

United States Court of Appeals for the Federal Circuit

03-1155

SCIMED LIFE SYSTEMS, INC., BOSTON SCIENTIFIC CORPORATION, and
BOSTON SCIENTIFIC SCIMED, INC.,

Plaintiffs,

and

MEDINOL LTD.,

Plaintiff-Appellants.

v.

JOHNSON & JOHNSON, CORDIS CORPORATION, and
JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS, INC.,

Defendants-Appellees.

DECIDED: January 14, 2004

Before CLEVINGER, BRYSON, and GAJARSA, Circuit Judges.

CLEVINGER, Circuit Judge.

This suit was brought in the United States District Court for the District of Delaware by Scimed Life Systems, Inc. ("Scimed"), Boston Scientific Corporation, Boston Scientific Scimed, Inc., and Medinol, Ltd. ("Medinol") (collectively "plaintiffs"). The plaintiffs allege Johnson & Johnson, Cordis Corporation, and Johnson & Johnson Interventional Systems, Inc. (collectively "Cordis") infringed several patents owned by Medinol directed to balloon expandable stents. After a two-week trial, a jury returned a verdict finding only one of the asserted claims not invalid and infringed. The jury found Cordis did not infringe the remaining claims and that these claims would have been obvious to a person of ordinary skill in the art at

the time they were filed with the United States Patent and Trademark Office ("PTO"). Medinol appeals the district court's denial of the plaintiffs' post-trial motions for judgment as a matter of law ("JMOL") and a new trial on the issues of infringement and validity of the remaining claims. See Scimed Life Sys., Inc. v. Johnson & Johnson, 225 F. Supp. 2d 422, 441 (D. Del. 2002). We affirm.

I

The build-up of fatty deposits in coronary arteries, known as atherosclerosis, can eventually block the flow of blood to the heart. Id. at 425. During the 1970s, physicians began treating atherosclerosis by inserting a balloon attached to a wire catheter into a constricted artery and inflating the balloon so as to compress the fatty deposits against the vessel wall, thereby enlarging the space through which blood could flow. Id. This procedure is commonly known as balloon angioplasty. Id. Within a few months of this procedure, an artery would often become blocked again by the recurrence of fatty deposits in a process known as restenosis. Id.

Physicians utilize balloon expandable stents to minimize the incidence of restenosis. Id. A stent is a medical device much like a miniature scaffolding that physically holds open a diseased artery into which it is inserted. Id. Stents have two positions: closed and open. A stent is inserted into an artery by placing it on a balloon and snaking it into the desired location with a catheter. Id. When the balloon is inflated, the stent expands from the closed position to the open position, and it remains in the artery after the physician removes the balloon and catheter.

This appeal concerns three patents directed to balloon expandable stents owned by Medinol: U.S. Patent No. 5,733,303 (the "303 patent") issued on March 31, 1998; U.S. Patent No. 5,843,120 (the "120 patent") issued on December 1, 1998; U.S. Patent No. 5,972,018 (the "018 patent") issued on October 26, 1999. The patents-in-suit are part of the same patent family and share the same drawings and substantially similar written descriptions. None of the

parties disputes that the key date for the purposes of invalidity is July 28, 1994, the filing date of a priority document common to each of the patents-in-suit.

One object of the patents-in-suit is to provide a flexible stent. See, e.g., '303 patent, col. 1, ll. 52-53. Another object is to minimize the tendency of expandable stents to shrink longitudinally during expansion. See, e.g., id. at col. 1, ll. 53-54. This property is known as compensation for foreshortening. Foreshortening made prior art stents hard to place accurately in blood vessels and led to scraping of the arterial wall during expansion. The district court identified "continuous uniform scaffolding, and resistance to radial deformation and collapse upon expansion" as additional features of the stents disclosed in the patents-in-suit. Id. at 425.

The plaintiffs alleged Cordis infringed several claims of the patents-in-suit by selling the BX Velocity Stent, the Corinthian Stent, the Crown Stent, and the Mini-Crown Stent. The asserted claims included claim 6 of the '303 patent which is directed to:

An expandable stent defining a longitudinal aperture, including: a plurality of flexible connected cells, each of said flexible cells comprising:

- a) a first member having a longitudinal component having a first end and a second end;
- b) a second member having a longitudinal component having a first end and a second end,
 - c) a third member having a longitudinal component having a first end and a second end;
 - d) a fourth member having a longitudinal component having a first end and a second end;
 - e) a first loop defining a first angle disposed between said first end of said first member and said first end of said second member;
 - f) a second loop defining a second angle disposed between said second end of said third member and said second end of said fourth member, and disposed generally opposite to said first loop;
 - g) a first flexible compensating member or flexible link having a first end and a second end disposed between said first member and said third member, said first end of said first flexible compensating member or flexible link communicating with said second end of said first member

- and said second end of said first flexible compensating member or flexible link communicating with said first end of said third member, said first and said second ends disposed a variable longitudinal distance from each other;
- h) a second flexible compensating member or flexible link having a first end and a second end disposed between said second member and said fourth member, said first end of said second flexible compensating member or flexible link communicating with said second end of said second member and said second end of said second flexible compensating member or flexible link communicating with said first end of said fourth member, said first and said second ends disposed a variable longitudinal distance from each other, said first and said second flexible compensating member or flexible links differentially extendable or compressible when said stent is bent in a curved direction away from the longitudinal axis of said aperture; and
- i) said first, said second, said third, and said fourth members and said first and said second loops, and said first and said second flexible compensating member or flexible links disposed so that as said stent is expanded the distance between said first and said second flexible compensating member or flexible links increases and the longitudinal component of said first, second, third and fourth members decreases while said first and said second loops remain generally opposite to one another, the ends of said first and said second flexible compensating member or flexible links open so as to increase said variable longitudinal distance between said first and said second ends of said first flexible compensating member or flexible link and so as to increase said variable longitudinal distance between said first and said second ends of said second flexible compensating member or flexible link so as to compensate for the decreasing of the longitudinal component of said first, second, third, and fourth members and substantially lessen the foreshortening of said stent upon its expansion.

'303 patent, col. 7, ll. 1-65. Cordis was also charged with infringement of claim 12 of the '303 patent which is directed to: "The stent of claim 6, wherein said cells define a uniform cellular structure." '303 patent, col. 8, ll. 18-19.

In addition, the plaintiffs charged Cordis with infringement of claims 35, 47, and 60 of the '018 patent, which, in seriatim, recite:

35. A flexible, expandable stent, comprising:

a plurality of flexible cells provided with a plurality of first loops and a plurality of second loops, said first loops and said second loops disposed and adapted to cooperate so that upon the expansion of said stent said first loops and said

second loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

47. A generally longitudinally extending tubular stent which is substantially uniformly flexible with respect to its longitudinal axis by the flexibility of its cells with respect to said axis including:

- (a) a plurality of cells flexible around said longitudinal axis connected to one another about the circumference of said stent to form a band of flexible cells, each of said flexible cells having apices disposed apart and generally opposite to one another,
- (b) each of said flexible cells having a plurality of flexible links disposed apart and generally opposite to one another,
- (c) each of said flexible links including a plurality of portions with neighboring portions having an area of inflection therebetween, and
- (d) said flexible cells in said adjacent bands of flexible cells connected to one another.

60. A stent having a longitudinal axis formed of a tube having a patterned shape, the patterned shape comprising:

- a. first meander patterns having axes extending in a first direction;
- b. second meander patterns having axes extending in a second direction, different than said first direction, wherein said second meander patterns intersect with said first meander patterns;
- c. wherein said first meander patterns have loops;
- d. wherein said first meander patterns are spaced apart to leave a portion of said second meander patterns between each pair of adjacent first meander patterns;
- e. wherein each of said second meander patterns has at least one loop between at least one pair of adjacent first meander patterns, and

- f. wherein said loops disposed on said first meander patterns and said loops disposed on said second meander patterns are disposed and adapted to cooperate so that upon the expansion of said stent said loops change shape to compensate for the tendency of said stent to foreshorten when said stent is expanded.

'018 patent, col. 10, ll. 8-15; col. 12, ll. 24-40; col. 16, ll. 4-25.

Finally, the plaintiffs contended that Cordis infringed claim 13 of the '120 patent which recites:

An expandable stent formed of an elongated cylindrical unitary tube suitable for insertion into a lumen or blood vessel in which it may be expanded, comprising: a plurality of first meanders extending in a first direction on the cylinder of the tube and a plurality of second meanders extending in a second direction, on the cylinder of the tube, wherein the first and second meanders are formed with loops and are interconnected such that at least one of the loops of each of the first meanders is disposed between each consecutive second meander to which the first meander is connected, and at least one of the loops of each of the second meanders is disposed between each consecutive first meander to which it is connected; the first and second meanders defining a plurality of enclosed spaces.

'120 patent, col. 7, ll. 13-26.

During the proceedings below, the district court concluded that the accused stents sold by Cordis did not, as a matter of law, literally contain the "communicating with" limitation of claim 6 of the '303 patent. Scimed Life Sys., 225 F. Supp. 2d at 432 n.1. The district court held a trial in which a number of issues were put to the jury, including, infringement of claim 12 of the '303 patent under the doctrine of equivalents; literal and equivalent infringement of claims 35, 47, and 60 of the '018 patent; literal and equivalent infringement of claim 13 of the '120 patent; validity of the claims asserted against Cordis.

At the conclusion of the two-week trial, the jury returned a verdict finding only claim 13

of the '120 patent not invalid and literally infringed by Cordis's sale of the Corinthian Stent. Id. at 433. The jury determined Cordis did not infringe any of the asserted claims, literally or under the doctrine of equivalents, by selling the three remaining accused stents. Id. at 432-33. The jury also found the asserted claims of the '303 and '018 patents invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1 and for obviousness under 35 U.S.C. § 103(a). Id. at 432-34.

The plaintiffs subsequently moved for JMOL and for a new trial on the issues of infringement which the jury resolved adverse to them and on the issue of the validity of the asserted '303 and '018 patent claims. Applying the substantial evidence standard of review, the district court held that a reasonable jury could have concluded that the accused stents sold by Cordis do not contain, literally or by equivalence, several of the claim limitations found in the asserted claims of the '303 and '018 patents. Id. at 434-38. The district court also held that the jury's written description determination was unsupported by substantial evidence, id. at 438-39, but concluded nevertheless that, "[t]he record reflect[ed] substantial evidence that support[ed] the jury's finding by clear and convincing evidence that the asserted claims of the '303 and '018 patents are invalid for obviousness over the prior art." Id. at 441. The district court denied the plaintiffs' motions accordingly. Of all the plaintiffs, only Medinol appealed the district court's decision to us. We have jurisdiction over Medinol's appeal pursuant to 28 U.S.C. § 1295(a)(1).

II

A

We review a denial of a motion for JMOL by reapplying the district court's standard of review. See Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1318 (Fed. Cir. 2003) ("We review the grant or denial of JMOL without deference by reapplying the JMOL standard of the district court."). To prevail on appeal, the party that moved the district court for JMOL "must prove that the jury's factual findings were not supported by substantial evidence or that

the facts were not sufficient to support the conclusions necessarily drawn by the jury on the way to its verdict[.]" Applied Med. Res. Corp. v. U.S. Surgical Corp., 147 F.3d 1374, 1376 (Fed. Cir. 1998). "We review the trial court's denial of a motion for a new trial for abuse of discretion." BJ Servs. Co. v. Halliburton Energy Servs., Inc., 338 F.3d 1368, 1374 (Fed. Cir. 2003) (citing Stryker Corp. v Davol, Inc., 234 F.3d 1252, 1259 (Fed. Cir. 2000)).

B

Although Medinol has appealed those aspects of the district court's decision relating to infringement as well as validity, we do not address its contentions as to infringement because we hold there was substantial evidence in the record to support the conclusion that the asserted claims of the '303 and '018 patents were obvious over the prior art at the time they were filed with the PTO. "[O]bviousness is a question of law based on underlying facts[.]" Med. Instrumentation and Diagnostics Corp. v. Elekta, AB, 344 F.3d 1205, 1220 (Fed. Cir. 2003) (citation omitted). We review the ultimate determination of obviousness de novo. See Akamai Techs. v. Cable & Wireless Internet Servs., 344 F.3d 1186, 1195 (Fed. Cir. 2003). When, as here, the obviousness issue is submitted to the jury, we presume "the jury resolved . . . underlying factual disputes in favor of the verdict winner and leave those presumed findings undisturbed if they are supported by substantial evidence." See Jurgens v. McKasy, 927 F.2d 1552, 1557 (Fed. Cir. 1991) (reviewing jury determination on issue of obviousness) (citation omitted).

Claim interpretation is the first step of a validity analysis. See Amazon.com, Inc. v. Barnesandnoble.com, inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001). The second step entails determining whether or not the prior art renders the properly construed claim obvious. Id. A claim is invalid if the differences between it and the prior art "are such that the [claimed] subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art[.]" 35 U.S.C. § 103(a) (2002); Graham v. John Deere Co., 383 U.S. 1, 13 (1966). The legal conclusion of obviousness is driven by several factual

determinations, including, "(1) the scope and content of the prior art; (2) the differences between the prior art and the [properly construed] claims; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness." Riverwood Int'l Corp. v. Mead Corp., 212 F.3d 1365, 1366 (Fed. Cir. 2000) (quoting Graham, 383 U.S. at 13-14).

Even if all of the elements of a claim are present in the prior art, the claim will not be obvious unless the prior art also contained, at the time the claim was filed, a motivation to combine prior art elements into the claimed invention. See C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352 (Fed. Cir. 1998) (upsetting jury verdict of obviousness because record lacked evidence of motivation to combine). The conclusion that the prior art contained a motivation to combine is a conclusion of fact. See Med. Instrumentation and Diagnostics, 344 F.3d at 1221 (citing In re Gartside, 203 F.3d 1305, 1316 (Fed. Cir. 2000)). "The suggestion or motivation to combine references does not have to be stated expressly; rather it 'may be shown by reference to the prior art itself, to the nature of the problem solved by the claimed invention, or to the knowledge of one of ordinary skill in the art.'" Id. at 1221-22 (quoting Beckson Marine, Inc. v. NFM, Inc., 292 F.3d 718, 728 (Fed. Cir. 2002)).

C

Although Medinol argues the district court committed several errors of claim interpretation, only one of these alleged mistakes goes to the issue of validity. Medinol argues that the district court construed improperly the "uniform cellular structure" limitation of claim 12 of the '303 patent, and as a result, that the jury's determinations regarding the differences between the prior art and the properly construed claims were unsupported by substantial evidence. The district court stated in its instructions to the jury that "uniform cellular structure" means "[t]he flexible connected cells of claim 6 have the same structure." (J.A. at 8735.) This definition is, verbatim, the definition the district court gave "uniform cellular structure" during Markman proceedings held before trial. Furthermore, it is nearly the exact definition Medinol proffered below in its Opening Brief on Claim Construction. Medinol proposed "uniform cellular

structure" meant that "[a]ll of the cells of the stent have the same structure." (J.A. at 4535.) Although pressed on the issue at oral argument, counsel for Medinol was unable to explain exactly how the district court's construction of "uniform cellular structure" was inconsistent with the express words of claim 12. We do not perceive any error in the district court's construction of "uniform cellular structure" that warrants upsetting the district court's conclusion that claim 12 was invalid for obviousness.

D

During oral argument, counsel for Medinol conceded that the prior art contained each and every element of the asserted claims of the '303 and '018 patents at the time they were filed with the PTO. However, on rebuttal, counsel retreated from this position, and asserted the prior art did indeed lack a teaching of compensation for foreshortening, which is a requirement of each of the claims the district court held invalid. Medinol thereby called into question the existence of substantial evidence of the presumed jury finding that compensation for foreshortening was present in the prior art.

Our review of the record indicates the jury was presented with substantial evidence of the existence of compensation for foreshortening in the prior art. Direct examination of Cordis's expert at trial, Dr. Nigel Buller, demonstrated as much. Dr. Buller first testified that stents made from a combination of rings (members) and flexible connectors (links), as required by the asserted claims of the '303 and '018 patents, were in the prior art. On direct examination, Dr. Buller was asked whether compensation for foreshortening was in the prior art and answered:

Yes. It was an obvious result of combining one of these flexible connectors with the ring structure that was known to shrink. So any of these serpentine rings were known to shrink when they expand. And if you combine a flexible connector that can get bigger, then it is an obvious result that foreshortening will be compensated for.

(J.A. at 2825.) Dr. Buller proceeded to identify three prior art references disclosing stent designs that compensated for foreshortening. This testimony was substantial evidence for the jury to have found that the compensation for foreshortening element was present in the prior art at the time the claims asserted against Cordis were made.

E

Medinol argues that even if each of the elements of the asserted claims was in the prior art, the record does not demonstrate there was a motivation to combine these elements in such a way that a person of ordinary skill would have arrived at the stents disclosed in the '303 and '018 patents. Again, we are not persuaded by Medinol's arguments. The record contains substantial evidence that a person of ordinary skill in the art, did, in fact, combine the elements of the stent design claimed by the '303 and '018 patents prior to July 28, 1994. As the district court recounted in its Memorandum Opinion in which it ruled on motions for summary judgment, in May 1994, Scimed engineers Paul Burmeister et al., ("Burmeister") "evaluated the concept of a hybrid stent that would partially self-expand and then fully expand with a balloon." Burmeister filed a patent application with the PTO on May 19, 1994 that included several drawings and that was subsequently abandoned. At trial, Dr. Buller testified the Burmeister design contained the design aspects of the stents claimed in the '303 and '018 patents, including serpentine rings, flexible connectors, compensation for foreshortening and flexible cells.^[1]

At oral argument, counsel for Medinol contended that the Burmeister application was not sufficient evidence of motivation to combine because it was ultimately abandoned. Medinol believes Burmeister failed to realize the commercial success his stent would enjoy in the marketplace, and as a result, failed to conceive the full scope of the invention as-claimed in the '303 and '018 patents. At trial, Cordis elicited testimony from Dr. Buller that Burmeister was not trying to design a better stent per se, but rather, was experimenting with different metals from which an improved stent might be manufactured. Dr. Buller added that he believed Burmeister abandoned the application because a suitable metal for an improved stent could not be found and the design itself was obvious.

At bottom, the subjective reasons for abandonment are irrelevant to assessing the probative value

of the Burmeister application on the issue of an existence in the prior art of a motivation to combine. The question "is what a hypothetical ordinarily skilled artisan would have gleaned from the [Burmeister application] at the time that the patent application leading to the ['303 and '018 patents] was filed." Amazon.com, 239 F.3d at 1364. That Burmeister may have improvidently given up attempts to secure patent protection for his design is irrelevant to the question of whether the knowledge of an ordinarily skilled artisan contained a motivation to combine the claim elements of the '303 and '018 patents that were present in the art prior to July 28, 1994. See id. (holding individual skilled artisan's personal failure to realize prior art elements could be combined based on actual knowledge was irrelevant to ultimate question of existence of motivation to combine). The jury had before it expert testimony that a person of ordinary skill in the art, on July 28, 1994, would inspect the drawings of the Burmeister application and conclude it disclosed a stent design that combined the claimed elements of the balloon expandable stent design taught by the patents-in-suit. This was legally sufficient evidence from which the jury could have found a motivation to combine in the knowledge of one of ordinary skill in the art, a finding of fact we must presume the jury to have made given that it returned a verdict on the validity issue in favor of Cordis.

For the reasons stated above, and because we find Medinol's other arguments on the issue of obviousness unpersuasive, we affirm the district court's decision denying the plaintiffs' motions for JMOL. We also hold the district court did not abuse its discretion when it denied the plaintiffs' motion for a new trial.

[1] The district court held the drawings filed with the Burmeister application did not anticipate the asserted claims of the '303 and '018 patents as a matter of law because they were not publicly accessible, and therefore, were not prior art. This issue is not before us in this appeal.