#### United States Court of Appeals for the Federal Circuit

96-1304

STANTON J. ROWE,

Appellant,

v.

MICHAEL DROR and PAUL TRESCONY,

Appellees.

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Appealed from: Patent and Trademark Office

Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

96-1304

Interference No. 103,157

STANTON J. ROWE,

Appellant,

v.

MICHAEL DROR and PAUL TRESCONY,

Appellees.

DECIDED: April 21, 1997

Before LOURIE, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

## RADER, Circuit Judge.

This is an appeal from a final decision in Interference No. 103,157. The interference involves United States Patent Application No. 07/865,781, filed by Stanton J. Rowe (Rowe) with a priority date of March 14, 1989 and assigned to Cordis Corp. (Rowe application), and United States Patent No. 5,102,402, issued to Michael Dror and Paul Trescony (collectively, Dror) based on an application filed on January 4, 1991 and assigned to Medtronic, Inc. (Dror patent). The Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board) found that Jerome H. Lemelson's United States Patent No. 4,900,303 (Lemelson patent) anticipated both parties' claims corresponding to the count. Because the Board clearly erred in finding anticipation, this court reverses and remands.

# BACKGROUND

The subject matter of this interference relates generally to balloon angioplasty catheters. These catheters include a balloon that inflates within a blood vessel to reduce internal blockage and allow blood to flow freely. In particular, the balloon catheters aid angioplasty procedures by treating an area of stenosis, or accumulated plaque along the inner walls of a blood vessel. <u>See generally C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.</u>, 911 F.2d 670, 671, 15 USPQ2d 1540, 1541 (Fed. Cir. 1990) (describing angioplasty procedures). In such a procedure, the balloon catheter inflates radially in the area of stenosis, thereby compressing the plaque against the blood vessel walls.

The balloon angioplasty catheters in this case have a covering of microcapsules on the outer surface of the balloon. These microcapsules can administer a medicinal or diagnostic substance during the angioplasty procedure. The action of the balloon inflating against the inner wall of a vessel ruptures the microcapsules and releases the substance. The microcapsules may administer, for example, a chemical that will cause the accumulated plaque to harden and maintain its dilated shape, or a chemical that will cause dissolution of the plaque.

Figure 3 of the Rowe application illustrates a balloon catheter used in an angioplasty operation. The illustration shows an angioplasty catheter (14) with a balloon section (16) in an area of stenosis (12) in a coronary artery (10). The balloon has expanded the stenosis and, simultaneously, deposited a therapeutic agent (20).

Similarly, Figures 1 and 3 of the Dror patent illustrate a balloon catheter (10) having an inflatable balloon (12) covered with microcapsules (16).

Although Rowe is the senior party in this interference, the Dror patent issued before completion of the examination of the Rowe application, which is still pending. When the Dror patent issued, Rowe copied several claims from the Dror patent into his application. The PTO declared an interference and designated the first copied claim as the sole interference count. That count, which corresponds to claims 53-66 of the Rowe application and claims 1-8, 10-15 and 17-21 of the Dror patent, reads:

1. In a balloon <u>angioplasty</u> catheter of the type comprising a catheter body and <u>a balloon positioned along the</u> <u>length of the catheter body</u>, said balloon including <u>means for remotely inflating and deflating said balloon</u>; the improvement comprising:

(a) a plurality of microcapsules on the exterior of said balloon, each of said microcapsules carrying a drug or

combination of drugs for treatment or diagnostics within a body lumen when said catheter is positioned and inflated therewithin such that the drug or drugs may be released from said microcapsules.

(Emphasis added to show disputed passages).

During the motion period before the PTO, Dror filed a motion seeking judgment against Rowe on the ground that the Lemelson patent anticipated some of Rowe's claims corresponding to the count. <u>See</u> 37 C.F.R. § 1.633(a) (1996).

The Lemelson patent describes a general purpose catheter with a swab or balloon (with microcapsules) for applying medicine into a body duct. Figure 12 of the Lemelson patent shows the head of a catheter with a tubular catheter sidewall (137) surrounding a medicated swab (144). The medicated swab (144) may extend out the end of the catheter (by the pushing action of a piston (140)) to apply medicine to internal body tissue. The reference teaches as well that the swab (144) could carry the medicine in microcapsules.

Although the Lemelson patent does not illustrate a balloon catheter, it teaches that the medicated swab (144) in Figure 12 "may be replaced by an inflatable enclosure, such as a rubber finger or balloon, which is controllably inflated from within the catheter chamber or upon being projected therefrom as described."

Acting on Dror's motion, the administrative patent judge found that the Lemelson patent anticipates all of Rowe's and Dror's claims corresponding to the count. <u>1</u> The Board upheld the decision of the administrative patent judge and entered final judgment against both Rowe and Dror. Rowe filed this appeal. On appeal Rowe contends that the Board erred by failing to treat "angioplasty" as a claim limitation. Rowe further argues that the Lemelson patent cannot anticipate his claims because it discloses neither "a balloon positioned along the length of the catheter body" nor a "means for remotely inflating and deflating said balloon."

# DISCUSSION

The PTO may, during the course of an interference, determine the patentability of any claim involved in the interference. <u>See</u> 37 C.F.R. § 1.633(a) (1996) (allows a party to an interference to move for judgment against the other party on the grounds that the count is not patentable to that party for any reason other than priority or derivation); <u>see also</u> 37 C.F.R. § 1.641 (1996) (allows administrative patent judge to

raise the issue of patentability <u>sua sponte</u>). In such cases, the PTO is passing on the patentability of claims, not counts. <u>See In re Van Geuns</u>, 988 F.2d 1181, 1184, 26 USPQ2d 1057, 1059 (Fed. Cir. 1993). Thus, the PTO must separately determine the patentability of each claim in the interference, just as it would in an <u>ex</u> <u>parte</u> prosecution. <u>See Eiselstein v. Frank</u>, 52 F.3d 1035, 1037, 34 USPQ2d 1467, 1468-69 (Fed. Cir. 1995); <u>Van Geuns</u>, 988 F.2d at 1186; <u>see also</u> PTO Notice of Final Rule, Patent Appeal and Interference Practice, 60 Fed. Reg. 14488, 14506, 1173 Off. Gaz. Pat. Office 36, 51 (1995) ("There is no presumption in an interference that because one claim designated to correspond to a count is unpatentable over the prior art (35 U.S.C. 102(a), (b) and (e)), that all claims are unpatentable over the same prior art."); 37 C.F.R. § 1.633(a) (1996) (requiring motions filed after April 21, 1995, to "separately address the patentability of each claim corresponding to a count, the Board has reason to treat all claims together. <u>See Van Geuns</u>, 988 F.2d at 1186. In such cases, all claims corresponding to the count stand or fall together. <u>See id.; see also In re King</u>, 801 F.2d 1324, 1325, 231 USPQ 136, 137 (Fed. Cir. 1986) (dependent claims stand or fall with independent claims unless argued separately). Because Rowe did not separately argue the patentability of his

various claims before the administrative patent judge or the Board, this court need not treat those claims separately either.

This court reviews the Board's finding of anticipation as a question of fact subject to the clear error standard. <u>See id.</u> at 1326. "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." <u>United States v. United States Gypsum Co.</u>, 333 U.S. 364, 395 (1948).

A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim. <u>See Verdegaal Bros., Inc. v. Union Oil Co.</u>, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "[A]bsence from the reference of any claimed element negates anticipation." <u>Kloster Speedsteel AB v. Crucible, Inc.</u>, 793 F.2d 1565, 1571, 230 USPQ 81, 84 (Fed. Cir. 1986).

This appeal depends on whether the claim phrase "balloon <u>angioplasty</u> catheter," which appears only in the claim preamble, is or is not an affirmative limitation of the claim. The Board interpreted the claim as "drawn to the subject matter of a balloon catheter of general utility" and gave no meaning to the word "angioplasty." On this basis, the Board concluded that the Lemelson patent, which admittedly discloses only a general purpose catheter, anticipated Rowe's claims. Rowe urges that the Board erred in failing to limit the claims at issue to angioplasty catheters.

"[A] claim preamble has the import that the claim as a whole suggests for it." <u>Bell Communications Research,</u> <u>Inc. v. Vitalink Communications Corp.</u>, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). Where a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage. <u>See id.</u>; <u>Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.</u>, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Conversely, where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. <u>See Bell Communications</u>, 55 F.3d at 620; <u>Kropa v. Robie</u>, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." <u>Corning Glass Works</u>, 868 F.2d at 1257. The inquiry involves examination of the entire patent record to determine what invention the patentee intended to define and protect. <u>See Bell Communications</u>, 55 F.3d at 621 (looking to patent specification to determine whether claimed invention includes preamble recitations); <u>In re Paulsen</u>, 30 F.3d 1475, 1479, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (examining "patent as a whole"); <u>Vaupel Textilmaschinen KG v.</u> <u>Meccanica Euro Italia SPA</u>, 944 F.2d 870, 880, 20 USPQ2d 1045, 1053 (Fed. Cir. 1991) (looking to claims, specification, and drawings); <u>Gerber Garment Tech., Inc. v. Lectra Sys., Inc.</u>, 916 F.2d 683, 689, 16 USPQ2d 1436, 1441 (Fed. Cir. 1990) (noting that preamble recitations provided antecedent basis for terms used in body of claim); <u>Corning Glass Works</u>, 868 F.2d at 1257 (considering the specification's statement of the problem with the prior art); <u>Kropa</u>, 187 F.2d at 152 (noting that preamble sets out distinct relationship among remaining claim elements).

Inspection of the entire record in this case reveals that "angioplasty" is, in fact, a structural limitation of Rowe's claims. To begin with, the form of the claim itself, the so-called "Jepson" form, suggests the structural importance of the recitations found in the preamble. The Jepson form allows a patentee to use the preamble

to recite "elements or steps of the claimed invention which are conventional or known." 37 C.F.R. 1.75(e) (1996). When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope. See Pentec, Inc. v. Graphic Controls, Corp., 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985) ("Although a preamble is impliedly admitted to be prior art when a Jepson claim is used, . . . the claimed invention consists of the preamble in combination with the improvement.") (citations omitted); United States Patent and Trademark Office, Manual of Patent Examining Procedure § 608.01(m) (6th ed. rev. Sept. 1995) ("[The Jepson form of claim] is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination."). Thus, the form of the claim itself indicates Rowe's intention to use the preamble to define, in part, the structural elements of his claimed invention. The device for which the patent claims "an improvement" is a "balloon angioplasty catheter."

The court looks next to the specification and drawings to determine whether those sources convey a clear structural meaning for the phrase "balloon angioplasty catheter." The parties argue over whether this court should interpret the claim with reference to the Dror patent, in which it originated, or the Rowe application, into which it was copied. The nature of this inquiry provides the answer. At this juncture, this court and the PTO examine claims to determine their patentability over the prior art. In effect, section 1.633(a) allows the PTO to consider the novelty or non-obviousness of each application's claims as if the application stood alone. In this posture, the PTO properly interprets the claim in light of its host disclosure, just as it would during <u>ex parte</u> prosecution. Thus, this court looks to the Rowe application to determine the meaning of the phrase at issue.

Notwithstanding Dror's arguments, this court's holding in <u>In re Spina</u>, 975 F.2d 854, 24 USPQ2d 1142 (Fed. Cir. 1992), does not apply to the present case. In <u>Spina</u>, this court considered whether an applicant was eligible to copy a patentee's claim and thereby challenge priority of invention, a question that turned on whether the copying party's specification adequately supported the subject matter claimed by the other party. <u>Id.</u> at 856. This court held, in that context, that a copied claim is interpreted in light of its originating disclosure. <u>Id.</u> This <u>Spina</u> rule sought to ensure that the PTO would only declare an interference if both parties had a right to claim the same subject matter. However, that rule does not apply in cases, such as this one, where the issue is whether the claim is patentable to one or the other party in light of prior art. In this posture, the PTO and this court must interpret the claim in light of the specification in which it appears.

Without question, the Rowe specification evinces a particular and distinct structural meaning for "balloon angioplasty catheter" that distinguishes it from "balloon catheters" generally. In particular, an angioplasty catheter must be capable of "expand[ing] a stenosis in a coronary artery." The specification repeatedly refers to "dilation of coronary arteries," "expanding the coronary artery," and other unique functions of "PCTA [percutaneous transluminal coronary angioplasty] catheters." Figures 2 through 4 illustrate the radial expansion of an area of stenosis by the forceful inflation of a balloon catheter. The specification also indicates that the pressure exerted against the vessel walls upon balloon inflation forces the medication into the stenosis. These and similar phrases limit the claimed "balloon angioplasty catheters" to catheters that can be inflated radially outward to dilate a narrowed region in a blood vessel.

Dror argues that Rowe's claim broadly includes all balloon catheters because Rowe's specification indicates that "[t]he invention of this application can be used in a wide variety of medical procedures above and beyond dilation of stenoses in coronary arteries." Rowe's specification also teaches the use of "catheters and flexible probes which do not carry a balloon" in non-angioplasty procedures as an alternative embodiment of

Rowe's invention. Quite to the contrary of Dror's argument, these passages indicate that Rowe recognized a difference between angioplasty catheters and other types of catheters. Thus, when he uses the phrase "balloon <u>angioplasty</u> catheter" in his claim, it is that device, not some other, that he defines.

In concluding that "angioplasty" was not a structural limitation of the claim, the Board relied on claim language requiring that the microcapsules contain "a drug or combination of drugs for treatment or <u>diagnosis</u> within a body lumen" (emphasis added). According to the Board:

Since a diagnostic procedure is completely different from expanding a stenosis, [Rowe's] argued narrow interpretation of the preamble directly conflicts with the broader literal language of the claim. Interpreting the invention as a whole, we agree with the APJ that the claim language should be interpreted as drawn to the subject matter of a balloon catheter of general utility.

Contrary to the Board's reasoning, the claim term "diagnosis" is consistent with limiting the claim to angioplasty apparatus. Indeed, Dror's specification provides an example of an angioplasty procedure being performed contemporaneously with a diagnostic procedure. Specifically, the specification expressly teaches the use of diagnostic agents, such as radiopaque dyes, in angioplasty procedures to "allow the vessel to be visualized."

During the patent examination process, claims receive their broadest reasonable meaning. <u>See In re Zletz</u>, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). However, this does not relieve the PTO of its essential task of examining the entire patent disclosure to discern the meaning of claim words and phrases. <u>See, e.g., Paulsen</u>, 30 F.3d at 1479- 80; <u>In re Bulloch</u>, 604 F.2d 1362, 1365, 203 USPQ 171, 174 (CCPA 1979) (looking to specification and record to discern what the applicant claimed).

Thus, when properly interpreted, Rowe's claims require a balloon angioplasty catheter capable of expanding radially and exerting pressure on the plaque-encrusted walls of a surrounding blood vessel. The Lemelson patent does not show such a catheter, but instead describes a general purpose balloon catheter. Lemelson describes a medicated swab that extends out the end or side of the catheter to allow contact with the internal surface in need of medication. Although the Lemelson patent does describe substitution of a balloon for the medicated swab, it does not illustrate this balloon embodiment. Thus, even an artisan of ordinary skill must guess about how exactly the balloon would substitute for the medicated swab and whether the resulting balloon catheter would be capable of radial, as well as axial, expansion. In fact, Lemelson makes no suggestion of any kind about its structural suitability for angioplasty procedures. About the most that can be said for the Lemelson patent is that it does not explicitly describe anything inconsistent with angioplasty procedures. However, this negative pregnant is not enough to show anticipation. See In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990) (in order to anticipate, "the [prior art] reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it").

Although anticipation is a question of fact, <u>see In re Bond</u>, 910 F.2d 831, 833, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990), this court can conclude from this record that the Lemelson patent does not anticipate Rowe's properly interpreted claim. Neither the administrative patent judge nor the Board indicated that the Lemelson patent disclosed a "balloon angioplasty catheter." In fact, the Board would not have likely paid so much attention to whether Rowe's claim was limited to balloon angioplasty catheters if it had believed that the Lemelson patent showed such a catheter anyway. Further, the record does not show that Dror argued, either

before the PTO or before this court, that the Lemelson patent discloses a "balloon angioplasty catheter." Dror's failure to deny Rowe's clear and forcible allegations is tantamount to an admission.

### CONCLUSION

Because the Board clearly erred in its conclusion that the Lemelson patent anticipated Rowe's claims corresponding to the interference count, this court reverses. The case is remanded to the PTO for further proceedings in the interference.

## COSTS

Each party shall bear its own costs.

#### REVERSED AND REMANDED

# Footnotes

<u>1</u> The administrative patent judge, the Board, and the parties did not track the claims in this case with precision. The interference involves Rowe's claims 53-66. Dror's initial motion sought a determination that Rowe's claims 53-55, 59-60, 62, and 64-66 were unpatentable over the prior art. The administrative patent judge, however, issued a show cause order pertaining to all Rowe's claims 53-66. See 37 C.F.R. § 1.640(d)(1) (1996). In its appeal to the Board, Rowe pointed out that the administrative patent judge "incorrectly state[d]" the subject of Dror's motion, and appealed the prior art rejection only as to claims 53-55, 59-60, 62, 64-66. In spite of Rowe's objection, the Board treated claims 53-66 together. Because the administrative patent judge is authorized to raise <u>sua sponte</u> the patentability of any claim involved in the interference, 37 C.F.R. § 1.641, this apparent disconsonance in the record does not prevent this court from considering the validity of all of Rowe's claims 53-66. See, e.g., Chester v. Miller, 906 F.2d 1574, 1576, 15 USPQ2d 1333, 1335 (Fed. Cir. 1990) (examiner-in-chief issued a show cause order based, in part, on a party's motion and, in part, on examiner's own motion).

2 This court is aware of the PTO's 1995 amendment to 37 C.F.R. § 1.633(a), which added a sentence: "In deciding an issue raised in a motion filed under this paragraph (a), a claim will be construed in light of the specification of the application or patent in which it appears." 37 C.F.R. § 1.633(a) (1996) (effective date of amendment, April 21, 1995); <u>see also</u> 60 Fed. Reg. 14488, 14505, 1173 Off. Gaz. Pat. Office 36, 51 (1995) (explanatory notes on adoption of amended provision). This court does not accept the PTO's statement that it can "administratively set aside the judicially created rule of <u>In re Spina</u>," <u>see</u> 59 Fed. Reg. 50181, 50185, 1167 Off. Gaz. Pat. Office 98, 101 (1994). Judicial precedent is as binding on administrative agencies as are statutes. However, the PTO had good reason to promulgate a new rule in light of the new practice in which patentability of claims can be considered during the motion period of an interference. <u>See</u> 37 C.F.R. 1.633(a) (effective date February 11, 1985). Earlier case law did not deal with such a situation. Moreover, <u>Spina</u> did not involve a Rule 633(a) motion. Thus, the PTO was writing on a clean slate, not flouting judicial precedent.

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