

United States District Court,
D. Minnesota, Fourth Division.

CORDIS CORPORATION,
Plaintiff.

v.

MEDTRONIC, INC,
Defendant.

Civ. No. 4-86-820

December 1, 1986.

Leonard J. Keyes and Alan Maclin, Briggs & Morgan, St. Paul, Minn., Granger Cook, Jr. and Stephen B. Heller (of counsel), Cook, Wetzel & Egan, Ltd., George Gerstman (of counsel), Piggott, Gerstman & Gilhooley, Ltd., Chicago, Ill. Henry W. Collins (of counsel) Cordis Corporation, Miami, Fla. 33102, for plaintiff.

John D. Gould and Albert Underhill, Merchant, Gould, Smith, Edell, Welter & Schmidt, P.A., Joseph F. Breimayer (of counsel), Medtronic, Inc., Minneapolis, Minn., for defendant.

MEMORANDUM AND ORDER

McLAUGHLIN, District Judge.

FACTS

Plaintiff Cordis is a manufacturer of medical devices and has been making and supplying cardiac pacemakers and related equipment such as cardiac pacing leads (endocardial leads) for at least 24 years. Defendant Medtronic owns two patents, Nos. 3,902,501 (the '501 patent) and 3,939,843 (the '843 patent), for endocardial leads that connect heart pacemakers to an interior surface of the heart.

An endocardial lead is implanted in the patient by introducing the lead into a vein leading into the heart. The lead is then fed into the interior of the heart through a heart valve. The electrical impulses generated by the pacemaker are then transmitted to the heart muscle via the lead.

To ensure that the electrical impulses reliably reach the heart, the endocardial lead must be in firm contact with the wall of the heart chamber. Medtronic owns the patent on the '501 lead (the patented lead in issue in this motion) which keeps the pacemaker in contact with the heart through the use of a plurality of pliant non-conducting tines which are adjacent to the tip of the pacemaker electrode. The tines cooperate with the tissue of the heart, urging the conductive tip of the lead into contact with the heart wall. The tines particularly cooperate with the trabeculae, lattice-like structures of small muscle fibers in the heart, to hold the electrode tip in place.

In 1979 Cordis introduced two types of endocardial leads for use with pacemakers. One type included 'tined' leads made of silicone elastomer. By late 1980, Cordis realized that a substantial question of patent infringement was raised by use of its 'tined leads' and the '501 patent belonging to Medtronic. Cordis and Medtronic then negotiated a license agreement, allowing Cordis to manufacture, use, or sell tined leads under Medtronics' '501 patent.

Tined leads have slender, free-floating, and pliable projections extending solely from the pacing lead body at their distal ends. Tined leads penetrate the interstices of the trabeculae of the heart and tend to 'lock into' them. Because of this, tined leads may undesirably snag on such things as minor obstructions in a blood vessel or various structures within the heart itself, making maneuvering of the electrode to its appropriate site within the heart difficult. Additionally, tined leads may become suspended between the trabeculae, making it difficult to establish contact between the electrode and the heart wall. Tined leads are also difficult to remove after implantation, since extensive tissue ingrowth tends to occur around the lead tip. Thus tined leads are preferred in implantation in the atrial or upper chamber of the heart where these problems are less apparent. Tined leads are employed in the vast majority of all pacemaker implants. See *Medtronic, Inc. v. Daig Corp.*, 221 U.S.P.Q. 594, 610 (D.Minn. 1983) (noting testimony that 'the tined endocardial lead is now the lead of choice in the medical profession').

The other type of endocardial lead introduced by Cordis in 1979 is the 'finned' lead. Finned leads have continuous wings, formed by webbing that extends out from the pacing lead body. Finned leads have a straight back edge that connects the rearward-most point of the leading edge of the fin into the lead body and facilitates migration of the electrode into the trabeculae. Finned leads do not penetrate the interstices of the trabeculae as deeply as tined leads, and are therefore more easily manipulated during insertion through a blood vessel and are more easily removed. Finned leads are preferred for use in the ventricular or lower chamber of the heart, and for use in pediatric cases.

The underlying issue of the *Cordis v. Medtronic* action here is whether the finned lead is covered by the Cordis-Medtronic licensing agreement and the Medtronic patents, and thus whether Cordis owes Medtronic royalties for its manufacture and sale of finned leads. The licensing agreement, section 2.02, Plaintiff's Memorandum in Support of Motion, Plaintiff's App. at 30, Exh. I, provides that Cordis agrees to grant a royalty-free, non-exclusive license to Medtronic of any patent rights of Cordis 'which claim improvement to the configuration of flexible tined elements or medical leads equipment.' *Id.*

The scope of this 'grant-back' provision appears to have been limited. According to a letter from Medtronic's chief patent counsel, John L. Rooney, dated January 28, 1982, 'we have examined product literature relative to your Cordis Model 325161 Finned, Bipolar Lead. It is apparent to us that with respect only to the grant-back provisions of Section 2.02 of the tined lead license agreement sent to you [Cordis] on January 8, 1982, Section 2.02 does not contemplate your granting to Medtronic any rights to your improvements to fins of the type embodied in the Model 325161 lead.' Plaintiff's Memorandum in Support of Motion, Plaintiff's App. 24, Exh. G.

Since entering the licensing agreement, Cordis has made royalty payments to Medtronic of almost \$2 million on its tined leads. Plaintiff's Memorandum in Support of Motion, Plaintiff's App. 50, Exh. J, Eggert Declaration para.16. Royalty payments are made pursuant to quarterly summary reports in which the royalties are identified as being tined leads. *Id.* However, by letter dated June 27, 1986, Medtronic informed Cordis that it believed finned leads were subject to royalty payments under the license agreement as 'Royalty Apparatus,' and that Cordis' use of finned leads were an infringement of Medtronic's licensed patents. Plaintiff's Memorandum in Support of Motion, Plaintiff's App. 51, Exh. K, Eggert Declaration para. Section 1.06 of the license agreement provides:

'Royalty Apparatus' shall mean medical leads equipment having flexible tines for lodging an electrode in a selected portion of the body, the tines being sufficiently pliable to avoid piercing the body, including that apparatus supplied to order and sold to the customer by CORDIS during one particular sales transaction, including all elements and components thereof that are (a) integral portions of the apparatus functioning only to make up the medical lead, or (b) especially described or claimed as means or otherwise in a patent included in the MEDTRONIC patent rights. 'Royalty Apparatus' shall not include pulse generators.

By letter dated August 29, 1986 Medtronic advised Cordis that Medtronic intended to terminate the license agreement within 90 days due to the nonpayment of royalties by Cordis on the finned leads unless Cordis would pay \$1 million for a paid-up, non-exclusive license. Plaintiff's Motion App. 55, Exh. L, Eggert Declaration.

Cordis now seeks a preliminary injunction restraining Medtronic from terminating the licensing agreement pending outcome of the underlying action.

DISCUSSION

The test for whether preliminary injunctive relief should be granted is set out in *Dataphase Systems, Inc. v. C.L. Systems, Inc.*, 640 F.2d 109 (8th Cir. 1981). There are four factors to be considered by the Court:

- (1) the threat of irreparable harm to the movant;
- (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant;
- (3) the probability that movant will succeed on the merits; and
- (4) the public interest.

Dataphase, 640 F.2d at 114. The grant or denial of a preliminary injunction rests in the discretion of the trial court. 11 C.Wright and A. Miller, *Federal Practice and Procedure* s. 2947 (1973); *Chicago Stadium Corp. v. Scallen*, 530 F.2d 204, 205 (8th Cir. 1976). The United States Court of Appeals for the Eighth Circuit has stated that '[a]t base, the question is whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined.' *Dataphase*, 640 F.2d at 113.

A. Threat of Irreparable Harm to the Movant

In order to warrant the grant of injunctive relief on the ground of threatened irreparable injury, the injury contemplated must be real, not fancied; actual, not prospective; and threatened, not imagined. 11 C.Wright and A.Miller, *Federal Practice and Procedure* s. 2947 (1973); *Association of Professional Engineering Personnel v. Radio Corp. of America*, 183 F.Supp. 834, 839 (D.C.N.J. 1960).

Plaintiff Cordis argues that termination of the license agreement for the tined lead would affect its ability to market both its tined and finned leads, and would seriously disrupt Cordis' electrode lead business. Cordis points out that if the license agreement is terminated, any customers of Cordis' tined leads could be subject to patent infringement actions by Medtronic, as well as subjecting Cordis to such an action. Additionally, Cordis argues that termination of the license agreement is likely to result in reduced market share of sale of leads simply because customers will be reluctant to buy devices that are the subject of a legal controversy. Plaintiff's Memorandum in Support of Motion App. at 8, Eggert Declaration para.19.

Cordis notes also the significance of tined endocardial leads in the pacemaker industry. The validity of the '501 patent has been upheld in several lawsuits, see, e.g., *Medtronic, Inc. v. Daig Corp.*, 789 F.2d 903 (Fed.Cir. 1986); aff'g, 611 F.Supp. 1498 (D.Minn. 1985); *Medtronic, Inc. v. Intermedics, Inc.*, 230 U.S.P.Q. 641 (Fed.Cir. 1986), and while other types of leads are available on the market, the tined lead is the most widely used in atrial implantations. If the license agreement is terminated, Cordis argues it could be enjoined by Medtronic from manufacture and sale of the tined leads.

The highly competitive nature of the pacemaker industry and the disruption of sales and loss of market share thereof has been held to constitute irreparable harm in this district. *Medtronic, Inc. v. Catalyst Research Corp.*, 518 F.Supp. 946, 954 (D.Minn. 1981). Injury to market share has also been held to constitute irreparable harm because it is so difficult to recover from such a loss, see, e.g., *American Home Products Corp. v. Abbott Laboratories*, 552 F.Supp. 1035 (S.D.N.Y. 1981).

Cordis notes that the only way in which it could avoid irreparable injury without preliminary injunctive relief would be to pay Medtronic the \$1 million demanded royalties on finned leads to maintain Cordis' license during pendency of litigation. Yet even if Cordis was ultimately successful in its suit, it may not be able to recover that \$1 million because of a provision in the license agreement which states:

Royalties paid by CORDIS to MEDTRONIC under this Agreement shall not be refundable for any purpose except for amounts due to computational errors, and in such case any overpayment shall be taken as a credit against future royalties payable under this Agreement.

Plaintiff's Memorandum in Support of Motion App. at 28, Exh. I s. 4.05. In *Precision Shooting Equipment, Inc. v. Allen*, 199 U.S.P.Q. 459 (N.D.Ill.), *aff'd*, 646 F.2d 313 (7th Cir. 1978), cert. denied, 454 U.S. 964 (1981), the court held that a licensee is irreparably injured and has no remedy at law where it was likely that it would be unable to recoup royalties paid with respect to a challenged patent. *Allen*, 199 U.S.P.Q. at 460. Thus Cordis argues because of the contractual restriction in section 4.05 of the license agreement, Cordis would suffer irreparable harm if it pays Medtronic the \$1 million to maintain the license agreement.

Defendant Medtronic argues Cordis will not suffer irreparable harm if the Court does not grant preliminary injunctive relief. Defendant argues that Cordis will be able to adequately address recovery of any legally cognizable losses stemming from a wrongful termination of the license agreement through an action for breach of contract.

Additionally, Medtronic relies heavily on *Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991 (Fed.Cir. 1985) in which Cordis had sued Medtronic seeking a declaratory judgment that the two Medtronic patents (the '501 and the '843) were invalid and that the license agreement was void in its inception. The United States for the District of Florida, relying partially on *Precision Shooting v. Allen*, had granted Cordis' motion for a preliminary injunction preventing Medtronic from terminating the license agreement, and permitted Cordis to deposit any royalty payments due Medtronic *pendente lite* into an escrow account. The Federal Circuit, on appeal, vacated the district court's order and remanded, stating:

'We believe that if the plaintiffs wish to continue to invoke the protections of their licensing agreements, they should be required to continue paying their royalties to the defendant. Ultimately, all royalties paid after the filing of the complaint may have to be returned to plaintiffs . . . At present, plaintiffs already have the option of withholding royalties and thereby breaching the licensing agreement; of course, they would then run the risk of an injunction if they should lose on the merits. It would not be fair for the plaintiffs to be allowed simultaneously to reap all the benefits of the licensing agreement and to deprive the licensor of all his royalties. Patents are presumed valid, 35 U.S.C. s. 282; until invalidity is proven, the patentee should ordinarily be permitted to enjoy the fruits of his invention . . .'

Cordis, 780 F.2d at 995, quoting *Warner-Jerkinson Co. v. Allied Chemical Corp.*, 567 F.2d 184 (2d Cir. 1977). See also *Intermedics Infusaid, Inc. v. Regents of the University of Minnesota*, No. 85-2811, slip op. at 9 (Fed.Cir. Oct. 22, 1986) (citing *Cordis v. Medtronic*, 780 F.2d 991), holding 'a licensee is not entitled . . . to preclude a licensor from terminating the license agreement for breach by reason of nonpayment of royalties.'

Defendant additionally argues that the Federal Circuit's decision in *Cordis v. Medtronic* on Cordis' prior

preliminary injunction motion should act as a bar to injunctive relief here. Essentially Medtronic is relying on the law of the case doctrine. The law of the case doctrine 'expresses the practice of courts generally to refuse to reopen what has been decided . . .' *Messinger v. Anderson*, 225 U.S. 436, 444 (1912). This doctrine was judicially created to ensure judicial efficiency and prevent the possibility of endless litigation. As one court explained, '[n]o litigant deserves an opportunity to go over the same ground twice, hoping that the passage of time or changes in the composition of the court will provide a more favorable result the second time.' *United States v. Turtle Mountain Band of Chippewa Indians*, 612 F.2d 517, 520 (Ct.Cl. 1979). The Federal Circuit relied on this doctrine in denying review of a Tenth Circuit decision over which the Federal Circuit had jurisdiction by virtue of an act of Congress. *Central Soya Co., Inc. v. Geo. A. Hormel & Co.*, 723 F.2d 1573 (Fed.Cir. 1983) (determination of liability by Tenth Circuit in patent case). The Central Soya decision by the Federal Circuit stated:

While the law of the case doctrine is applicable [to this case], and acts as a heavy deterrent to vacillation on arguable issues, Moore's Federal Practice para. 0.404[1] at 119, it is not an inexorable command and should be applied

'as a matter of sound judicial practice, under which a court generally adheres to a decision in a prior appeal in the case unless one of three 'exceptional circumstances' exists: 'the evidence on a subsequent trial was substantially different, controlling authority has since made a contrary decision of the law applicable to such issues, or the decision was clearly erroneous and would work a manifest injustice.'

Central Soya, 723 F.2d at 1580, citing *Short v. United States*, 661 F.2d 150, 154 (Ct.Cl. 1981); *Northern Helix Co. v. United States*, 634 F.2d 557, 561 (Ct.Cl. 1980); *Turtle Mountain Band*, 612 F.2d at 520, all quoting *White v. Murtha*, 377 F.2d 428, 431 (5th Cir. 1967). Moreover, the Federal Circuit has held that the doctrine of law of the case extends to cases even where a court 'do[es] not discuss certain propositions [and this] do[es] not make the decision inadequate or suggest the . . . court failed to understand them.' *Perkin-Elmer Corp. v. Computervision Corp.* 732 F.2d 888, 900 (Fed.Cir.), cert. denied, 105 S.Ct. 187 (1984), citing *Schilling v. Schwitzer-Cummins Co.*, 142 F.2d 82, 84 (D.C.Cir. 1944). The Federal Circuit has also held that 'the current view is that a decision is the law of the case not only with respect to 'questions in terms discussed and decided' but also questions decided by necessary implication.' *Smith Intern. v. Hughes Tool Co.*, 759 F.2d 1572, 1577 (Fed.Cir. 1985).

Cordis argues in its reply brief that the law of the case doctrine does not apply here, and that therefore the Federal Circuit's earlier vacation and remand of Cordis' preliminary injunction in the *Cordis v. Medtronic*, 780 F.2d 991 (Fed.Cir. 1985) does not prevent preliminary injunctive relief in the present case. Cordis points out that the earlier case presented evidence that was substantially different, a factor constituting an exceptional circumstance barring application of law of the case doctrine here.

Cordis argues in the present case that it is seeking only to maintain the license agreement with respect to finned leads, not void it as in the first case, and is not asking the Court to allow Cordis to cease payment of royalties for finned leads pursuant to that agreement. Instead, this action is to determine whether the license agreement includes finned leads, which is a separate issue not necessarily implicated in the earlier patent infringement/voiding of license agreement action before the Federal Circuit. Cordis argues that in this case, Medtronic only recently asserted that finned leads, sold by Cordis since 1979, are included as royalty apparatus under the license agreement. Thus Cordis reiterates that termination of the license agreement will cause a loss of market share with respect to finned leads, causing irreparable injury. Cordis also notes that the earlier Federal Circuit case did not address the issue of preclusion of recovery of royalties by the licensing agreement, s. 4.05, and that the cases discussed by the Federal Circuit in the earlier *Cordis v. Medtronic* case did not involve such a license agreement provision. See, e.g., *Teletronics PTY Ltd v. Cordis Corp.*, 533 F.Supp. 453 (D.Minn. 1982) (no evidence that licensor would be unable to repay the royalties in the event it was ordered to do so, making preliminary injunctive relief inappropriate); *Warner-Jenkinson Co. v. Allied Chemical Corp.*, 567 F.2d 184 (2d Cir. 1977) (holding absent indication licensor might be judgment proof at

end of litigation, licensor should not be deprived of its right to royalties in the interim).

The Court finds that Cordis' request for preliminary injunctive relief is not barred by the law of the case doctrine. The earlier case before the Federal Circuit involved a challenge to Medtronic's patent, and sought to void the license agreement. The present case presents only the question of whether the license agreement includes finned leads. Cordis is not seeking to avoid royalty payments on the valid Medtronic tined leads under the agreement, but only to enjoin Medtronic from terminating the agreement until the issue of whether the finned leads come under the license agreement is resolved.

The Court further finds that Cordis has shown irreparable injury. Termination of the agreement will cause loss of market share and possible further litigation, against Cordis and its customers, for patent infringement, and thus would irreparably injure Cordis.

B. State of Balance of Harms

If the grant of a preliminary injunction would cause defendant financial loss or damage to reputation which significantly outweighs any damage to the plaintiff, preliminary injunctive relief is not appropriate. *Arco Fuel Co. v. Atlantic Richfield Co.*, 427 F.2d 517 (2d Cir. 1970) (denial of preliminary injunction affirmed); *Schneider, Hill Spangler, Inc. v. Cudmore*, 325 F.Supp. 173 (D.Conn. 1971) (preliminary injunction denied).

Plaintiff Cordis argues that Medtronic's rights are not threatened and Medtronic would suffer no injury if preliminary injunctive relief were granted. Cordis asserts that if Medtronic succeeds in proving that finned leads are included in the license agreement, it can be fully compensated by payment of legal damages. Cordis has demonstrated its ability to make royalty payments by the nearly \$2 million it has already paid in royalties for the tined leads, and any royalties due on finned leads could be calculated with certainty.

On the other hand, Cordis argues, the potential damage to Cordis' good will and market share should Medtronic terminate the license agreement is incapable of measurement and the loss of market share may never be recoverable. Plaintiff's Memorandum in Support of Motion, Plaintiff's App. at 8, Eggert Declaration para.19. Further, as argued before, if Cordis is forced to pay the \$1 million royalties demanded by Medtronic on finned leads to maintain its finned lead license, Cordis may not be able to recover that money. Consequently, Cordis argues the balance of harm between Cordis and Medtronic if preliminary injunctive relief were to issue is strongly in favor of Cordis.

Defendant Medtronic argues that by permitting Cordis to retain the license agreement while not paying royalties Medtronic claims are due on finned leads, Medtronic is deprived of full benefit of the license agreement during the pendency of the litigation. Medtronic additionally argues that under the license agreement, s. 9.01, Medtronic is obligated to prosecute infringers of its patents in suit whose net sales exceed specific limits, thereby protecting Cordis from competition with unlicensed competitors. Therefore, a preliminary injunction would deprive Medtronic of its claimed royalties while obligating it to defend, at its own expense, the patents in suits against other infringers and against Cordis' current action.

Moreover, defendant Medtronic argues that Cordis may not be able to satisfy an eventual adverse judgment if it is allowed to cumulate unpaid royalties during the pendency of this action. Medtronic asserts that Cordis is experiencing significant business difficulties. Medtronic states that Cordis posted a net loss last year of more than \$5 million. Defendant's Memorandum in Opposition to Motion, Exh. L, Rooney Aff. para.14. Cordis has also announced that it is seriously considering the sale of all or part of its business to third parties. *Id.*; Exh. M, N. Thus Medtronic argues its harm will substantially outweigh the harm to plaintiff of not getting a preliminary injunction if such relief is granted.

Cordis responds, in its reply brief, that it is perfectly able to respond in damages should Medtronic prevail at trial. Cordis' annual report for 1986 indicates that Cordis has nearly \$220 million in current assets, with

shareholders' equity exceeding \$107 million. Plaintiff's Memorandum in Support of Motion, Exh. 1 at 26-27.

After careful consideration, the Court finds that Medtronic's arguments are insufficient to show that the balance of harm it will suffer if the motion is granted will significantly outweigh the harm to Cordis if the motion is not granted. Therefore this factor in the issuance of a preliminary injunction is satisfied.

C. Likelihood of Success on the Merits

Plaintiff must show 'some likelihood of prevailing on the merits of its claim . . . the strength of this showing varies depending on the weight of the other three elements listed in *Dataphase*, but absent some showing of probability of success an injunction will not issue.' *Sperry Corp. v. City of Minneapolis*, 680 F.2d 1234 (8th Cir. 1982); *Road Runner Transportation, Inc. v. Purolator Courier Corp.*, CIVIL 4-86-758 (D.Minn. Oct. 30, 1986). When considering the probability of success needed for an award of a preliminary injunction, it does not necessarily require the movant to prove a greater than 50 percent likelihood that he will prevail on the merits, only a probability of success. See, e.g., *Dataphase*, 640 F.2d at 113; *Medtronic, Inc. v. Gibbons*, 527 F.Supp. 1085, 1092 (D.Minn. 1981).

Cordis asserts three separate grounds on which it claims it shows likelihood of success on the merits justifying issuance of preliminary injunctive relief. A finding of likelihood of success in favor of Cordis on any one of these three grounds would support such relief. The three grounds are: (1) there is no literal infringement of the licensed Medtronic patents; (2) the term 'Royalty Apparatus' in the license agreement does not include finned leads; and (3) Medtronic is barred by laches/estoppel from trying to include finned leads in its patents and licenses.

1. Infringement of Patents

Infringement is made out if the accused device falls clearly within the terms of the claims, *Envirotech, Corp. v. Al George, Inc.*, 730 F.2d 753, 759 (Fed.Cir. 1984). The pertinent portions of Claims 1, 7, and 14, the independent claims of the '501 patent, are set forth below. If there is no infringement of these independent claims, there can be no infringement of any of the dependent claims.

Claim 1:

'nonconducting tine means extending from said encasing material and away from said tip from a location adjacent said tip for cooperating with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said encasing material and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.'

Claim 7:

'nonconducting tine means extending from said catheter means and away from said tip from a point adjacent said tip means for cooperation with heart tissue, to hold the tip in position, said tine means forming a generally acute angle with said catheter means and being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent penetration of said heart tissue, said pliant material being generally inert to body fluids.'

Claim 14:

'nonconducting tine means including a plurality of tines each extending from said catheter and away from said tip from a point adjacent said tip and forming an acute angle with said catheter for cooperating with heart tissue to hold the tip in position, said tine means being entirely of a pliant material having sufficient rigidity to maintain said angle when said tine means are unrestrained, but sufficiently pliant to prevent

penetration of said heart tissue.'

In construing the words in a claim, they will be given their ordinary and customary meaning unless it appears that the alleged inventor used them differently. *Envirotech*, 730 F.2d at 759. Under the independent claims stated above, the '501 patent applies to 'tine means' which extend 'away from said tip' at 'an acute angle' with respect to the 'encasing material' or 'catheter means' of introduction of the electrocardial lead into the heart muscle.

When given its ordinary and customary meaning, the term 'tine' refers to a slender, pointed projecting part or prong, Plaintiff's Memorandum in Support of Motion, Dann Declaration, para.8; Vigil Declaration, para.14, Plaintiff's App. at 107; Cummings Declaration, para.6(b), Plaintiff's App. at 136; Miller Declaration para.3, Plaintiff's App. at 57. Nothing in the specification of the '501 patent indicates that the term 'tine' is used in anything other than its ordinary and customary sense. Dann Declaration, para.10, Plaintiff's App. at 107; Vigil Declaration, para.13, Plaintiff's App. at 127; Cummings Declaration, para.6(b), Plaintiff's App. at 136; Miller Declaration, para.13, Plaintiff's App. at 60. The ordinary and customary meaning of the term 'tine' also corresponds to the meaning given the term by those skilled in the pacer lead field. Miller Declaration, para.3, Plaintiff's App. at 57.

Cordis argues that a 'fin' (as in finned lead) is very different than a tine. A fin resembles a wing-like or web-like paddle process. Dan Declaration para.8, Plaintiff's App. at 106; Vigil Declaration, para.15, Plaintiff's App. at 127; Cummings Declaration, para.6(c), Plaintiff's App. at 136; Miller Declaration para.4, Plaintiff's App. at 58. Cordis argues that persons knowledgeable in the field of pacing leads understand fins to be continuous wings, or wings formed by webbing extending out from the pacing lead body, Miller Declaration, para.5, Plaintiff's App. at 58; and to have a triangular or wedge shape with a straight back edge, MacGregor Declaration, para.8, Plaintiff's App. at 66.

Thus, Cordis argues, when given either its ordinary and customary meaning, or its meaning to persons in the pacer lead field, the term 'finned' indicates something entirely distinct from the term 'tined,' and a 'fin' is not considered to be encompassed by the term 'tine.' Miller Declaration, para.5, Plaintiff's App. at 58; MacGregor Declaration para.9, Plaintiff's App. at 66; Dann Declaration, para.8, Plaintiff's App. at 106; Vigil Declaration, para.16, Plaintiff's App. at 128; Cummings Declaration, para.6(c), Plaintiff's App. at 136.

All of the claims in the '501 patent require the lead to have 'tine means.' Because Cordis' finned leads do not have 'tines' and there is no basis for giving the term 'tine' anything other than its ordinary and customary meaning, Cordis' argues that its finned leads do not literally infringe the claims of the '501 patent, Dann Declaration, para.11, Plaintiff's App. at 107; Vigil Declaration, para.20, Plaintiff's App. at 102; Cummings Declaration, para.6, Plaintiff's App. at 136.

If actual literal infringement is absent, infringement may be made out under the Doctrine of Equivalents if the accused product performs substantially the same function in substantially the same way to obtain the same results as the claimed product. *Hughes Aircraft Co. v. United States*, 717 F.2d 1351, 1361 (Fed.Cir. 1983). Cordis argues there are substantial differences between tined and finned leads, precluding the application of the doctrine of equivalents.

Cordis argues the following in support of this assertion. In contrast to a tined lead, the rear edges of the fins on the finned leads hook on to the trabeculae of the heart wall, with the straight back edge facilitating the migration of the electrode among the trabeculae and into its final proper position in contact with the heart wall. MacGregor Declaration, para.8, Plaintiff's App. at 66. Tines penetrate the spaces between the trabeculae much more deeply than do fins, MacGregor Declaration, para.5, Plaintiff's App. at 65; Miller Declaration, para.6, Plaintiff's App. at 58, and because of their free-floating projections, tined leads are much more likely to accidentally catch onto undesirable areas during implantation than are finned leads. Miller Declaration, para.7, Plaintiff's App. at 58; MacGregor Declaration, para.6, 7, Plaintiff's App. at 65. In

addition, after implantation, finned leads can be removed with relative ease and safety due to the fins having a natural 'tear line' which allows the fin to tear away from the lead body and fold back to allow the lead to be withdrawn. Miller Declaration, para.9, Plaintiff's App. at 59; MacGregor Declaration, para.9, Plaintiff's App. at 66. Removal of 'tined' leads often results in pulling out tissue from the heart as the pacing lead is withdrawn, and tearing of the heart wall has been reported. Miller Declaration, para.8, 9, Plaintiff's App. at 59. Finally, finned leads are preferred for ventricular lead implantation and for pediatric cases, while tined leads are preferred for atrial implantations. Miller Declaration, para.10, 11, Plaintiff's App. at 60.

For these reasons, Cordis argues, a finned lead is not the equivalent of a tined lead, and infringement of the '501 patent cannot be made out under the Doctrine of Equivalents. Dann Declaration, para.14, 15, Plaintiff's App. at 108-09; Vigil Declaration, para.22-25, Plaintiff's App. at 129, 131; Cummings Declaration, para.8, Plaintiff's App. at 139.

Thus, Cordis argues, because its finned leads neither literally infringe the '501 patent nor infringe it under the Doctrine of Equivalents, there are no royalties due under the license agreement because of Cordis' manufacture, use, and/or sale of its finned leads and there is no breach of the license agreement for such nonpayment.

Defendant Medtronic argues first that there is literal infringement of patent '501, relying on *Medtronic Inc. v. Daig Corp.*, 611 F.Supp. 1498 (D.Minn. 1985), where the court held that Daig's tine lead infringed the patent '501 claim 1. Daig argued its tined lead did not have 'tines' per se, but rather had 'fins' which were rigid and pliant because of their structure, a urethane wedge, and not because of the physical properties of the material from which they were made. Also, Daig argued that its tined lead operated differently from Medtronic's because its tines wrapped around the lead body, as opposed to moving up or down, towards or away from the lead body. The court rejected this argument, finding literal infringement. The court referred to Daig's arguments as 'makeweight,' but went on to say that even if valid, the Daig tine leads infringed Medtronic's under the Doctrine of Equivalents since 'the Court finds that this Daig endocardial lead performs substantially the same function in substantially the same way to achieve the same result as the Claim 1 device' since the Daig lead had a plurality of nonconducting tine means located near the electrode tip, extending away from the lead body and forming an acute angle. *Daig*, 611 F.Supp. at 1539.

Cordis, in its reply brief, states that the inventors of the '501 patent, Paul Citron and Gene Dickhudt, confirm in their deposition testimony that the term 'tined leads' was not intended to cover a structure such as the fin in Cordis' finned leads. According to Citron, a tine is something cylindrical in shape, with a free end. Citron Dep., Sept. 22, 1982, at 53, line 20, 54 line 22, Plaintiff's Exh. 1. Furthermore, a 'projection' in a tined lead is a tine attached to the lead body at one point and free at the other end. *Pacesetter Systems v. Medtronic, Inc.*, Citron Dep., Jan. 3, 1984, at 63, lines 19-23, Plaintiff's Exh. 2. Additionally, Dickhudt agreed that a tine has one end attached to a lead body with the other end free. Dickhudt Dep. Jan. 31, 1986, at 5, lines 17-24, Plaintiff's Exh. 3.

In contrast, Cordis argues, its fins are not generally cylindrical and both ends of the fins are firmly attached to the lead body. Moreover, Cordis argues that the Doctrine of Equivalents does not apply, since the operation of tined leads and finned leads is different. First, as noted earlier, finned leads are more easily implanted and removed than tined leads, since they attach differently (depth-wise) to the trabeculae of the heart wall. MacGregor Declaration para.5, 8, Plaintiff's App. at 65-66; Miller Declaration para.6, 7, Plaintiff's App. at 58. Also, as noted earlier, tined leads are used for atrial implantations, whereas finned leads are used for ventricular implantations and pediatric cases.

Both types of leads serve the same purpose-to attach pacemaker electrodes to the walls of the heart. However, there are technical differences between the two types of leads which the Court finds may be significant. Cordis has submitted a number of experts' testimony to support its argument; Medtronic has also submitted testimony, but relies primarily on the Daig case. However, the Daig case relied on by Medtronic

involved a device which may not be similar to the Cordis finned lead; the Daig court used the term 'fin' only in describing the shape of the device in question.

The Court finds as a matter of law that Cordis need not prove a greater than 50 percent likelihood of prevailing on the merits, only a probability of success. See, e.g., *Dataphase*, 640 F.2d at 113; *Medtronic v. Gibbs*, 527 F.Supp. at 1092. The Court therefore finds that Cordis has shown probability of success on the merits of its claim that finned leads do not infringe Medtronic's '501 patent.

2. Royalty Apparatus

The license agreement requires payment of royalties on 'royalty apparatus,' which is defined in the agreement, s. 1.06, as 'medical leads equipment having flexible tines.' Cordis argues that the term 'tine' is unambiguous, that finned leads are not tined leads and thus do not constitute 'Royalty Apparatus.'

Under Minnesota law the Court must look to the contract as a whole in construing a disputed contract term, and any ambiguity in the language of the contract will be resolved against the drafter, *William B. Tanner Co. v. Waseca-Owatonna Broadcasting*, 549 F.Supp. 411, 413 (D.Minn. 1982). If there is an ambiguity, the Court will look to other evidence to decide what the parties meant. The Court is to discover the intent of the parties and enforce it, *Oskey Gasoline & Oil Co., Inc. v. OKC Refining, Inc.*, 364 F.Supp. 1137, 1141 (D.Minn. 1973). The conduct of the parties when performing is also relevant in defining the contract terms. *Id.* at 1142.

Referring to the license agreement, the term 'tine' appears only in section 1.06, which defines 'Royalty Apparatus,' and section 2.02, the grant-back provision. The only evidence, other than the definition of 'Royalty Apparatus' itself, bearing on the intent of the parties during the negotiations with respect to the term 'tine,' is in connection with the grant-back provision. Cordis argues that in arriving at the agreement, Medtronic agreed that the term 'tine' did not include Cordis' finned lead. Eggert Declaration, Plaintiff's Exh. F and G, Plaintiff's App. at 23, 24. In referring to the contract as a whole, argues Cordis, this understanding of the meaning of the term 'tine' should not be contradicted by giving a contrary meaning to the term when referring to it in the definition of 'Royalty Apparatus.'

Cordis further notes that Medtronic drafted the license agreement, noting that it included its 'standard terms,' Eggert Declaration, Exh. E, Plaintiff's App. at 22, and the definition of 'Royalty Apparatus' remained unchanged throughout the negotiations leading up to the signing of the Agreement. Medtronic was well aware of Cordis' finned lead, as evidenced by negotiations with respect to the grant-back provision, Eggert Declaration, para.9-11, Plaintiff's App. at 3, 4, Plaintiff's Exh. F-H, Plaintiff's App. at 23-25, and if Medtronic intended the term 'Royalty Apparatus' to include Cordis' finned lead, it could have clearly expressed so in the definition. Because any ambiguity should be resolved against the drafter, Cordis argues the term 'Royalty Apparatus' should not now be construed to include Cordis' finned leads.

In determining the meaning of express terms of an agreement, they are to be construed whenever reasonable in accordance with their usage in the trade and by the parties' conduct during the course of performance of the contract. See, e.g., *Oskey Gasoline*, 364 F.Supp. at 1141-43; Minn. Stat. s.s. 336.1-205, 336.2-208. Cordis argues the trade clearly recognizes the differences between 'tined' leads and 'finned' leads and does not consider a finned lead to be a tined lead. Miller Declaration, para.3-6, Plaintiff's App. at 57, 58; Eggert Declaration, para.6, 7, Plaintiff's App. at 2; MacGregor Declaration, para.9, Plaintiff's App. at 66. Further, Cordis has performed its obligations under the license agreement consistent with its belief that a finned lead is not a 'Royalty Apparatus.' Eggert Declaration, para.15, 16, Plaintiff's App. at 6. In the quarterly summary statements submitted in accordance with the license agreement, Cordis has always identified the report as a 'Schedule of Royalties Payable to Medtronic, Inc. on Tined Leads' (emphasis added). Plaintiff's Exh. J, Eggert Declaration, Plaintiff's App. at 50. Significantly, says Cordis, Medtronic made no objection at any time to the basis of the royalty payments until its letter of June, 1986.

Thus Cordis contends that when one considers the objective evidence relating to the definition of the term 'Royalty Apparatus,' i.e., the definition of 'Royalty Apparatus' itself, the grant back provision excluding 'fins,' the different treatment by the trade of 'tined' leads and 'finned' leads, the conduct of the parties themselves in regard to the payment of royalties on 'tined' leads only-all in the context of the legal principle that ambiguities are to be resolved against Medtronic as the drafter of the agreement-it is clear that the parties did not intend to treat 'finned' leads as 'tined' leads, and that this intent should prevail.

Defendant Medtronic argues that the term 'Royalty Apparatus' is defined in section 1.06 as 'all elements and components . . . that . . . are especially described or claimed as means or otherwise in a patent included in the MEDTRONIC patent rights.' Rooney Aff. para.5. The license agreement lists the '501 and '843 patents as included in the patent rights. Rooney Aff., Defendant's Exh. C. Medtronic contends the clear intent of this language is to include within the definition of 'Royalty Apparatus' every device sold by Cordis that falls within the claims of those patents, and that finned leads are included therein.

Additionally, Medtronic argues that the negotiations regarding the grant-back provision which resulted in the January 28, 1982 letter stating that in regard to the license agreement Medtronic did not contemplate getting any rights from Cordis on Cordis' improvements to fins of the type in Cordis' finned lead Model 325161, see Rooney Aff. para.9, Defendant's Exh. E, were only for the purpose of the grant-back provisions and not to narrow the meaning of 'Royalty Apparatus' in such a way as to exclude finned leads.

Medtronic's arguments are unpersuasive. Medtronic asks the Court to read the license agreement so broadly as to essentially encompass all endocardial leads. Again, Cordis has shown a probability of success on the merits in its argument that the license agreement does not include the finned leads. Cordis has made several arguments based on the language of the agreement, which Medtronic drafted. Since any ambiguity is resolved against the drafter of the agreement under Minnesota law, and since Cordis has presented evidence that usage in the trade and by the parties differentiates between tined and finned leads, the Court finds that Cordis has a probability of succeeding on the merits of this issue.

3. Laches/Estoppel

Plaintiff Cordis argues that defendant Medtronic is barred by laches and estoppel from claiming infringement of the '501 patent and terminating the license agreement.

Laches and estoppel are equitable defenses that prevent the enforcement of a patent, *Mainland Industries, Inc. v. Standal's Patents Ltd.*, 799 F.2d 746 (Fed.Cir. 1986). The defense of laches, which prevents recovery of damages for past infringement, requires (1) unreasonable and unexcusable delay in the assertion of the claim of infringement and (2) material prejudice resulting from the delay, *Mainland*, 799 F.2d at 748. Estoppel, which bars claims for patent infringement, requires the two elements of laches plus (1) affirmative conduct by the patentee inducing a belief of abandonment of claims against the alleged infringer and (2) detrimental reliance by the infringer. *Id.*

Cordis argues that it has been manufacturing its finned leads since May of 1979, more than seven years prior to Medtronic's first assertion that the finned leads infringed the '501 patent. Eggert Declaration, para.4, Plaintiff's App. at 1. Cordis argues its finned leads were widely advertised to the trade, including Medtronic, by sales brochures, Plaintiff's Exh. C, Eggert Declaration, Plaintiff's App. at 12. Thus, Cordis contends, it is presumed that Medtronic's delay in asserting that Cordis' finned leads infringe the '501 patent is unreasonable and unexcusable. Cordis claims it has been prejudiced by continuing its sale of its finned leads for more than seven years before Medtronic first charged infringement. See, e.g., *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1550 (Fed.Cir. 1984). Thus Cordis asserts it has established a prima facie case of laches.

Cordis further argues that there has been affirmative conduct by Medtronic during the negotiations leading up to the license agreement, and in the course of performance afterwards, that induced Cordis to believe that Medtronic did not consider Cordis' finned leads to infringe either of Medtronic's licensed patents. Since Medtronic indicated that Cordis' finned leads are not considered a tined lead in its January 28, 1982 letter, four years ago, Cordis has invested in excess of \$1 million on its finned lead products, including the purchase of additional equipment for the manufacture of such finned leads. Eggert Declaration, para.16, Plaintiff's App. at 6. Additionally, Cordis asserts it has paid more than \$600,000 in royalties in a license with a third party with respect to the finned leads. See Eggert Declaration, para.5, Plaintiff's App. at 2. Thus Cordis argues equity requires that Medtronic be estopped from asserting that Cordis' finned leads infringe the '501 patent; be barred from recovery of any alleged damage due to Cordis' manufacture, use, and/or sale of its finned leads; and be barred from claiming that royalties are payable on the finned leads under the license agreement.

Defendant Medtronic argues that no issue of estoppel or laches exists in this case. Medtronic argues that Cordis failed to identify the specific leads covered by its royalty payment in the required quarterly statements, and therefore Medtronic could not discern whether royalties were being paid on the finned endocardial leads. Medtronic argues that it did not learn that Cordis' sales of pacemaker leads actually exceeded the number for which royalties had been paid until recently, and upon so learning, promptly told Cordis to pay the royalties or Medtronic would terminate the license agreement. Rooney Aff. para.13-15, Defendant's Exh. G, I, J.

Medtronic further argues that the license agreement allows Medtronic to audit for past royalties and assert them retroactively under section 4.02 of the agreement. Rooney Aff. para.14. Section 4.02 allows this for a period of four years preceding the start of any audits, and Medtronic argues that when it gave notice to Cordis that it was disputing royalties owed on August 21, 1986, the license agreement had been in effect four and one-half years. Therefore, Medtronic argues, there can be no estoppel in this case since there was no unreasonable delay upon which Cordis could have reasonably relied in believing finned leads were not covered by the license agreement.

Medtronic states 'it is apparent from these facts that Medtronic has not engaged in any conduct even resembling the unreasonable and unexcusable delay necessary to create an estoppel or laches.' Defendant's Memorandum in Opposition to Motion at 19, citing Mainland Industries, 799 F.2d 746 (Fed.Cir. 1986); Tripp v. United States, 406 F.2d 1066 (Ct.Cl. 1969). See generally, 4 Chisum, Patents, para.19.05[2][a][i] (1986). It is not so apparent to the Court. Contrary to Medtronic's assertion that the required quarterly statements failed to identify the specific leads royalties were being paid on, those statements clearly state:

CORDIS CORPORATION ROYALTIES PAYABLE TO MEDTRONIC, INC. ON TINED LEADS.

Defendants' Exh. F.

Moreover, Medtronic's right to audit and collect past royalties on tined leads is not at issue here. Cordis is not challenging its responsibility to pay royalties on tined leads or any portion of the license agreement. Cordis is instead arguing that finned leads aren't included in the agreement and thus royalties aren't due and the agreement should not be terminated.

Cordis has presented evidence, including Medtronic's own January 28, 1982 letter, showing that Medtronic was aware of Cordis' finned leads and that such leads had been discussed in negotiating the grant-back provision of the license agreement. Additionally, for many years the finned leads had been advertised to the trade, including Medtronic, and thus Medtronic must have been aware of the Cordis finned leads. Therefore the Court finds there is a probability of success on the merits of a finding that Medtronic's conduct was unreasonable and unexcusable delay, creating an estoppel or laches.

D. The Public Interest

Cordis argues that the electrode leads in question in this action are components of life-saving medical devices. Medtronic's termination of the license agreement would result in a decreased availability of both tined and finned leads supplied by Cordis, and that therefore, a preliminary injunction preventing the termination of the license agreement pending litigation is in the public interest.

Medtronic argues that the short term benefit of having Cordis' supply endocardial leads, rather than forcing physicians to go to alternative sources, is outweighed by the long-term benefits of upholding the integrity of the patent system. See, e.g., *Eli Lilly & Co. v. Premo Pharmaceutical Labs*, 630 F.2d 120, 137-38 (3d Cir. 1980).

The Court finds that if there is any public interest to be served in this matter, it is best served by the grant of preliminary injunctive relief. The public would not be harmed and the patent system will not lose its integrity if injunctive relief issues in this case. On the other hand, the supply of endocardial leads for life-saving devices, i.e., pacemakers, is an issue of public interest, and maintaining the greatest supply of such leads best serves that interest.

The Court has carefully considered the arguments of the parties in this matter. The Court has considered the four factors set out in *Dataphase*, and on balance finds that the equities so favor Cordis that justice requires the Court to issue preliminary injunctive relief, preserving the status quo, until the merits of this litigation are determined.

Accordingly, based on the foregoing, and upon review of all the files, records, and proceedings herein,

IT IS ORDERED that defendant is preliminarily enjoined from terminating its license agreement with plaintiff for the manufacture, sale, and use of tined leads pending the outcome of this litigation. The parties should confer and submit to the Court within a reasonable time their proposal (and hopefully one that has been agreed upon) for the terms and amount of the bond.

D.Minn., 1986.

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