United States Court of Appeals for the Federal Circuit

2008-1073

BOSTON SCIENTIFIC SCIMED, INC. and BOSTON SCIENTIFIC CORPORATION,

Plaintiffs-Appellees,

v.

CORDIS CORPORATION and JOHNSON & JOHNSON, INC.,

Defendants-Appellants.

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Appealed from: United States District Court for the District of Delaware

Judge Sue L. Robinson

United States Court of Appeals for the Federal Circuit

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Plaintiffs-Appellees,

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CORDIS CORPORATION and JOHNSON & JOHNSON, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of Delaware in Case No. 03-CV-283, Judge Sue L. Robinson.

DECIDED: January 15, 2009

Before LOURIE, RADER, and PROST, Circuit Judges.

LOURIE, Circuit Judge.

Cordis Corporation and Johnson & Johnson, Inc. (collectively "Cordis") appeal from the judgment of the United States District Court for the District of Delaware denying a motion for a new trial and judgment as a matter of law ("JMOL") following a jury verdict of infringement of claim 8 of U.S. Patent 6,120,536 ("the '536 patent"). <u>See</u> <u>Boston Scientific Scimed, Inc. v. Cordis Corp.</u>, No. 03-283-SLR, 2005 U.S. Dist. LEXIS 10735 (D. Del. June 3, 2005) ("<u>Claim Construction Opinion</u>"); <u>Boston Scientific Scimed</u>, Inc. v. Cordis Corp., 434 F. Supp. 2d 308 (D. Del. 2006) ("Opinion Denying JMOL"); Boston Scientific Scimed, Inc. v. Cordis Corp., Nos. 03-027-SLR, 03-283-SLR, 2007 WL 2775087 (D. Del. Sept. 24, 2007) ("Opinion Denying New Trial"). Because the court erred as a matter of law in failing to hold the '536 patent to have been obvious, we reverse the judgment.

BACKGROUND

Boston Scientific Scimed, Inc. and Boston Scientific Corporation (collectively "Boston Scientific") own the '536 patent, which relates to a drug-eluting expandable stent with a coating that has a non-thrombogenic surface. Boston Scientific sued Cordis in March 2003, alleging, <u>inter alia</u>, that Cordis's Cypher stent infringed claim 8 of the '536 patent. Claim 8, the only claim on appeal, depends from claim 6, which depends from claim 1. Claims 1, 6, and 8 read as follows:

1. A medical device having at least a portion which is implantable into the body of a patient, wherein at least a part of the device portion is metallic and at least part of the metallic device portion is covered with a coating for release of at least one biologically active material, wherein said coating comprises an undercoat comprising a hydrophobic elastomeric material incorporating an amount of biologically active material therein for timed release therefrom, and wherein said coating further comprises a topcoat which at least partially covers the undercoat, said topcoat comprising a biostable, non-thrombogenic material which provides long term nonthromobogenicity to the device portion during and after release of the biologically active material, and wherein said topcoat is substantially free of an elutable material.

6. The device of claim 1 wherein the medical device is an expandable stent.

8. The device of claim 6 wherein the stent comprises a tubular body having open ends and an open lattice sidewall structure and wherein the coating conforms to said sidewall structure in a manner that preserves said open lattice.

'536 patent col.13 l.13-col.14 l.4 (filed June 13, 1996).

In June 2005, the district court construed certain limitations of claim 8. The court held that the phrase "non-thrombogenic material which provides long term non-thrombogenicity to the device portion during and after release of the biologically active material" in claim 1 means "a material that does not promote thrombosis for a period of time that extends both during and after release of the biologically active material." <u>Claim Construction Opinion</u>, 2005 U.S. Dist. LEXIS 10735, at *3. The court relied on medical dictionary definitions for the meaning of "thrombogenic" ("causing thrombosis or coagulation of the blood") and "thrombolytic" ("break[ing] up or dissolv[ing] a thrombus"), "thrombolytic" being a term the patentee used in the specification, but not the claims. <u>Id.</u> at *3 n.6. The court relied Cordis's proposed definition of "non-thrombogenic," which required a "significant reduction in thrombogenicity over that experienced with bare metal stents." <u>Id.</u> at *4 n.7. The court also construed the phrase "substantially free of an elutable material" to mean "largely or approximately free of an elutable material." Id. at *4.

Cordis makes the Cypher drug-eluting expandable stent. The Cypher stent has two coatings: an undercoat containing the drug and a topcoat. Early in the manufacturing process, the Cypher stent's topcoat is drug-free. The topcoat is sprayed on as a solution containing no drug but containing a polymer and two solvents, tetrahydrofuran (or THF) and toluene, both of which are toxic to humans. The solvents dissolve the drug, allowing it to diffuse from the undercoat into the topcoat. Thus, when the Cypher stent is sterilized, removing any remaining solvent, the drug has moved into the topcoat to such an extent that the topcoat and undercoat contain the same

concentration of drug. The topcoat is thinner than the undercoat; it contains about 23% of the total amount of the drug in the stent after sterilization.

At trial, the jury found that claim 8 of the '536 patent would not have been obvious based on, among other prior art references, U.S. Patent 5,545,208 ("Wolff") and U.S. Patent 5,512,055 ("Domb"). The jury also found that the Cypher stent infringed claim 8. After trial, Cordis filed a renewed motion for JMOL or, in the alternative, a new trial on infringement and validity. The court denied Cordis's motion.

In doing so, the district court upheld the jury's nonobviousness finding over Domb, Wolff, and several other references. The court reasoned that Domb, which discloses esophageal stents, does not suggest the use of metal in a stent, and that there was no evidence of motivation to combine Domb with other references. <u>Opinion</u> <u>Denying JMOL</u>, 434 F. Supp. 2d at 320. The court reasoned that Wolff, according to one expert, does not teach a metallic stent having a two-layer coating, and the failure of Wolff's assignee to create the claimed stent after more than a decade of work evidenced a lack of motivation to combine the features of its various prior art stents with each other. <u>Id</u>. Finally, as a secondary consideration of nonobviousness, the court found from expert testimony that the praise for and commercial success of the Cypher stent were due to the claimed features and that, even after identifying an appropriate drug and stent, it took Cordis a great deal of time to develop a drug-eluting stent. <u>Id</u>. at 321.

Regarding infringement, the district court reasoned that the jury's infringement finding was based on substantial evidence because three experts had testified that Cypher was non-thrombogenic. <u>Id.</u> at 316–17. As for the "substantially free" limitation,

the court found support for the jury's infringement finding in a witness's testimony that the topcoat is drug-free when applied and "has about 1 to 2% drug . . . after manufacturing is completed," finding that 1 to 2% drug may be considered "substantially free." <u>Id.</u> at 315. The court also pointed to evidence that a stent need not be sterilized to be implantable and thus that the stent could infringe during manufacture, when the topcoat was first applied and was then drug-free. <u>Id.</u> The court referred to testimony that concluded, after applying the court's claim construction, that the Cypher stent was substantially free of elutable material. <u>Id.</u> Finally, the court found that the '536 patent specifically contemplates that the drug will move into the topcoat prior to implantation, implying that the "substantially free" limitation does not preclude the topcoat from containing 23% of the drug. <u>Id.</u> The court thus held that the jury's finding of infringement was based on substantial evidence.

After the district court denied Cordis's motions, Cordis again moved for a new trial, based on newly discovered evidence that the FDA had found an increased risk of thrombosis in patients who had been treated with drug-eluting stents. Thus, according to Cordis, the Cypher stent could not "provide[] long term non-thrombogenicity." '536 patent col.13 II.23–24. The court denied Cordis's second motion for a new trial because the FDA had opined that an increased risk of death and heart attack was only possibly due to stent thrombosis, and thus that the new evidence was too speculative to warrant either dismissal or a new trial. <u>Opinion Denying New Trial</u>, 2007 WL 2775087, at *3.

Cordis timely appealed the district court's claim construction, the denial of JMOL on both obviousness and noninfringement, and the denial of a new trial. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. <u>Claim Construction</u>

1. <u>Construction of "Non-Thrombogenic"</u>

Cordis asserts that the district court erred by declining to construe the "nonthrombogenic" limitation to require less thrombogenicity than an uncoated metal stent. Cordis argues that, according to the language of claim 8, the specification, and the prosecution history, the non-thrombogenic material must have an effect different from the stent's natural effect, and that the specification itself compares the invention to metal stents. Also, according to Cordis, Boston Scientific admits that "nonthrombogenic" is a relative term requiring a comparison, and it waived any argument that the comparison should be to rough, porous coatings as opposed to bare metal Cordis also argues that the court should not have relied on dictionary stents. definitions, especially of unclaimed terms. Cordis asserts that undisputed evidence showed that Cypher stents and bare-metal stents were equally thrombogenic, such that Cypher stents would not infringe under the correct claim construction. Although Cordis publicly declared that its stents were non-thrombogenic, seemingly meeting the claim language and thus infringing, Cordis argues that its public statements used the term in a different sense from the patent and that its stents do not infringe.

Boston Scientific responds that nothing in the specification or prosecution history requires a comparison with bare metal stents; any comparison is to other coatings that promote thrombosis, so even if the Cypher stent were more thrombogenic than a bare metal stent, it would still infringe. Indeed, Boston Scientific points out that the claim language allows some metal to be left uncoated, so that a comparison to bare metal

stents would not make sense. According to Boston Scientific, the court's definition conforms with both the ordinary meaning and experts' definitions of "non-thrombogenic." Boston Scientific adds that the Cypher stent infringes claim 8 of the '536 patent under either the district court's claim construction or Cordis's proposed claim construction. Boston Scientific notes that Cordis admitted in FDA submissions and promotional literature that the Cypher coating is "non-thrombogenic." Boston Scientific also points out that Cordis uses toluene to smooth the surface and remove pores, preventing thrombosis, indicating that its stents are non-thrombogenic. Finally, according to Boston Scientific, a new claim construction would require a remand to allow Boston Scientific to present a new infringement case.

We review claim construction <u>de novo</u> on appeal. <u>Cybor Corp. v. FAS Techs.</u>, <u>Inc.</u>, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). We agree with Boston Scientific that the district court reasonably construed the "non-thrombogenic" limitation to mean "a material that does not promote thrombosis for a period of time that extends both during and after release of the biologically active material." To determine the meaning of "nonthrombogenic," we begin by considering the language of the claims. <u>See Phillips v.</u> <u>AWH Corp.</u>, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The language of claim 1 requires that the non-thrombogenic topcoat material "provide[] . . . non-thrombogenicity" to the stent, but it does not require a comparison to any other stent, either bare metal or coated. '536 patent col.13 II.22–26. As the claims themselves provide no other insight into the meaning of "non-thrombogenic," we turn to the specification in order to determine if it provides a clearer indication of the scope of "non-thrombogenic."

"[C]laims must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315 (quotation marks omitted). The abstract of the invention states that the "non-thrombogenic surface . . . is provided with sites . . . which aid in . . . reduc[ing] thrombogenic activity." '536 patent abstract; see also id. at col.2 II.36-46 (using heparin "to impart a non-thrombogenic surface to the material"). Thus, we can discern that the non-thrombogenic material must reduce thrombogenic activity because of its particular properties. This conclusion accords with the fact that stents are known to promote thrombosis, and the goal of the patent is to have the claimed stent promote thrombosis as little as possible, or not promote thrombosis at all. However, it is clear from the specification that the reduced thrombogenic activity is not necessarily reduced from that of bare metal stents. Indeed, the specification discusses various ways of formulating a topcoat and then states that "a top coat or surface coating modified . . . to make the surface more non-thrombogenic presents a distinct advantage." Id. at col.6 II.49–55. Thus, the reduced thrombogenic activity is clearly reduced from that of other coated stents whose topcoats have not been so modified.

Cordis argues that the prosecution history precludes the district court's construction of "non-thrombogenic" and that the claimed device must have had a reduced risk of thrombosis over that of a bare metal stent. "[A] court should also consider the patent's prosecution history, if it is in evidence. . . . Like the specification, the prosecution history provides evidence of how the [Patent Office] and the inventor understood the patent." <u>Phillips</u>, 415 F.3d at 1317 (citations and quotation marks omitted). During prosecution, the applicant added the "non-thrombogenic" limitation to overcome an anticipation rejection, explaining that the topcoat "renders the coated

device non-thrombogenic" and arguing that the prior art did not provide the same benefit. However, the prior art device, according to the applicant, was directed to "drug containing coatings . . . for metal stents." Parties' Joint App. at A482 (prosecution history of '536 patent, amendment dated July 30, 1997). Thus, if the amendment required reduced thrombogenicity over anything, it would be reduced over the prior art stent that is coated, not the bare metal prior art stent. The applicant therefore could not have considered "non-thromobogenic" to require reduced thrombogenicity over a bare metal stent.

Cordis also argues that the district court should not have compared dictionary definitions of "thrombogenic" and "thrombolytic" because "thrombolytic" does not appear in the claim, and because it is treated synonymously with "non-thrombogenic" in the specification. We disagree. Courts may of course "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents," <u>Phillips</u>, 415 F.3d at 1322–23, and the court here did not err in relying on dictionary definitions to inform the meaning of the claim terms. The district court here permissibly looked to the definitions of "thrombogenic" and "thrombolytic" to inform the meaning of "non-thrombogenic." Because the court's definition accords with the specification, prosecution history, and the dictionary definition of a related term, we affirm the district court's definition of the term "non-thrombogenic." We therefore need not address Cordis's arguments that, under a different claim construction, the Cypher stent does not infringe claim 8 of the '536 patent.

2. <u>Construction of "Long Term"</u>

Cordis also argues that the district court erred by construing "long term" to mean a "period of time" and abused its discretion in denying Cordis's motion for a new trial based on newly discovered data. According to Cordis, the district court's construction improperly erases the claim requirement of "long term" because the claim requires both "long term non-thrombogenicity" and that the non-thrombogenicity be provided "during and after release of the biologically active material," whereas the court's definition only required "a period of time that extends both during and after release of the biologically active material." Cordis argues that the court's claim construction lessened the significance of what the specification describes as an important objective of the invention. Moreover, according to Cordis, data that became available after the trial but before entry of judgment showed that its Cypher stent had long-term thrombosis risks, and Boston Scientific itself publicly stated that the Cypher stent had a higher incidence of late thrombosis than bare metal stents.

Boston Scientific responds that the "long term" requirement has not been read out of the claim because the district court's construction includes a time limitation. Neither the specification nor the prosecution history limits "long term" to the phenomenon of late stent thrombosis, which occurs more than one year after implantation. Moreover, according to Boston Scientific, Cordis has publicly stated that the same data it now relies on is flawed. Boston Scientific also argues that the data Cordis seeks to include is cumulative and existed before trial, so it is not new evidence.

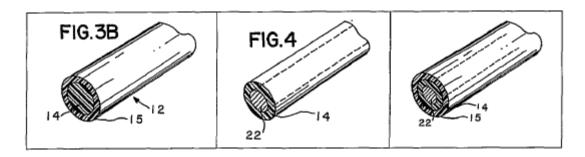
We agree with Boston Scientific that the district court correctly construed the "long term" aspect of the "non-thrombogenic" limitation. Neither the specification nor the

prosecution history defines the period of time that is "long term," other than to require that it be longer than two weeks, '536 patent col.7 II.1–5, and the claim construction includes two time limitations, like the claim itself. The claim construction requires both "a period of time" and that the period "extends both during and after release of the biologically active material." Even assuming, as Cordis argues, that the specification describes long-term non-thrombogenicity as an important objective of the invention, it does not further elucidate the meaning of "long term" or require that those specific words be used in the claim construction. We thus affirm the district court's construction of the "non-thrombogenic" limitation, including the "long term" aspect.

B. <u>Validity</u>

We next turn to the issue of the validity of the '536 patent. Cordis argues that the district court erred in denying Cordis's motion for JMOL of invalidity of the '536 patent on the ground of obviousness. According to Cordis, the Wolff patent alone renders the invention of claim 8 obvious. Figure 3B of Wolff shows a polymer stent made of a drug-eluting polymer with a barrier topcoat, and Wolff also refers to the stent and topcoat as separate "layers." Figure 4 of Wolff then shows a metallic stent with a drug-eluting polymer coating, and the drug-eluting polymer coating is identified with the same numeral as the drug-eluting polymer stent of figure 3B. Cordis argues that it would have been obvious to combine Wolff's figure 3B, disclosing a drug-eluting polymer stent with a drug-free coat with the possibility of additional coats, and figure 4, disclosing a metal stent with a drug-eluting polymer coat, to arrive at the invention of claim 8. In figures 3B and 4, as shown in the drawing from Cordis's brief reproduced below, numeral 22 refers

to a metal stent, numeral 14 refers to a drug-eluting polymer layer, and numeral 15 refers to a separate layer of polymer that may be drug-free.



Principal Br. of Cordis at 56.

Cordis also argues that Domb alone also renders claim 8 obvious because Domb teaches every limitation except that the stent can be made of metal and have an open lattice. However, according to Cordis, both features were well known in the esophageal stent field of Domb. Cordis adds that at least four other references teach implantable devices with two-layer coatings that include a polymer undercoat containing a drug and a barrier topcoat that controls the drug's release rate. Combined, according to Cordis, they also disclose every other limitation. Finally, Cordis argues that witnesses described developing Cypher before the '536 patent's priority date and described the ease, at the time, of coating stents with the two claimed coats. Cordis argues that, in a pre-KSR-type analysis, Boston Scientific's expert relied on an unduly low skill level in asserting that the prior art did not explicitly suggest the modifications that led to the claimed invention. See KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007). Regarding secondary considerations of nonobviousness, Cordis argues that Boston Scientific failed to link Cypher's success to the polymer coating.

Boston Scientific responds that Wolff fails to recognize the additional nonthrombogenic benefits of a topcoat that is substantially drug-free over a topcoat that

contains drug, therefore not rendering claim 8 with its non-thrombogenic drug-free topcoat obvious. Boston Scientific also argues that Wolff only discloses a single coating layer, and Wolff does not disclose non-thrombogenicity. Although Wolff discloses silicone and polyurethane as topcoat materials, Boston Scientific asserts that non-thrombogenicity is not inherent in those materials because non-thrombogenicity depends on surface properties such as porousness. Boston Scientific adds that Cordis contradicted its own noninfringement argument about non-thrombogenicity, so the jury logically could have rejected both positions. Boston Scientific also argues that Domb does not disclose a non-thrombogenic topcoat, as the stent in Domb was designed to be used in the esophagus, where there is no circulating blood to cause thrombosis. Boston Scientific further argues that Domb teaches away from an open lattice structure because an open lattice promotes tissue in-growth, while the Domb stents were designed to be removable.

Boston Scientific argues that <u>KSR</u> is irrelevant to this obviousness inquiry because Cordis urged no particular combination of references. As a secondary consideration of nonobviousness, Boston Scientific argues that Wolff and two of the other references asserted by Cordis were assigned to Medtronic, who failed to develop a drug-eluting stent before the priority date of the '536 patent. Had it been so obvious, Boston Scientific argues, Medtronic would have made the claimed invention. Also, according to Boston Scientific, Cordis's expert admitted to the long-felt need to deliver drugs from stents. Finally, Boston Scientific argues that Cordis's witness stated that the success of the Cypher stent was due to the claimed polymer coating system.

We agree with Cordis that Wolff alone renders claim 8 of the '536 patent obvious and therefore invalid. Because we hold the claim obvious based on Wolff alone, we do not address Cordis's arguments for obviousness based on Domb or any other reference.

"We review the jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." <u>Johns Hopkins Univ. v. Datascope Corp.</u>, 543 F.3d 1342, 1345 (Fed. Cir. 2008) (quotation marks omitted). While a jury may render a decision on a question of obviousness when it is considering any underlying fact questions, <u>see id.</u>, obviousness is ultimately a question of law that this court reviews <u>de novo</u>. When we consider that, even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, we may reverse its obviousness determination. <u>See Richardson-Vicks, Inc. v. Upjohn Co.</u>, 122 F.3d 1476, 1479 (Fed. Cir. 1997) ("[I]n re-creating the facts as they may have been found by the jury, and in applying the <u>Graham</u> factors to the case, we assess the record evidence in the light most favorable to the verdict winner . . . , though this does not mean that we are free to abdicate our role as the ultimate decision maker on the question of obviousness. That decision remains within our province." (citation omitted)). That is the case here.

As we have discussed above, claim 8 recites a metallic stent with an open lattice structure. The stent includes an undercoat and a topcoat. The undercoat contains a drug, and the topcoat is drug-free and non-thrombogenic. Boston Scientific admits that Wolff contains most of the limitations of claim 8. Wolff discloses a metallic stent with an open lattice structure. In figures 2 and 4, where figure 4 is an enlargement of the

embodiment shown in figure 2, Wolff col.2 II.53–54, Wolff discloses a metallic stent, <u>id.</u> at col.6 II.57–61, with an open lattice structure, <u>id.</u> at Fig. 2.

Wolff also discloses a stent including an undercoat and a topcoat, where the undercoat contains a drug. In figure 3B, there is shown a "layer 14," <u>id.</u> at col.9 I.32, made of polymer, <u>id.</u> at col.9 I.28, covered by a "second layer of polymer 15," <u>id.</u> at col.9 I.26. Moreover, the specification describes that the stent shown in figure 3B "may be made from one or <u>several</u> layers of polymer." <u>Id.</u> at col.9 II.23–24 (emphasis added). Thus, even though figure 3B shows only two layers of polymer, the stent itself and a single coating, the specification clearly contemplates the use of several, or more than two, layers of polymer, meaning it contemplates at least two coatings. Wolff also discloses that the topcoat is drug-free, as layer 15 in figure 3B "may be a simple barrier which limits diffusion of drugs" and "could be as simple as a silicone or polyurethane." <u>Id.</u> at col.9 II.26–33.

Wolff also discloses that the topcoat is non-thrombogenic. In figure 3B, the "barrier coating 15 could be as simple as a silicone or polyurethane," <u>id.</u> at col.9 II.32–33, two materials that are generally non-thrombogenic. Even if, as Boston Scientific contends, silicone and polyurethane are not inherently non-thrombogenic, Wolff clearly contemplates that the topcoat will be non-thrombogenic. For example, as Wolff explains, "[t]he initial deposition of platelets and subsequent <u>thrombus formation</u> 38 <u>is</u> <u>controlled and minimized by the stent design</u> and the elution which limits platelet aggregation and other immediate repair responses described previously. Localized thrombus formations . . . [are] also decreased." <u>Id.</u> at col.9 II.46–52 (emphases added). In other words, Wolff contemplates using the design of the stent, which may contain a

silicone or polyurethane topcoat, to reduce thrombogenesis, in addition to using the elution of a thrombolytic drug to reduce thrombogenesis. Thus, the record did not contain substantial evidence for the jury to conclude that Wolff does not teach a nonthrombogenic topcoat.

Boston Scientific argues that Wolff fails to recognize the additional nonthrombogenic benefits of a topcoat that is substantially drug-free over a topcoat that contains drug, but Wolff need not have recognized the additional benefit of one embodiment to have rendered the claim obvious. <u>See, e.g., Merck & Co. v. Biocraft Labs., Inc.</u>, 874 F.2d 804, 807 (Fed. Cir. 1989) ("That the [prior art] patent discloses a multitude of effective combinations does not render any particular formulation less obvious. This is especially true because the claimed composition is used for the identical purpose taught by the prior art."); <u>In re Corkill</u>, 771 F.2d 1496, 1500 (Fed. Cir. 1985) (affirming obviousness rejection of claims in light of prior art teaching that "hydrated zeolites will work" in detergent formulations, even though "the inventors selected the zeolites of the claims from among 'thousands' of compounds").

As we have explained, Wolff teaches all of the limitations of claim 8, and the record did not contain substantial evidence for the jury to conclude otherwise. The only qualification to this statement of fact is that all of the limitations are found in two separate embodiments pictured side by side in the patent, not in one embodiment. However, "[i]f a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." <u>KSR</u>, 127 S. Ct. at 1740. We agree with Cordis that one of ordinary skill in the art would have been motivated to combine the embodiment in figure 3B of Wolff with the embodiment in figure 4 of Wolff to arrive at a metal stent with two

coating layers. Combining two embodiments disclosed adjacent to each other in a prior art patent does not require a leap of inventiveness. As shown in Cordis's drawing and described in the specification of Wolff, figure depicts a metal stent with a drug-eluting polymer coating, the coating represented by numeral 14. <u>See</u> Wolff col.6 II.59–62. Figure 3B, which is located directly below figure 4 in the patent, shows a drug-eluting polymer stent, also represented by numeral 14, coated with "a second layer of polymer 15." <u>Id.</u> at col.9 II.25–26. One of ordinary skill would have been motivated to coat the metal stent of figure 4, including its layer 14 of drug-containing polymer, with a second layer of polymer, like layer 15 depicted in figure 3B, that is substantially free of an elutable material. Just as the stent in figure 3B benefits from the two layers, one containing a drug and the other limiting diffusion of the drug, so would the stent in figure 4 benefit from the same two coating layers. A metal stent coated with a drug-eluting polymer and a second layer of drug-free polymer, as shown in figures 3B and 4, is what constitutes claim 8.

We also agree with Cordis that the weak secondary considerations of nonobviousness do not overcome the strong <u>prima facie</u> showing that Wolff renders claim 8 of the '536 patent obvious. Even though Medtronic owned the Wolff patent and two other prior art patents that Cordis relies on and failed to develop a drug-eluting stent, Cordis presented evidence that the failure was due to difficulty in finding a suitable drug, rather than an inability to conceive of a drug-containing undercoat combined with a drug-free topcoat. Moreover, "given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the claim] would have been obvious." Leapfrog

Enters., Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1162 (Fed. Cir. 2007); see also Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337, 1344 (Fed. Cir. 2008) (following Leapfrog).

The district court thus incorrectly upheld the jury's verdict of nonobviousness. "Where . . . the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment [or JMOL] is appropriate." KSR, 127 S. Ct. at 1745–46; see Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000) ("[T]he standard for granting summary judgment mirrors the standard for judgment as a matter of law, such that the inquiry under each is the same." (quotations omitted)). Here, the content of Wolff is not in material dispute. The expert's testimony that Wolff "does not teach a metallic stent having a two-layer coating," Opinion Denying JMOL, 434 F. Supp. 2d at 320, is undisputed; as we have explained above, we agree that Wolff does not expressly teach such a stent. However, it teaches two embodiments that together render such a stent obvious. The scope of claim 8 of the '536 patent is not in material dispute, nor is the level of ordinary skill in the art. Although Cordis argues that Boston Scientific relied on an unduly low level of ordinary skill, the parties agreed at trial to the level of ordinary skill and did not even present that question to the jury. Accordingly, we conclude that claim 8 would have been obvious over Wolff at the time the invention was made. We are free to override the jury's legal conclusion on the ultimate question of obviousness without deference. See Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1324-28 (Fed. Cir. 2008). We therefore hold as a matter of law that claim 8 would have been obvious in view of Wolff.

Because we have reversed the district court's judgment on validity, Cordis's arguments regarding infringement and a new trial need not be considered.

CONCLUSION

Accordingly, the judgment of the district court is reversed.

<u>REVERSED</u>