United States District Court,
D. Delaware.

MEDTRONIC AVE, INC,
Plaintiff.
v.
CORDIS CORPORATION,
Defendant.

No. 99-833-SLR

May 31, 2000.

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MEMORANDUM OPINION

ROBINSON**, J.**

I. INTRODUCTION

Pending before the court is a motion for preliminary injunction filed by plaintiff Medtronic AVE, Inc. ("AVE") against defendant Cordis Corporation ("Cordis"). (D.I.2) At issue is U.S. Patent No. 5,836,965 (the " '965 patent"), entitled "Stent Delivery and Deployment Method," and AVE's charge that Cordis' "MINICrown" stent delivery system, which encompasses the MINICrown stent and its associated "Dynasty Delivery System," infringes claims 1, 6-8, and 14 of the '965 patent.

For the reasons that follow, AVE's request for injunctive relief (D.I.4) shall be denied.

II. BACKGROUND

A. The '965 Patent

The invention disclosed in the '965 patent relates to "medical implant devices" for use in treating atherosclerosis and other forms of coronary and peripheral vessel narrowing caused by the deposition of plaques along artery walls. (Col. 1, lns. 9-12; col. 8, lns. 37-42) Generally, vessel narrowing is treated via angioplasty, the object of which is "to enlarge the lumen of the affected coronary artery by radial hydraulic expansion." (Col.1, lns.25-27) This objective is accomplished by introducing into the body through a large vessel, such as the femoral artery, a balloon catheter having an expandable balloon portion ("balloon"). (Col.1, lns.35-53) The balloon is conveyed to the affected area of the vessel (i.e., the lesion) by sliding the balloon catheter along a flexible guidewire. (Col.1, lns.45-48) Once in position, the balloon is "alternately inflated and deflated until the lumen of the artery is satisfactorily enlarged." (Col.1, lns.63-65)

In order to prevent vessel restenosis, expandable "mechanical endoprosthetic devices" or stents FN1 can be

used to mechanically keep the affected vessel open after completion of the angioplastic procedure. (Col.2, lns.9-11) These stents are compressed or "crimped" FN2 along the outside of a non-expanded balloon catheter and delivered along with the balloon to the affected area of the vessel. (Col.2, lns.24-28) Once the balloon segment of the catheter and the stent are positioned across the lesion, the balloon catheter is expanded "causing the length of the stent to contract and the diameter to expand. Depending on the materials used in construction of the stent, the stent maintains the new shape either through mechanical force or otherwise." (Col.1, lns.28-33)

FN1. Stents act as "scaffold-like devices that support the wall of previously narrowed portions of vessels, thereby keeping the vessels open and allowing body fluid (such as blood) to flow more freely." (D.I.5, para. 4)

FN2. Alternatively, some stent delivery systems retain the stent on the delivery catheter by employing a stent with "a small enough internal diameter to act as an interference fit with the outside diameter of the balloon catheter." (Col.2, lns.56-58)

By the time the '965 patent was filed, "significant difficulties ha[d] been encountered with deployment of known prior art stents." (Col.2, lns.49-50) These difficulties included maintaining positional stability of the stent on the balloon during delivery without use of an external sheath FN3 and achieving symmetrical expansion of the stent at deployment. (Col.3, lns.11-16) The stent delivery and deployment method of the '965 patent addresses these difficulties by providing "a frozen-in balloon in intimate contact with, and/or surrounding, a stent to assure stent attachment to the balloon, i.e., e [n]capsulation." (Col.3, lns.22-24)

FN3. Although the use of a removable sheath system protects the stent and provides a smooth surface for easier passage through the vessels, it increases the diameter of the delivery device thereby decreasing the device's ability to negotiate through narrow vasculature.

According to the specification, "[t]he frozen-in balloon form is achieved by encapsulating the stent so that the balloon may expand part way around the stent and adhere thereto." (Col.3, lns.29-32) "Adherence is required for encapsulation which includes both intimate contact between the stent and the balloon as well as contact where the balloon surrounds at least a portion of the stent." FN4 (Col.7, lns.12-15) In the preferred embodiment, encapsulation is achieved by

FN4. During the prosecution of the '965 patent, the applicants, who "desire[d] to maintain the record clear as to the meaning or scope of the term 'encapsulated'," responded to the Notice of Allowability, commenting that "it is considered to be clear that the term 'encapsulated' refers to a balloon which contacts at least a portion of the stent and at least partially conforms to said portion." (D.I.88, Exh. 3)

compressing the stent on the outside of the balloon, placing a sheath over the compressed stent to prevent expansion, and exposing the sheathed stent and balloon to an elevated temperature while pressurizing the balloon. The elevated temperature and pressurization causes the balloon to expand from below the stent to fill at least some of the spaces between the stent and the sheath. Following expansion and exposure to an elevated temperature, the balloon and stent are cooled while maintaining pressure in the balloon, so that the balloon profile will be "frozen around" (formed and somewhat adhered to) the stent.
(Col.3, lns.33-44) The encapsulated stent assembly is advanced to the area to be treated within the vessel and the balloon is inflated, resulting in uniform and symmetric expansion of the inner diameter of the encapsulated stent and the lumen of the vessel. (Col.7, ln.55-col.8, ln.13) Following expansion of the encapsulated stent, the balloon is deflated "so that it pulls away from the stent for removal." (Col.8, lns.20-

22) The deflated balloon "does not retain the creases created by the heat setting balloon formation process." (Col.8, lns.24-25)
The '965 patent issued on November 17, 1998.FN5 At issue in the present litigation are apparatus claims 1 and 7-9 and method claims 6 and 14. Claim 1 of the '965 reads:

FN5. AVE received a Notice of Allowability of the '965 patent claims on March 1, 1998. (D.I.43, Exh. Q)

1. An endovascular support device for implantation in a vessel within the human body comprising:
at least one compressible stent means mounted on a balloon of a balloon catheter; and

wherein said at least one compressible stent means is encapsulated by said balloon of said balloon catheter.

(Col.8, lns.56-61) Claim 7, and dependent claims 8 and 9, are directed to a delivery system. They read:
7. A delivery system for an endovascular support device comprising:

a balloon catheter having a catheter body and a balloon;

a means for selectively inflating and deflating said balloon;

at least one endovascular support device mounted on said balloon, said at least one endovascular support device having a first diameter for intraluminal delivery and a second expanded diameter for deployment in a vessel;

wherein said balloon at least partially surrounds at least a portion of said at least one endovascular support device thereby securing said at least one endovascular support device to said balloon for intraluminal delivery.

8. The delivery system according to claim 7 wherein the at least one endovascular support device is retained in indentations formed in said balloon.

9. The delivery system according to claim 7 wherein the balloon adheres to the at least one endovascular support device.

(Col.9, ln.25-col.10, ln.3)
Method claim 6 provides:

6. A method for treating narrowing of vessels within humans comprising the steps of:

providing at least one endovascular support device;

mounting the at least one endovascular support device on a balloon of a balloon catheter;

anchoring the at least one endovascular support device to the balloon by encapsulation of the at least one endovascular support device by the balloon;

advancing the balloon catheter and the at least one encapsulated endovascular support device to an area to be treated within the vessels;

inflating the balloon of the balloon catheter to expand the at least one encapsulated endovascular support device within the area to be treated; and

deflating the balloon of the balloon catheter so that the balloon pulls away from the at least one endovascular support device.

(Col.9, lns.7-24) Likewise, claim 14 is directed to a method for treating narrowing of vessels. It reads

14. A method for treating narrowing of vessels within humans comprising the steps of:

introducing a stent delivery system into a vessel, the stent delivery system comprising at least one endovascular support device mounted on a balloon of a balloon catheter, the at least one endovas[c]ular support device anchored to the balloon by encapsulation of the at least one endovascular support device by the balloon;

advancing the stent delivery system to an area to be treated within the vessels;

inflating the balloon of the balloon catheter to expand the at least one encapsulated endovascular support device within the area to be treated; and

deflating the balloon of the balloon catheter so that the balloon pulls away from the at least one endovascular support device.

(Col.10, lns.21-38)

Following issuance of the '965 patent, AVE began promoting the "pillowing" technology disclosed therein as a unique feature of AVE's stent delivery systems. (D.I.6, para. 8)

B. The Small Vessel Stent Market

Both Cordis and AVE compete in the small vessel (defined as less than 3.0 mm) stent market. Although the MINICrown stent was available abroad beginning in December 1998,FN6 Cordis did not enter the small vessel stent market in the United States until April 1999. In late April 1999, AVE became aware that Cordis' MINICrown stent delivery system employs "nesting" technology FN7 to secure the stent to the delivery balloon until its deploy. (D.I.6, para. 10)

FN6. Samples of the MINICrown stent on sale in Europe and "design history files" were supplied to AVE's counsel in April 1998 as part of ongoing litigation of another matter. (D.I.43, para. 27)

FN7. Although Cordis' promotional literature does not describe the "nesting" technology, the photographs illustrating the technology show balloon material protruding through the spaces of the stent structure and the stent resting in indentations in the balloon. (D.I.6, Exh. C)

Immediately after receiving FDA approval, on or about June 4, 1999, AVE launched commercially the S540 stent, which employs the "pillowing" technology. In mid July 1999,FN8 AVE tested the MINICrown stent and the associated delivery system, focusing on the manner in which the stent is secured to the balloon. (D.I.5, para.para. 22-27, Exhs.F-K) This testing confirmed that the MINICrown stent delivery system uses the "nesting" technology and that such technology involves retaining the stent to the balloon through the use of protrusions and indentations, i.e. the "nesting imprint." (D.I.5, para.para. 22-27, Exhs.F-K)

FN8. AVE contends that it had to wait to conduct this testing until the S540 was marketed because only then was it "able to swap S540 stent delivery systems for a sufficient quantity of MINICrown stent delivery systems to enable adequate testing." (D.I. 51 at 16 (citing Solar Dep. at 38))

Currently there are four stents in the small vessel stent market: AVE's S540; Cordis' MINICrown; Boston Scientific Corporation's 2.5 NIR; and Advance Cardiovascular Systems, Inc. and Guidant Corporation's 2.5 Duet. Neither of these latter stents employs the patented technology. By the end of December 1999, AVE through its sale of the S540 had "securely obtained the leadership position in the small vessel market" with a 47% market share. (D.I.10, Exhs.1, 3)

III. STANDARD OF REVIEW

The framework for analyzing a request for injunctive relief at the preliminary stages of litigation rests upon two fundamental principles: a preliminary injunction constitutes extraordinary relief and the grant or denial of such relief is within the discretion of the court. *See generally,* Bell & Howell Document Management Prods. Co. v. Altek Sys., 132 F.3d 701, 704 (Fed.Cir.1997). These underpinnings are not absolute, however, and the court's discretion "must be measured against the standards governing the issuance of an injunction." Hybritech Inc. v. Abbot Labs., 849 F.2d 1446, 1451 (Fed.Cir.1988).

To obtain a preliminary injunction pursuant to 35 U.S.C. s. 283, a party must demonstrate that: 1) it has a reasonable likelihood of success on the merits; 2) it would suffer irreparable harm if the injunction were not granted; 3) the balance of relative hardships tips in its favor; and 4) an injunction would not have a negative impact on the public interest. *See id.*

These factors, taken individually, are not dispositive; rather, the district court must weigh and measure each factor against the other factors and against the form and magnitude of the relief requested.

Id.

IV. ANALYSIS

A. Likelihood of Success

It is AVE's burden to demonstrate that, if this controversy were to be tried, it would prevail in proving (by a preponderance of the evidence) that Cordis is infringing the '965 patent and Cordis would not successfully prove (by clear and convincing evidence) that the '965 patent is invalid. If AVE "clearly establishe[s] a likelihood of success, it [is] entitled to a rebuttable presumption that it would be irreparably harmed if a preliminary injunction were not to issue." Bell & Howell, 132 F.3d at 705.

1. Claim Construction

As a threshold matter, it is the court's "power and obligation to construe as a matter of law the meaning of language used in the patent claim." Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995). At this stage of the proceedings, the parties have focused their contraventions on the term "encapsulation." FN9 Although it argued for an alternative interpretation in its briefing, at oral argument, Cordis indicated its willingness to accept for purposes of this motion AVE's proffered construction of the term. (D.I. 104 at 34) Thus, for purposes of the following analysis, the court shall construe "encapsulation" as requiring a balloon that is semi-permanently "frozen-in place" FN10 and in intimate contact with, and/or surrounding the stent, with portions of the balloon being forced into the spaces between the stent elements thereby forming protrusions and indentations in the balloon and securing the stent to the balloon.

FN9. It appears from the deposition testimony of AVE's expert, Dr. Ronald Jay Solar, that, with the possible exception of the "encapsulated" limitation, all of the remaining elements of the claims at issue are found in the prior art. (D.I. 88, Exh. 2 at 131-36)

FN10. AVE construes the term "frozen-in place" as requiring the shape of the balloon be "set" such that it retains its shape (mirroring the geometry of the stent) after the stent has been removed.

2. Validity

Cordis challenges the validity of the '965 patent under various theories, including anticipation under 35 U.S.C. s. 102 and obviousness under 35 U.S.C. s. 103.

Anticipation is established if every element of a properly construed claim is present in a single prior art reference. *See* Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc., 45 F.3d 1550, 1554 (Fed.Cir.1995); *see also* PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1566 (Fed.Cir.1996); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed.Cir.1991). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found., 927 F.2d at 1576.

In determining whether a patented invention is anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. If needed to impart clarity or avoid ambiguity, the prosecution history and the prior art may also be consulted in order to ascertain whether the patentee's invention is novel or was previously known to the art.

Glaverbel Societe Anonyme, 45 F.3d at 1554. Thus, the factual inquiry relevant to the anticipation analysis is whether a single prior art reference discloses every element of the challenged claim and enables one skilled in the art to make the anticipatory subject matter. *See, e.g.,* PPG Indus., Inc., 75 F.3d at 1566.

Included within the scope of the prior art at bar is the Gianturco-Roubin Flex-Stent coronary stent ("the Gianturco stent"), which was commercially marketed by Cook Incorporated ("Cook") as early as 1993.FN11 (D.I.88, para. 17) According to the training manual for this product,

FN11. The Gianturco stent is only one of many prior art stents asserted by Cordis.

this stent does not require a covering sheath to allow it to be inserted. This is because during its manufacture the stent coil is wrapped very tightly around the balloon; the coil actually embeds slightly into the balloon material, which prevents the stent from slipping on the balloon. The unexpanded balloon forms "shoulders" at both ends of the stent that also help prevent the unexpanded stent from slipping.
(D.I.88, Exh. 6) During a Circulatory System Devices Panel Meeting held by the FDA on May 11, 1992, Cook representatives indicated that the balloon partially surrounds the Gianturco stent "in order to minimize the stent coming off of the balloon catheter":
[T]he balloon is a little bit larger in diameter than the diameter of the folded stent.... [T]he stent actually imbeds itself into the folded balloon slightly.

If you look across the OD of the balloon there, you can see that the balloon material actually protrudes up between the wires a little way through the length of the stent. The forming process for the stent is actually completed on the balloon, so that it is not just a stent slipped on to a folded balloon, it is actually a complete system when it is finished.

(D.I.88, Exh. 8) Photographs of samples of the Gianturco stent FN12 taken with an optical microscope and/or a scanning electron microscope, demonstrate that the crimping process used to place the stent on the balloon forces the balloon into the recesses between the stent elements, causes indentations in the balloon, and results in "shoulders" at both ends of the stent. (D.I.88, Exhs.9-13) Optical and scanning electron

microscope photographs of the balloon after removal of a Gianturco stent reveal that the indentations caused by the stent remain in the balloon after the stent's removal. (D.I.88, Exhs.17-18) Photographs of the prior art Johnson & Johnson Interventional Systems Palmaz-Schatz PS 153 expandable stent delivery system ("the PS 153 stent") reveal similar findings. (D.I.88, Exhs.14-15, 19)
FN12. Although AVE questioned whether these samples were manufactured using the process employed in the 1993-1994 time period, this issue was not further developed in the briefing or at oral argument. Therefore, the court will rely on Cook's representation to Cordis that the tested stents "were substantially manufactured in the same way as they were in 1993." (D.I.88, Exh. 25)

Neither the specification of the '965 patent nor the prosecution history explicitly dictates the extent to which the balloon must partially surround the stent in order for the stent to be considered "encapsulated." Moreover, neither party's expert indicated that one of ordinary skill in the art reading the '965 patent would interpret the claims as requiring the indentations in the balloon be of a specific depth to establish "encapsulation." In fact, Dr. Solar opined that "[t]here's no requirement for depth. It's more or less that [the balloon] fills the spaces between the stent elements. So depending on the stent design you will get different imprints, different types of indentations." (D.I. 88, Exh. 2 at 67) AVE's proffered interpretation of "encapsulation" sets forth no requirement in this regard, mandating only that the protrusions and indentations be such that the stent is "secured" to the balloon. The court concludes, therefore, that AVE has not carried its burden of persuasion that it could withstand a challenge to the validity of the '965 patent in light of either the prior art Gianturco or the PS 153 stent.FN13

FN13. Given this finding, the court will not address the s. 103 challenge or AVE's assertion that the '965 patent is infringed by the MINICrown stent delivery system.

B. Irreparable Injury

The second factor the court must consider in determining whether to grant injunctive relief is the extent to which AVE will suffer irreparable injury if such relief is denied. Since AVE did not make a clear showing of validity, it is not entitled to a rebuttable presumption that it will be irreparably harmed if an injunction does not issue. This is particularly so given the presence of non-infringing alternatives in the market and AVE's failure to offer proof establishing that it is the "pillowing" technology disclosed in the '965 patent that drives the sales of its S540 stent. Nevertheless, the court recognizes that AVE will suffer some adverse consequences if Cordis is allowed to continue its sale of the MINICrown stent delivery system. For instance, AVE will experience some loss in sales of its S540 stent delivery system and accessory products as well as loss in market share. In addition, it will experience some degree of damage to its reputation as a technology innovator and its identity as the only manufacturer providing the "pillowing" technology and the goodwill associated with such identification. To a large extent, however, such economic harms are compensable by money damages.

AVE's delay in seeking a preliminary injunction does not preclude a finding of irreparable injury. While "outrageous, unreasonable, and inexcusable delay" bars all claims for relief, less egregious delay bars claims for past infringement, not for prospective injunctive relief. University of Pittsburgh v. Champion Products, Inc., 686 F.2d 1040, 1044-46 (3d Cir.1982); *see* W.L. Gore & Assocs., Inc. v. Totes Inc., 788 F.Supp. 800, 812 n. 19 (D.Del.1992). Although the court might question AVE's timing, the delay at issue is not sufficient to negate on its face irreparable injury. Nonetheless, the court concludes that Cordis can compensate AVE for any economic harm that might occur due to the continued sale of the MINICrown stent delivery system by money damages should AVE prevail at trial.

AVE having failed to establish either likelihood of success on the merits or irreparable harm, the court need not make a finding with respect to the remaining two factors in the injunctive relief analysis-balance of the

hardship and public interest. *See* Polymer Tech., Inc. v. Bridwell, H.A., 103 F.3d 970, 973-74 (Fed.Cir.1994); Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1556 (Fed.Cir.1994).

V. CONCLUSION

For the reasons discussed, the court concludes that AVE has failed to establish either of the first two factors deemed relevant to a preliminary injunction analysis. Accordingly, its motion for a preliminary injunction (D.I.4) will be denied. An appropriate order shall issue.

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