United States Court of Appeals for the Federal Circuit

05-1126

JOSEPH GRAYZEL,

Plaintiff-Appellant,

v.

ST. JUDE MEDICAL, INC., ST. JUDE MEDICAL, DAIG DIVISION, INC., and ST. JUDE MEDICAL S.C., INC.,

Defendants-Appellees.

DECIDED: December 23, 2005

Before MICHEL, Chief Judge, SCHALL and GAJARSA, Circuit Judges.

MICHEL, Chief Judge.

Dr. Joseph Grayzel ("Grayzel") appeals the United States District Court for the District of New Jersey's grant of summary judgment of invalidity of claims 13, 14, and 16 of U.S. Patent No. 4,850,960 ("the '960 patent") in favor of St. Jude Medical, Inc., St. Jude Medical S.C., Inc., and St. Jude Medical, Daig Division, Inc. (collectively, "St. Jude"). Grayzel v. St. Jude Med., Inc., No. 01-CV-3737 (D.N.J. Oct. 29, 2004) ("Summary Judgment Decision"). Grayzel also appeals the district court's grant of an injunction to enforce a protective order entered into by the parties during the course of discovery. Because we agree with the district court's construction of the "sheath," "flexible," and "uniformly-thin" claim limitations and its finding that the prior art

anticipates each and every limitation of claim 13 of the '960 patent, we affirm the summary judgment of invalidity. We further hold that the district court's grant of an injunction enforcing the protective order is moot as to claims 13, 14, and 16 and affirm as to claims 1-12, 15, and 17-26.

I. BACKGROUND

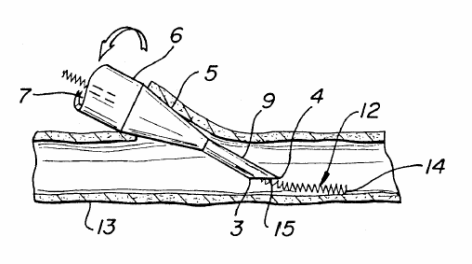
A. The Asserted Patent

In 1953, Dr. Sven Seldinger developed a new percutaneous technique for introducing a catheter into a patient's blood vessel. See Sven Seldinger, "Catheter Replacement of the Needle in Percutaneous Arteriography: A New Technique," Acta Radiologica 39: 368-76 (1953). His technique, which became known as the "Seldinger technique," involved: (1) inserting a hollow needle through the skin; (2) puncturing the blood vessel with the needle; (3) inserting a guidewire through the bore of the needle into the vessel; (4) removing the needle, leaving the guidewire in the vessel; (5) advancing a catheter over the guidewire into the vessel; and (6) removing the guidewire, leaving the catheter in the vessel through which a cardiologist may insert diagnostic and therapeutic devices. Prior to the "Seldinger technique," a doctor cut an incision in the skin and artery and then inserted the desired catheter.

In 1965, Drs. Donald Desilets and Richard Hoffman improved the Seldinger technique. See Donald T. Desilets & Richard Hoffman, "A New Method of Percutaneous Catheterization," Radiology 85: 147-48 (1965). They introduced a thin-walled, flexible sheath on top of the catheter and inserted that unit into the vessel as described above. The catheter was, however, removed along with the guidewire, leaving only the sheath in the vessel to act as a channel through which multiple devices

could be inserted and removed without having to pass each new device over a reinserted guidewire. This technique became known as the "modified Seldinger technique." Notably, because both the catheter and the sheath contained blunt or flat tips, considerable force was needed to insert the sheath-covered catheter into the vessel. That force often caused tearing and trauma at the puncture site.

In July of 1987, Grayzel filed a patent application claiming an improvement to the modified Seldinger technique. Specifically, he disclosed using a beveled tip at the end of the sheath, as shown in the figure below, to reduce the force needed to insert the sheath-covered catheter and to avoid traumatizing the insertion site. See '960 patent, col. 2, ll. 43-58.



'960 patent, fig. 9. The beveled tip is indicated by the number 15 with the leading point shown as number 4 and rearmost point shown as number 3. The catheter is designed number 6 with the distal portion shown as number 5 and cylindrical section leading to the beveled tip shown as number 9.

This application issued as the '960 patent in July of 1989. Independent claim 13 recites:

> 13. [1] A sheath of a size for use in the vascular system for assisting in the insertion of other devices in blood vessels through the wall of the blood vessel, said sheath comprising:
> [2] a flexible catheter for use in the vascular system;
> [3] said sheath having a flexible uniformly thin walled cylindrical shell body portion having a bore therethrough and a distal end and a proximal

end, said bore constructed to coact with and be supported by said flexible catheter extending within the bore;

[4] a bevelled tip portion formed on the distal end of said sheath, said bevelled tip being formed at an acute angle with respect to the longitudinal axis of said tubular portion, to facilitate entry into an existing puncture in the wall of a blood vessel.

'960 patent, col. 11, ll. 61-68 (emphases added) (underlined text shows disputed limitations; bracketed numbers reflect district court's designation of claim limitations).

B. The Prior Art

Two years before Grayzel filed his application, Dr. S. Murthy Tadavarthy and others published an article describing a percutaneous technique for introducing a filter into the inferior vena cava to snare blood clots ("Tadavarthy Article"). See S. Murthy Tadavarthy, "Kimray-Greenfield Inferior vena cava Filter: Percutaneous Introduction," Radiology 151: 525-26 (May 1984). The article disclosed a blood vessel dilation system having four parts: (1) a guidewire; (2) an 8 French dilator; (3) a 24 French dilator; and (4) a 24 French Teflon tube that fits over the 24 French dilator.[1] The article explained that after the two dilators and tube are inserted percutaneously into a patient's inferior vena cava by way of the guidewire, the dilators are removed, leaving the tube in position. It further explained that a Kimray-Greenfield filter may be placed into a patient's inferior vena cava through the tube to catch loose blood clots.

[1] The term "French" is a measurement for the diameter of tubular instruments and is equal to 0.013 inches. See McGraw Hill Dictionary of Scientific & Technical Terms 646 (3d ed. 1984).

C. The District Court Decision

In August of 2001, Grayzel filed a patent infringement action against St. Jude, alleging that St. Jude's Angio-Seal vascular closure device infringes independent claim 13 and dependent claims 14 and 16 of the '960 patent.[2]

During the course of discovery, St. Jude identified numerous prior art references that were not disclosed during the prosecution of the '960 patent. Grayzel in turn filed a request for an ex parte reexamination with the U.S. Patent and Trademark Office ("PTO") for claims 13, 14, and 16, and moved to stay the district court action pending reexamination. The PTO granted Grayzel's request for reexamination not just for claims 13, 14, and 16 as requested, but also for claims 1-12, 15, and 17-26. The district court denied Grayzel's motion to stay the litigation.

In response, St. Jude filed a motion for an injunction to enforce the protective order entered by the district court at the start of the litigation to bar both Grayzel and his litigation counsel from participating in the ex parte reexamination. That protective order identified two classes of information: (1) "Confidential Information;" and (2) "Attorneys' Eyes Only Information." Under the terms of the order, Grayzel had access to the Confidential Information, but not the Attorneys' Eyes Only Information. His use of Confidential Information was, however, restricted such that he could not use it "for any purpose other than in connection with [the] litigation." The protective order also contained a so-called "prosecution bar" provision, which prohibited any person "who

[2] Claim 14 is drawn to the invention of claim 13 wherein "visible indicia are provided along the length of the sheath to indicate the position of the tip of the beveled end." '960 patent, col. 12, ll. 8-10. Claim 16 is drawn to the invention of claim 1, 2, 3, or 13 wherein visible indicia are provided on the body portion of the catheter to indicate the orientation of the bevel. Id., col. 12, ll. 16-18.

ha[d] come into the possession of Attorney's [sic] Eyes Only Information" from "any involvement in the prosecution of" the '960 patent. That same provision likewise specifically stated: "Joseph Grayzel understands the terms of this Protective Order limiting the use of CONFIDENTIAL INFORMATION and ATTORNEY'S [sic] EYES ONLY INFORMATION only for purposes in connection with this litigation and that no patent application can be filed or prosecuted at any time based on CONFIDENTIAL INFORMATION or ATTORNEY'S [sic] EYES ONLY INFORMATION produced by St. Jude or Daig in this litigation." The district court referred the injunction motion to a magistrate judge for resolution.

Following briefing and a two-day hearing, the magistrate judge recommended barring Grayzel and his counsel from participating in the ex parte reexamination. The magistrate judge reasoned that the "entire tenor of the protective order was to protect information within the four corners of this litigation and not to allow discovery that is confidential to be used for outside purposes." The district court adopted the magistrate judge's recommendation and granted St. Jude's motion for an injunction to enforce the protective order. Grayzel v. St. Jude Med., Inc., No. 01-CV-3737 (D.N.J. Dec. 4, 2003).

In March of 2003, St. Jude filed a motion for summary judgment of invalidity due to anticipation under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103. The district court issued its claim construction and granted summary judgment in favor of St. Jude in October of 2004. It held that claim 13 of the '960 patent was anticipated by the Tadavarthy Article as well as two other prior art references. Summary Judgment Decision, slip op. at 16-19. The district court also held that claims 14 and 16 were obvious in light of other prior art references. Id., slip op. at 20-25.

With particular regard to anticipation of claim 13 by the Tadavarthy Article, the district court first found that

> the sheath picture in the article's diagram is clearly a "tubular member . . . used for accessing the vascular system through the skin and through which other devices . . . can be passed," and it is obviously "thin-walled" and "flexible enough for use in the vascular system." As the very title of the article demonstrates, this sheath is being inserted percutaneously into the vena cava. A device, specifically a so-called "Greenfield filter," is passed through the sheath following removal of the introducing catheters.

Id., slip op. at 18-19. It consequently concluded that the Tadavarthy Article teaches limitations [1] and [3] of claim 13. Next, the district court found that "the article shows an introducing catheter that visibly bends and is inserted into the vena cava, thus rendering it, by definition, flexible enough for use in the vascular system." Id., slip op. at 19. As such, it concluded that the Tadavarthy Article also teaches limitation [2] of claim 13. Finally, the district court found that the Tadavarthy Article "clearly reveals a sheath with a 'sloped edge' that would facilitate vein entry," thereby disclosing limitation [4] of claim 13. Id.

Grayzel timely appeals the district court's claim construction, its grant of summary judgment on anticipation grounds as to claim 13, and its grant of an injunction enforcing the protective order.[3] We have jurisdiction to consider the appeal pursuant to 28 U.S.C. § 1295(a)(1).

[3] Grayzel does not challenge the district court's invalidity ruling on obviousness grounds as to claims 14 and 16. He merely asserts those claims are not invalid because they depend from claim 13. The district court did not, however, hold claims 14 and 16 anticipated. Consequently, we shall not address Grayzel's argument regarding claims 14 and 16.

II. DISCUSSION

A. Claim Construction

Because claim construction is purely a matter of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), we review the district court's claim construction de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). In interpreting claims, a court's primary focus should be on the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification, and, if in evidence, the prosecution history. See Phillips v. AWH Corp., 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc).

Grayzel argues that the district court misconstrued the "sheath," "flexible," and "uniformly" limitations found in claim 13 of the '960 patent.[4] We consider each of his arguments in turn.

1. Sheath

The district court framed the dispute surrounding the "sheath" limitation as "whether the sheath described has a particular size range," ultimately concluding that it did not. Summary Judgment Decision, slip op. at 8. It thus construed the term to mean "any tubular member of any size that can be used for accessing the vascular system through the skin and through which other devices and elements can be passed." Id. Grayzel asserts that the district court erroneously relied on a dictionary definition to

[4] Grayzel also argued that the district court misconstrued the limitation "visible indicia are provided along the length of the sheath to indicate the position of the tip of the beveled end" of claim 14 to mean "visible indicia extending from the beveled tip portion to indicate the catheter's position in the vein." Summary Judgment Decision, slip op. at 15. The district court's construction of this limitation does not impact the resolution of this appeal since Grayzel does not properly raise any challenge with respect to claim 14. We thus need not address Grayzel's argument.

trump both the intrinsic and extrinsic record in rendering its construction. He contends that the correct construction for the "sheath" limitation, based upon the intrinsic record, is "a SDH sheath for use in the SDH technique." For support, he relies on the "Summary and Objects of the Invention" section, which he argues describes the introducing catheter and sheath as an assembly used in the SDH technique at least sixteen times. He also relies on the prosecution history, in particular a statement Grayzel made in response to an office action disclosing that "[b]asically, the present invention sets forth an introducing catheter and/or sheath having a beveled end."

We disagree with Grayzel. The '960 patent uses the term "sheath" in the ordinary sense of the word. First, as the district court noted, claim 13 recites that the "sheath" is "of a size for use in the vascular system for assisting in the insertion of other devices in blood vessels through the wall of the blood vessel." Second, as St. Jude points out, the specification expressly defines the term "sheath" as "[a] thin-walled outer tubular member" through which an operational catheter is inserted into the blood vessel. '960 patent, col. 1, ll. 58-59, 67-68. While that definition is disclosed in the "Background of the Invention" section of the specification in the context of describing the prior art, Grayzel does not depart from it when describing his invention. For example, the specification states in the context of describing figures 12, 13, and 14: "Once the sheath is in place, with entry to the lumen of the blood vessel properly dilated and the opening is secured, the introducing catheter 506 and the guide wire 514 can be removed leaving the sheath in place to allow for entry of the various devices that will then be placed into the blood vessel." '960 patent, col. 10, ll. 17-22. Third, logically, it is unlikely that Grayzel would have defined the term "sheath" distinct from the prior art

because his invention did not radically depart from the modified Seldinger technique. Rather his invention involved an improvement over the prior art wherein he simply terminated the tip of the prior art sheath at an angle to facilitate entry through the puncture site.

Given that the term "SDH sheath" does not appear anywhere in the '960 patent or its prosecution history, we suspect that Grayzel likely coined the term for purposes of this appeal. Indeed, the statements in the specification and prosecution history relied upon by Grayzel do not actually support his proffered construction. Instead, we read those statements to be consistent with an ordinary definition for the term as accorded by the district court. Additionally, we note that before the district court Grayzel argued only in favor of limiting the definition of "sheath" to a particular size range, numerical limits which the district court correctly found are not present in the intrinsic record. Grayzel did not advocate below that the term "sheath" means "SDH sheath." Accordingly, we agree with the district court's construction of the term "sheath" to mean "any tubular member of any size that can be used for accessing the vascular system through the skin and through which other devices and elements can be passed."

2. Flexible

The district court construed the term "flexible" to mean "flexible enough for use in the vascular system as a conduit for an introducing catheter and other devices." Summary Judgment Decision, slip op. at 12. Grayzel argues that such a construction "reverses the relationship between the SDH sheath and the introducing catheter in the SDH apparatus." The sheath, he contends, does not act as a conduit for the introducing catheter. Rather, Grayzel asserts that the introducing catheter enters the puncture site

carrying the sheath and that the sheath would "bend, fray, or buckle" if unsupported by an introducing catheter. Grayzel relies on the language of claim 13, which recites that the sheath "coacts with" and is "supported by" the introducing catheter, to support his contention. Hence, he advocates that the correct construction for the term "flexible" is "sufficiently flexible such that the sheath must be carried into the vessel wall puncture by the introducing catheter" and "would bend, fray, or buckle if it were introduced into the puncture site without the benefit of being carried in by the introducing catheter."

Grayzel's proposed construction is not consistent with the intrinsic record. The specification makes clear that the sheath may be supported by the catheter, but that it is not required to be. The specification states in the "Summary and Objects of the Invention" section: "After insertion of the catheter, the sheath can be inserted by sliding it over the catheter if the sheath is not already on the body of the catheter." '960 patent, col. 5, ll. 34-36 (emphasis added). Contrary to Grayzel's argument, this disclosure suggests that the introducing catheter may be inserted first followed by the sheath. Once inside the vessel, the sheath will be slid onto the introducing catheter so that the two are positioned in the vessel as a single unit. The specification does not caution that the sheath may "bend, fray, or buckle" if introduced without the support of the introducing catheter. Nor does it disclose that special care is necessary when handling an independent sheath. Alternatively, this disclosure suggests the way that St. Jude apparently contemplates for inserting the introducing catheter and sheath under the '960 patent, specifically, that the sheath may be placed over the introducing catheter at the outset and the two are inserted and positioned into the vessel as a single unit.

Significantly, either approach is consistent with the language of claim 13, which merely states that the bore of the sheath will "coact with" and "be supported by the said flexible catheter." This language does not proscribe that such coaction and support exist before the sheath is inserted into the vessel. Grayzel plainly misapprehends this language in arguing otherwise. Hence, because the specification teaches two approaches for inserting the sheath into a vessel, one where the sheath is independent of an introducing catheter, we conclude that the district court correctly construed the "flexible" limitation simply as "flexible enough for use in the vascular system as a conduit for an introducing catheter and other devices."

3. Uniformly

The district court construed the term "uniformly" as "always the same" or "unvarying." Summary Judgment Decision, slip op. at 13. Grayzel challenges this construction, arguing that the correct construction is "without fluctuation or variation; consistent." Grayzel is splitting hairs in arguing that the district court should have selected the definition "without fluctuation or variation; consistent" instead of the definition "always the same; unvarying" for the term "uniformly." The district court's definition is synonymous with Grayzel's proposed definition. See The Oxford Thesaurus 561 (Am. ed. 1992) ("consistent" and "unvaryingly" listed as synonyms for the adjective "uniform"). Moreover, either definition conveys that the walls of the sheath are thin for the entire length of the sheath. As such, we conclude that the district court did not err in construing the "flexible" limitation to mean "always the same" or "unvaringly."

B. Anticipation

We review the grant of summary judgment de novo, reapplying the same standard as the district court. Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc., 367 F.3d 1381, 1384 (Fed. Cir. 2004). Summary judgment is appropriate when there are no genuine issues of material fact or when the non-movant cannot prevail on the evidence submitted when viewed in a light most favorable to it. Id. "When ruling on a motion for summary judgment, all of the non-movant's evidence is to be credited, and all justifiable inferences are to be drawn in the non-movant's favor." Id. (quoting Caterpillar Inc. v. Deere & Co., 224 F.3d 1374, 1379 (Fed. Cir. 2000)). A claim is anticipated under § 102 "if each and every limitation is found either expressly or inherently in a single prior art reference." Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc., 246 F.3d 1368, 1374 (Fed. Cir. 2001).

Grayzel argues that the district court erred in holding that the Tadavarthy Article anticipates claim 13 of the '960 patent because it fails to disclose a "catheter" and a "sheath" as set forth in claim 13. As to the former, he contends that the neither the 8 French dilator nor the 24 French dilator discussed in the Tadavarthy Article serve as a "catheter" because they do not function to "introduce" diagnostic tools into a patient's vessel by expanding the puncture site. Instead, the 8 French dilator, he claims, serves a "diagnostic" purpose because it allows an inferior cavogram to be taken by a diagnostic catheter once that catheter is positioned in the inferior vena cava. Similarly, he maintains that the 24 French dilator also serves a "diagnostic" purpose because it expands the inferior vena cava to allow deliver of the Kimray-Greenfield filter. Grayzel also asserts that the Tadavarthy Article teaches that the 24 French dilator is made of a

stiff material and thus not flexible. He points out that claim 13, by contrast, requires the "catheter" to be "flexible."

Turning to the "sheath" limitation, Grayzel argues that the Tadavarthy Article does not disclose a "sheath" as required by claim 13 because the 24 French Teflon tube discussed in that reference is both too large and too rigid. For support, Grayzel relies on the testimony of his expert, Dr. David Eckmann, who explained in his declaration that "SDH sheaths" are normally much smaller than 24 French, and that he compared the representative flexibility of the claimed "SDH sheath" with that of the 24 French Teflon tube and found that the latter was 30 times more rigid. Grayzel also relies on three articles published by Dr. Wilfrido Castaneda-Zuniga wherein Dr. Castaneda referred to the Teflon tube used in conjunction with dilators as being "stiff." Additionally, Grayzel asserts that Tadavarathy Article does not disclose that the 24 French Teflon tube is "uniformly thin-walled" as required by claim 13. He contends that the district court merely speculated that this limitation was found in the Tadavarthy Article, stating that the "[24 French Teflon tube] is obviously thin-walled," Summary Judgment Decision, slip op. at 18, without conducting a proper anticipation analysis for that claim limitation.

St. Jude responds by asserting that the district court correctly found that the Tadavarthy Article discloses at least one "catheter" and a "sheath." St. Jude contends that either the 8 French dilator or the 24 French dilator qualifies as a "catheter" because they both expand the puncture site, even though they may also serve other purposes. It also contends that the 24 French Teflon tube is a "sheath" as claimed in claim 13. The size of the tube, St. Jude argues, is of no import because it is not a specific claim limitation. Moreover, St. Jude advocates that the 24 French Teflon tube is necessarily

flexible because it is inserted percutaneously into the vascular system via either the jugular vein in the neck or the femoral vein in the leg and navigated to the inferior vena cava without causing any internal damage. Finally, St. Jude maintains the Tadavarthy Article plainly illustrates that the "sheath" is "uniformly thin-walled." As such, it argues that the district court correctly found that the Tadavarthy Article anticipates each and every limitation of claim 13 of the '960 patent.

We agree with St. Jude that the Tadavarthy Article anticipates claim 13. First, as the district court correctly found, the 24 French dilator disclosed in the Tadavarthy Article operates as a "catheter" as set forth in claim 13. The 24 French dilator is inserted into either the jugular or femoral vein via a guidewire and carries the 24 French Teflon tube with it to the inferior vena cava, exactly like the claimed "catheter." That the 24 French dilator simultaneously expands the jugular or femoral vein and inferior vena cava to allow the Kimray-Greenfield filter to enter is immaterial. The language of claim 13 does not limit the function of the claimed "catheter" to only introducing a "sheath." In fact, claim 13 does not prescribe any specific function for the "catheter." Moreover, as pointed out by St. Jude, neither the specification nor the prosecution history of the '960 patent limits the function of the "catheter." If anything, the specification actually appears to recognize that the introducing catheter offers more than one function: "A further object of the present invention is to provide an introducing catheter which separates the entry function of the catheter from the dilation function of the catheter." '960 patent, col. 3, ll. 34-36 (emphases added).

Second, although the Tadavarthy Article does not explicitly address whether the 24 French dilator is flexible, it does so implicitly by virtue of the fact that the 24 French

dilator is inserted via either the jugular or femoral vein and delivered to the inferior vena cava, some internal distance away from the puncture site. If the 24 French dilator was rigid, then it would be difficult to maneuver it through the vascular system around internal organs to position it in the inferior vena cava. Indeed, the Tadavarthy Article specifically recognizes the difficulty in accessing the inferior vena cava stating that it is preferable to reach it via the transjugular approach through the neck rather than by the transfemoral approach through the leg. Accordingly, we conclude that the Tadavarthy Article discloses a "catheter" as claimed in claim 13.

Third, the district court correctly found that the 24 French Teflon tube disclosed in the Tadavarthy Article operates as the claimed "sheath." The Tadavarthy Article teaches that the 24 French Teflon tube is placed over the 24 French dilator and inserted into the inferior vena cava, precisely as the claimed "sheath" is positioned over the claimed "catheter" and inserted into a blood vessel. Grayzel's argument that the 24 French Teflon tube is too large to qualify as the claimed "sheath" is unavailing. Claim 13 does not place any numerical restriction on the size of the claimed "sheath," and it stands to reason, as St. Jude acknowledges, that sheath size varies with blood vessel size. Grayzel's argument that the 24 French Teflon tube is too rigid to qualify as the claimed "sheath" is equally unavailing. As discussed above, the 24 French Teflon tube implicitly must be "flexible" for the same reason that the claimed "sheath" is flexible. That is, the 24 French Teflon tube travels atop the 24 French dilator through either the jugular or femoral vein to be positioned in the inferior vena cava. If the 24 French dilator was rigid as asserted by Grayzel, it is unlikely that it could be routed through the vascular system around various internal organs. Moreover, Figure 2 in the Tadavarthy

Article shows the 24 French Teflon tube in a bent position upon removal from the jugular vein after insertion of the Kimray-Greenfield filter.

Furthermore, Grayzel's reliance on the three Castaneda articles is misplaced. The "stiff" sheaths discussed in those articles were inserted via the ureter into a kidney to remove kidney stones; they were not inserted into a blood vessel like the sheath employed in the '960 patent. This functional difference explains why those sheaths were of a more rigid nature than the claimed "sheath." Indeed, one of the articles explains that the stiffness was needed to prevent the dilator from buckling at the renal capsule, which was a common problem in renal dilation systems. Grayzel thus takes Dr. Castaneda's statements about the sheath out of context in asserting that they apply to the claimed "sheath."

Fourth, while Grayzel is correct that the Tadavarthy Article does not explicitly state that the 24 French Teflon tube is "uniformly thin-walled," it inherently must be because the size is set at 24 French. The diameter therefore must be "unvarying" or "always the same" for the entire length of the tube. Moreover, the dilator over which the Teflon tube fits is 24 French in diameter. If the Teflon tube were of varying diameter along the length or of a diameter that increased or decreased, respectively, from the beveled tip to the far end, then the tube either potentially would not fit atop the dilator and/or would not remain in position through the insertion process. Hence, like the district court, we conclude that the Tadavarthy Article implicitly discloses a "uniformly thin-walled sheath" as claimed in claim 13.

In sum, because the Tadavarthy Article discloses each and every limitation of claim 13 of the '960 patent, we hold that it anticipates claim 13 and thereby renders it

invalid under § 102. As such, we need not decide whether the district court correctly found that the remaining two references also anticipate claim 13.

C. Injunction to Enforce the Protective Order

Grayzel argues that the district court erred in barring him from participating in the ex parte reexamination of the '960 patent based upon the "prosecution bar" provision of the protective order.[5] That provision, he contends, does not apply to him for three specific reasons. First, Grayzel asserts both that it applies only to recipients of Attorneys' Eyes Only Information and that he is not such a recipient. Second, he asserts that it applies only to applications either corresponding to the '960 patent or related to the subject matter of the '960 patent, but not to the '960 patent itself. Third, he asserts that the "prosecution bar" provision does not name a reexamination as a prohibited proceeding.

In response, St. Jude asserts that we need not review Grayzel's challenge to the district court's order issuing an injunction to enforce the protective order because Grayzel only appealed the final judgment granting St. Jude's motion for summary judgment based on invalidity. Moreover, the district court's order, St. Jude argues, is not an interlocutory decision with substantial connection to the summary judgment of invalidity such that it merged into that judgment. Rather, it claims that the district court granted the injunction to protect its confidential information; such protection is in no way related to the validity of the '960 patent. Even if Grayzel had properly appealed the district court's ruling, St. Jude contends that Paragraphs 15 and 19 of the protective order expressly prevent Grayzel from using protected information, except in the litigation

[5] Grayzel does not challenge the district court's order as to his litigation counsel.

itself. Accordingly, it maintains that the district court did not abuse its discretion in enforcing the protective order against Grayzel.

Grayzel's challenge to the district court's issuance of an injunction enforcing the protective order is not simple and involves dividing the claims subject to reexamination into two groups, namely, (1) claims 13, 14, and 16, which were subject to the St. Jude litigation, and (2) claims 1-12, 15, and 17-26, which were not. As to the former group, we need not reach the merits of Grayzel's appeal in view of Manual of Patent Examining Procedure § 2286. That section requires the PTO to terminate a reexamination proceeding where the Federal Circuit has issued a final decision holding that the claims subject to reexamination are invalid. Specifically, "[u]pon the issuance of a final holding of invalidity or unenforceability, the claims held invalid or unenforceable will be withdrawn from consideration in the reexamination. The reexamination will continue as to any remaining claims." U.S. Pat. & Trademark Off., Manual of Patent Examining Procedure § 2286 (8th ed. 2001, rev. May 2004). Here, Grayzel sought, and the PTO granted, reexamination of claims 13, 14, and 16 of the '960 patent. We hold that claim 13 is invalid under § 102 herein, and Grayzel failed to appeal the district court's ruling that claims 14 and 16 are invalid under § 103, thus waiving his rights to do so in the future. Accordingly, we conclude that there can be no substantial new question of patentability as to claims 13, 14, and 16 and that Grayzel's challenge is moot as to those claims.

With respect to the latter group, claims 1-2, 15, and 17-26 were not implicated in the St. Jude litigation. Nor were they listed in Grayzel's request for reexamination. The PTO, nevertheless, included them in its reexamination grant and has proceeded to

consider the patentability of these claims in light of the prior art references disclosed by Grayzel during the reexamination proceeding. We are, as a result, in the position of having to decide the merits of Grayzel's challenge to the issuance of an injunction enforcing the protective order. In doing so, we apply the law of the regional circuit since the nature of his challenge does not involve a patent issue. See Phonometrics, Inc. v. Hospitality Franchise Sys., 203 F.3d 790, 793 (Fed. Cir. 2000).

Federal Rule of Appellate Procedure 3(c) provides, in pertinent part, that a notice of appeal "must designate the judgment, order or part thereof appealed from . . . ." Fed. R. App. P. 3(c). If a party does not satisfy the requirements of this rule, then an appellate court does not acquire jurisdiction over the undesignated judgment or order. United States v. Rivera Constr. Co., 863 F.2d 293, 298 (3d Cir. 1988). Here, Grayzel stated in his notice of appeal that he appeals "from the final judgment entered in this action on November 8, 2004 granting defendant's motion for summary judgment based on invalidity of claims 13, 14 and 16 of U.S. Patent No. 4,850,960 and dismissing the case." Plainly, he did not mention the district court's interlocutory order. Consequently on first blush, it appears that the St. Jude may be correct that we lack appellate jurisdiction.

Nevertheless, the Third Circuit has opted to liberally construe notices of appeal. Drinkwater v. Union Carbide Corp., 904 F.2d 853, 858 (3d Cir. 1990). It has, in fact, held that it may properly exercise appellate jurisdiction over orders not specified in the notice of appeal if "'there is a connection between the specified and unspecified order, the intention to appeal the unspecified order is apparent and the opposing party is not prejudiced and has a full opportunity to brief the issues.'" Lusardi v. Xerox Corp., 975

F.2d 964, 972 (3d Cir. 1992) (quoting Williams v. Guzzardi, 875 F.2d 46, 49 (3d Cir. 1989)). Here, we conclude that these three requirements are met. First, Grayzel procedurally could not appeal the district court's interlocutory order until the district court entered final judgment in favor of St. Jude. The Third Circuit has explained that an appeal from a final judgment incorporates all prior non-final orders and rulings, since only a final judgment or order is appealable. Drinkwater, 904 F.2d at 858 (citing Elfman Motors, Inc. v. Chrysler Corp., 567 F.2d 1252, 1254 (3d Cir. 1977)). To conclude otherwise in this case would prevent Grayzel from ever challenging the district court's interlocutory ruling, and we do not think such an outcome comports with the Third Circuit's jurisprudence regarding Rule 3(c). Because of this, we conclude that the requisite connection exists. Second, Grayzel has clearly manifested his intent to appeal the district court's interlocutory order. He specifically raised this issue in clear terms in both his opening and reply briefs. Third, St. Jude would not be prejudiced if we decide this issue since it had the opportunity to fully respond to Grayzel's challenge and has done so. Accordingly, contrary to St. Jude's contention, we hold that we have jurisdiction to review the district court's interlocutory order granting an injunction to enforce the protective order.

The Third Circuit reviews the grant of injunctive relief under the abuse of discretion standard. United States v. Bell, 414 F.3d 474, 478 (3d Cir. 2005). In the disputed protective order, Paragraph 15 works together with Paragraph 19, the so-called "prosecution bar" provision, to restrict the use of all Confidential and Attorneys' Eyes Only Information involved in the litigation. Read together, those provisions expressly prohibit persons who come into possession of any such information from

disclosing it outside of the litigation, regardless of the use. Paragraph 19, in fact, specifically discusses Grayzel's use of the two kinds of protected information, stating "Joseph Grayzel understands the terms of this Protective Order limiting the use of CONFIDENTIAL INFORMATION and ATTORNEYS' EYES ONLY INFORMATION only for purposes in connection with this litigation . . . ." On this basis, we have no choice but to conclude that Grayzel, who had access to Confidential Information, although not Attorneys' Eyes Only Information, falls squarely into the prohibitions set forth in Paragraphs 15 and 19. Thus, he is plainly precluded from using any of the Confidential Information he acquired through this litigation in any proceeding outside of the litigation, such as the ongoing reexamination proceeding.

Grayzel's arguments regarding the scope of Paragraph 19 are unpersuasive. In asserting that he is unaffected by the prohibition on the use of ATTORNEYS' EYES ONLY INFORMATION found in Paragraph 19, Grayzel mistakenly ignores Paragraph 15. Moreover, that Paragraph 19 only mentions applications corresponding to the '960 patent or related subject matter and does not specifically list a reexamination proceeding is of no consequence in the face of the express prohibition found in Paragraph 15. Far from producing "Draconian results," as asserted by Grayzel, the district court's order granting an injunction to enforce the protective order does nothing more than effect the parties' intent, just as the magistrate judge essentially acknowledged in his recommendation. To allow Grayzel to escape the very provisions he agreed to before learning of potentially invalidating prior art during discovery and filing a request for reexamination would, we fear, render the protective order under which discovery proceeded in this case meaningless. We, therefore, conclude that the

district court did not abuse its discretion in granting the injunction to enforce the protective order, and we affirm that grant.

III. CONCLUSION

For the foregoing reasons, we affirm the summary judgment of invalidity of claim 13 under § 102, hold that the district court's issuance of an injunction enforcing the protective order is moot as to claims 13, 14, and 16, and affirm the district court's order granting an injunction to enforce the protective order as to claims 1-12, 15, and 17-26.