as "invention-coated," *id*. col. 21 ll. 5-7. In its final section, entitled "Ramifications and scope," the patent describes the device again in the context of bone fractures, *id*. col. 21 ll. 49-59, but then mentions applications in "the medullary canal, hollow organs, and blood vessels," *id*. col. 21. ll. 66-67, and states that "the device and method provided is not only a major advance in bone fracture treatment over the prior art, but is also a significant advance in the treatment of other seemingly unrelated soft tissue pathology," *id*. col. 22 ll. 18-22.

In sum, while long-winded and rambling at times, the written description provides a broad disclosure touching upon several medical applications and physical structures. Its primary focus is the treatment of bone fractures with a minimally-porous sheet, but it also discloses a laundry list of other embodiments. Following this broad disclosure, the patent contains several claims that are limited to no specific medical application. Instead, they are directed generally to devices that "promote healing of a damaged tissue," *id*. col. 22 l. 30, methods "of treating damaged tissue to promote repair," *id*. col. 23 ll. 14-15, and methods "of treating tissues in human or veterinary medicine," *id*. col. 24 ll. 13-14. With this broad disclosure in mind, I turn to the present claim construction dispute.

Given the host of medical applications disclosed for the claimed device and the various structural forms the invention can take, I am unable to limit the broadly worded claims to any particular embodiment or application. The term "device" provides no vehicle for doing so. It is not possible, moreover, to describe some of the disclosed embodiments as "sheets." For example, one would not describe a thin film on the surface of a solid rod, *see id*. col. 18 ll. 12-14, or wire-like structures used to treat finger fractures, *see id*. col. 18 ll. 21-29, as "sheets." This is so even if one can stretch the spray and stent-coating embodiments so as to call them sheets. *See* Majority Op. at 17-19. Additionally, the patent indicates that it is the claimed "layer," as opposed to the claimed "device," that is a sheet; it makes several references to the "minimally porous sheet," and it is the "layer" that, according to the claims, is "minimally porous." *Compare* '760 patent col. 22 ll. 32-34 (claim 1 indicating that the "layer" is made "of flexible material that is minimally porous to macromolecules"), *with id*. col. 8 l. 4 ("minimally-porous sheet"), *and id*. col. 8 ll. 33 ("the minimally-porous sheet"). I simply cannot agree that the written description clearly redefines "device" as a "sheet." *See Elekta Instrument*, 214 F.3d at 1307.

The portion of my colleague's construction excluding "stents having open mesh holes" is unnecessary, moreover. *See* Majority Op. at 19. It is true that the patent distinguishes U.S. Patent No. 5,383,928 ("Scott") because the sheath-covered stent disclosed in Scott "does not have means to restrain macromolecules between their sheath and the vessel wall," and "cannot have the 'directional drug delivery means' necessary to restrain the medicine that their sheath delivers." '760 patent col. 20 ll. 46-55. But the claims themselves already require that "the device be[] capable of substantially restricting the through passage of at least one type of macromolecule therethrough" and that "the layer hav[e] material release

means for release of an at least one treating material in a directional manner. . . ." *Id.* col. 22 ll. 40-41, 45-47. By focusing on the stent embodiments, my colleague's construction loses sight of the various other embodiments disclosed in the written description.

Perhaps aware of the weakness of their position under standard claim construction principles, my colleagues resort to the concept of prosecution history disclaimer to justify reversing the district court's construction of this claim language. Indeed, they take the unusual step of beginning with a discussion of the prosecution history, elevating it to a prominence it does not deserve under *Phillips*. As noted by this court en banc, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317. The majority does not heed the hierarchy counseled in *Phillips* and, instead, begins by finding disclaimer and then searches the specification for disclosures consistent with their take away from the prosecution history. I cannot agree with either the structure or the result of their analysis.

As my colleagues concede, prosecution disclaimer requires "clear and unambiguous disavowal of claim scope." *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 833 (Fed. Cir. 2003). The burden to show prosecution disclaimer is high because "[c]laim terms are entitled to a heavy presumption that they carry their ordinary and customary meaning to those skilled in the art in light of the claim term's usage in the patent specification." *Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) (internal quotation marks omitted). In this vein, we have "consistently rejected prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1325 (Fed. Cir. 2003). Instead, "we have

required the alleged disavowing statements to be both so clear as to show reasonable clarity and deliberateness and so unmistakable as to be unambiguous evidence of disclaimer." *Id.* at 1325 (citations omitted). I see no such unambiguous, deliberate disavowal in the relevant exchanges with the examiner.

During prosecution, Saffran admittedly distinguished U.S. Patent No. 4,911,717 ("Gaskill") by stating that "[t]he device is a sheet rather than a pre formed chamber (Gaskill)." *See*, A1100; A119; A1127. This statement no-doubt clearly and unambiguously disclaims the embodiments disclosed in Gaskill; i.e., pre-formed chambers. But this statement does not unambiguously limit to "sheets" all forms which the claimed device can take. There was no need to do so to differentiate the claims at issue here from what was disclosed in Gaskill. Gaskill was not about stents or treating bone fractures. Gaskill is addressed to an "intravascular emplaced" "artificial organ" "having a cell culture chamber adapted to receive living cells or tissue." Gaskill col. 3 ll. 54-58. In context, the point of Saffran's disclaimer over Gaskill was that pre-formed chambers such as the disclosed "cell culture chamber" were not even within the scope of his claims. Instead, Saffran's claims cover either chambers that are not pre-formed—because they are formed by the physician using a sheet[6]—or embodiments, both with and without sheets, that do not involve chambers at all. It would make no sense for Saffran to disclaim multiple embodiments in his own specification that have nothing to do with pre-formed chambers when a far narrower disclaimer was sufficient to differentiate his invention from Gaskill, as the district court found.

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[6] Allowed claims in the '760 patent expressly include chambers formed during implantation—i.e., ones not "pre-formed." *See* '760 patent col. 22 ll. 60-61.

Although Saffran made this supposedly damning disclaimer when discussing a prior art reference dealing with pre-formed chambers—not sheets—my colleagues feel that his disclaimer is sufficient to notify the public that Saffran definitively and unambiguously redefined "device" as a "sheet." *See Omega Eng'g*, 334 F.3d at 1325 ("To balance the importance of public notice and the right of patentees to seek broad patent coverage, we have thus consistently rejected prosecution statements too vague or ambiguous to qualify as a disavowal of claim scope."). To find so, they must not only take Saffran's statement out of the context of the actual negotiation with the examiner, but disregard the multiple other embodiments disclosed in the patent. What Saffran unambiguously, clearly, and deliberately disclaimed were *pre-formed* chambers. I cannot find from this very directed exchange regarding Gaskill that Saffran unambiguously intended to disclaim such a substantial number of the embodiments disclosed in the written description.

Because a special definition of "device" is not mandated by either the written description or the prosecution history, I do not join Parts II-A-1 or II-B-1 of the majority opinion. I would instead affirm the district court's construction of this term.

II. CONSTRUCTION OF "RELEASE MEANS" LIMITATION

As stated above, I join Judge Lourie's decision regarding the construction of the "release means" limitations. I write separately on this term only to note that, since this is a means-plus-function element construed under 35 U.S.C. § 112 ¶ 6, the scope of the term is inherently narrowed by the disclosure. Therefore, unlike our task when construing "device," we are not required to examine the intrinsic record for a clear and unmistakable disavowal of claim scope when construing the "release means"

limitation.[7] Limiting the scope of the "release means" limitation is analytically distinct from limiting the meaning of the term "device." While, had Saffran chosen not to use a means-plus-function limitation, I might hesitate to limit the scope of the "release means" term, the outcome I reach today flows from his drafting choice.

[7] We look instead to the specification or prosecution history for a clearly linked structure to perform the recited function. *See B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997).