United States District Court,
N.D. California.

CARDIOGENESIS CORPORATION,
Plaintiff.
v.
PLC MEDICAL SYSTEMS, INC,
Defendant.

No. CIV. 96-20749 SW

Dec. 2, 1998.

ORDER CONSTRUING CLAIMS; DENYING CARDIOGENESIS' MOTION FOR SUMMARY JUDGMENT REGARDING (1) MATERIALITY, (2) INTENT, AND (3) INEQUITABLE CONDUCT; GRANTING PLC'S COUNTERMOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT

WILLIAMS, District J.

On October 22, 1998, the Court conducted a claim construction hearing in this matter involving a dispute over a patent owned by Defendant and Counterclaimant PLC Systems, Inc. ("PLC"). In addition, Plaintiff CardioGenesis Corp. ("CardioGenesis") has moved pursuant to Fed.R.Civ.P. 56 for summary judgment on the issues of (1) materiality, (2) intent, and (3) inequitable conduct. PLC has countermoved for summary judgment that CardioGenesis cannot prove, as a matter of law, inequitable conduct.

Upon consideration of the papers submitted and the arguments of counsel presented at the October 22, 1998 claim construction hearing and at the November 5, 1998 hearing on summary judgment, the Court now rules as follows.

BACKGROUND

CardioGenesis, a potential infringer of United States Patent No. 5,125,926 owned by PLC (the "PLC '926 patent"), brought this suit for a declaratory judgment that the PLC '926 patent is unenforceable due to inequitable conduct, is invalid, and is not infringed by CardioGenesis. PLC has counterclaimed for patent infringement. Robert I. Rudko ("Dr.Rudko") is the patent's first named inventor. Dr. Rudko was the founder and president of Laser Engineering, Inc., the predecessor to PLC. The patent concerns a system for using lasers to drill tiny holes into heart muscle for the purpose of directly increasing bloodflow to the heart muscle (laser transmyocardial revascularization, or laser TMR). In particular, the PLC '926 patent addresses a mechanism for automatically synchronizing the laser pulses with the beat of the heart so as to permit laser pulses only during the safest possible portions of the heartbeat cycle.

The field of TMR was pioneered at least in part by cardiovascular surgeon Dr. Sid Mahmood Mirhoseini,

who performed groundbreaking research on the hearts of dogs in the 1970s. Dr. Mirhoseini sought to develop a technique to revascularize the heart without having to first arrest the beating of the heart and put the patient on a heart-lung machine. Importantly, Dr. Mirhoseini's research revealed that firing a laser at the heart during a phase of the heartbeat cycle when the heart is least electrically sensitive minimized the risk of triggering heart fibrillation, a condition which could lead to heart failure.

In his prosecution of the PLC '926 patent, Dr. Rudko informed the patent examiner of the fibrillation phenomenon resulting from ill-timed TMR:

[T]he laser technique introduced a host of new problems. The heart is extremely sensitive to a laser pulse at certain times during its cycle. A laser pulse striking the heart at the T time of the ECG wave, for example, could cause the heart to fibrillate and result in heart failure.

Application, dated September 24, 1990, at 2. This passage ultimately was incorporated in the "Background of Invention" section of the PLC '926 patent.

The PLC '926 patent includes an independent claim for a device that senses the contraction and expansion of a beating heart, generates a trigger pulse, positions that pulse during an electrically safe moment of the heartbeat cycle, and allows a laser to fire during that safe period (Claim 1). Fifteen dependent claims follow Claim 1 (Claims 2 through 16). Claim 17, the only other independent claim, is a corresponding method claim.

CLAIM CONSTRUCTION

Claim construction is a question of law to be decided by the court. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995)(en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). The first requirement in claim interpretation is to examine the claim language. *See* SmithKline Diagnostics v. Helena Lab., Corp., 859 F.2d 878, 882 (Fed.Cir.1988). Words in a claim will be given their ordinary meaning unless it appears that the inventor used them differently. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984). Moreover, the claims should be construed as one skilled in the art would construe them. *See* SmithKline, 859 F.2d at 882.

In interpreting a claim, the court should look first to the intrinsic evidence, consisting of "the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996) (citing Markman, 52 F.3d at 979). In addition, a number of canons, such as the doctrine of claim differentiation, guides construction. *See* Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1578 (Fed.Cir.1996).

In those cases where the intrinsic evidence unambiguously describes the scope of the patent, reliance on extrinsic evidence is improper. In such situations, extrinsic evidence, such as expert testimony, may not be used to interpret the claim language. *See* Vitronics, 90 F.3d at 1584.

SUMMARY JUDGMENT

To prevail on summary judgment, the moving party must demonstrate that no genuine issue of material fact exists for trial. *See* Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Once the moving party demonstrates that there is no genuine issue of material fact, the nonmoving party must designate "specific facts showing that there is a genuine issue for trial." Id. at 324. The nonmoving

party must "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322.

The adjudication of a summary judgment motion is not a "trial on affidavits." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Credibility determinations and weighing of the evidence are solely jury functions. *See Id*. Inferences drawn from underlying facts must be viewed in the light most favorable to the nonmoving party. *See* Matsushita Elec. Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986)(citing United States v. Diebold, Inc., 369 U.S. 654, 655, 82 S.Ct. 993, 8 L.Ed.2d 176 (1962)).

DISCUSSION

A. Claim Construction

The contested elements of the PLC '926 patent are set forth below, with disputed language underlined:

1. A heart-synchronized pulsed laser system for performing *transmyocardial* revascularization on a beating heart comprising:

a laser;

means for sensing FN1 a contraction and expansion of a beating heart to be synchronized with the laser;

FN1. CardioGenesis no longer disputes PLC's interpretation that the "means for sensing" is an electrocardiogram and its equivalents.

means, responsive to said means for sensing, *for generating a trigger pulse* having a width and a leading edge;
means for positioning the leading edge of said trigger pulse only at a time during the contraction and expansion cycle of the heartbeat which would not cause fibrillation of the heart;

means for defining the width of the trigger pulse to occur during the heartbeat cycle; and

means, responsive to said trigger pulse, *for firing* said laser to strike the beating heart *at the time indicated by the trigger pulse position and for a period indicated by the width of the trigger pulse*.

...

10. The heart-synchronized pulsed laser system of claim 5 in which said means for generating includes a *marker pulse circuit* for detecting a specific time in a heartbeat cycle of the ECG signal and providing a marker pulse representative thereof.

...

12. The heart-synchronized pulsed laser system of claim 11 in which said trigger pulse circuit includes a *means for delaying* said marker pulse to locate it at a selected position relative to said pulse's initial position in the heartbeat cycle, and *means for adjusting the duration of the marker pulse to a selected time to create*

said trigger pulse having a positioned leading edge and a defined width.

13. The heart-synchronized pulsed laser system of claim 1 in which said means for firing includes *gate means* for inhibiting delivery of said trigger pulse to said laser.

14. The heart-synchronized pulsed laser system of claim 13 in which said means for firing includes *switch means* for enabling said gate means to deliver said trigger pulse to said laser.

...

16. The heart-synchronized pulsed laser system of claim 15 in which said means for firing includes *arming switch means* for enabling said arming circuit to deliver said trigger pulse to said laser.

1. "Transmyocardial revascularization**" (Claims 1 and 17)**

To interpret the disputed language, the court first looks to the words of the claim itself to define the scope of the patented invention. "Words will be given their ordinary and accustomed meaning unless it appears that the inventor used them differently." Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 882 (Fed.Cir.1988).

PLC has presented ample evidence that the ordinary and accustomed meaning of transmyocardial revascularization ("TMR") refers to creating small holes in the tissue of the heart to allow for blood to be delivered to otherwise oxygen-starved tissue, and that the holes may, but *need not,* go completely through the heart muscle tissue. Nothing in the specification or prosecution history contradicts this common meaning. Even though the "Background of the Invention" section of the patent cursorily refers to holes being healed from the outside during early attempts at TMR, PLC '926 patent, col. 1:38-43, this section does not purport to provide an independent definition of TMR that varies from the ordinary and accustomed meaning.

Accordingly, the Court adopts PLC's interpretation as follows: the term "transmyocardial revascularization" means creating small holes in the tissue of the heart to allow blood to be delivered to the otherwise oxygen-starved heart tissue. It does not require that the holes to go completely through the heart muscle tissue.

2. "Trigger pulse" (Claims 1 and 17)

The intrinsic evidence supports PLC's interpretation. Accordingly, the Court construes the term "trigger pulse" as follows: an electrical pulse having a width and a leading edge.

3. "Means ... for generating a trigger pulse" (Claim 1)

Claims drafted in a means-plus-function format are interpreted under 35 U.S.C. s. 112, para. 6, which provides that such claims must be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof. The Court must determine which structure, material, or acts disclosed in the specification "correspond" to the function described in the claim element. Sage Products, Inc. v. Devon Industries, Inc., 126 F.3d 1420, 1428 (Fed.Cir.1997). The Court also must construe the claim as limited to that corresponding structure and its "equivalents." 35 U.S.C. s. 112, para. 6.

The device covered by this claim has a structure which is the same as or the equivalent of the structure in

the specification which performs the function of generating a trigger pulse. The means for generating a trigger pulse disclosed in the specification is a microprocessor board, PLC '926 patent, col. 4:62-67, a trigger generator, PLC '926 patent, col. 4:62-63, and trigger pulse circuit, PLC '926 patent, col. 4:27-28, col. 5:13-14.

The Court adopts the following construction: a trigger generator, a trigger pulse circuit, or a microprocessor board, and equivalents of these structures.

4. "Means for positioning" (Claim 1)

The means for positioning the leading edge of said trigger pulse disclosed in the specification is a "pulse positioning circuit," PLC '926 patent, col. 4:63, which "may be included as an additional board in a PC or a microprocessor," PLC '926 patent, col. 4:63-65.

The Court adopts the following construction: a pulse positioning circuit, which may optionally be included in a microprocessor or PC, and equivalents.

5. "Means for defining the width of the trigger pulse" (Claim 1)

The patent specification discloses several means for defining the width of the trigger pulse: a pulse width circuit, PLC '926 patent, col. 4:9-10, col. 5:15-17, a pulse width touch switch, PLC '926 patent, col. 5:48-50, and a PC or microprocessor, PLC '926 patent, col.4:64-65. Some of these embodiments are user-adjustable (e.g., the pulse width touch switch), and others are not (e.g., the pulse width circuit).

The claim includes a pulse width circuit, a pulse width touch switch, and a PC or microprocessor, and equivalents, and is not limited to user-adjustable means.

6. "Means ... for firing" (Claim 1)

The means for firing the laser disclosed in the specification is a power supply, PLC '926 patent, col. 5:32-35, that fires the laser in response to the trigger pulse. It is not, as CardioGenesis argues, the laser firing circuit, which the specification describes as inhibiting the delivery of the trigger pulse to the laser. *See* PLC '926 patent, col. 5:21-23.

The Court adopts the following construction: a power supply that fires in response to the trigger pulse, and equivalents.

7. "At the time indicated by the trigger pulse position and for a period indicated by the width of the trigger pulse" (Claim 1)

CardioGenesis appears to have abandoned its argument that this language indicates that the trigger pulse "directly controls and determines the laser pulse width." *See* CardioGenesis' Proposed Order Re: Claim Construction, filed October 28, 1998. In any event, the uncontroverted extrinsic evidence showed that physical principles preclude a one-for-one temporal correlation between the trigger pulse and laser pulse. The Court notes that the intrinsic evidence was insufficient to resolve the ambiguity in the phrase.

The Court adopts the following construction: the position of the trigger pulse indicates (that is, relates to) the time of the laser pulse, and the width of the trigger pulse indicates (that is, relates to) the period of time that

the laser is fired.

8. "Marker pulse circuit" (Claim 10)

The claim includes a "marker pulse circuit for detecting a specific time in a heartbeat cycle of the ECG signal and providing a marker pulse representative thereof." PLC argues that the term can be interpreted according to its plain meaning and need not be construed. CardioGenesis, pointing to the patent specification, asks the Court to limit the claim to circuits that generate a pulse when the electrical signal of the heart crosses a threshold. It would be improper for the Court to import any such limitation from the specification into this structure claim. *See* E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co., 849 F.2d 1430, 1433 (Fed.Cir.1988).

Accordingly, the Court agrees with PLC that the term can be interpreted according to its plain meaning and need not be construed.

9. "Means for delaying" (Claim 12)

Claim 12 includes a "means for delaying said marker pulse to locate it at a selected position relative to said pulse's initial position in the heartbeat cycle." The "means for delaying" disclosed in the specification are a delay timer, PLC '926 patent, col. 4:8-9, and a PC or microprocessor board, col. 4:62-67. In addition, Figure 2 shows a pulse positioning circuit receiving a signal from a delay selection switch. *See also* PLC '926 patent, col. 5:44-48.

The means for delaying is construed as including a delay timer, a PC or microprocessor board, or a pulse positioning circuit which receives a signal from a delay selection switch, as well as equivalents of these structures.

10. "Means for adjusting" (Claim 12)

Claim 12 includes a "means for adjusting the duration of the marker pulse to a selected time to create said trigger pulse." The specification discloses a pulse width circuit, PLC '926 patent, col.4:60-62, and a PC or microprocessor, PLC '926 patent, col.4:64-65.

Accordingly, the means for adjusting includes a pulse width circuit, or a PC or microprocessor, and equivalents.

11. "Gate means" (Claim 13)

Claim 13 includes a "gate means for inhibiting delivery of said trigger pulse to said laser." According to the patent specification, the "gate means" is a gate circuit. PLC '926 patent, col. 4:39-43, 5:21-25, and Fig. 2. The term is construed to include a gate circuit, and equivalents.

12. "Switch means" (Claim 14)

Claim 14 includes a "switch means for enabling said gate means to deliver said trigger pulse to said laser." Consistent with the disclosures of the specification, the "switch means" is a foot switch. PLC '926 patent, col. 4:41-43, 5:23-25, 6:17-21, and Figs. 2 and 5B. The term is construed to include a foot switch and equivalents.

13. "Arming switch means" (Claim 16)

Claim 16 includes an "arming switch means for enabling said arming circuit to deliver said trigger pulse to said laser." Consistent with the disclosures of the specification, the "arming switch means" is an arming switch. PLC '926 patent, col. 5:25-32, 6:12-17. The term is construed to include an arming switch, and equivalents.

B. CardioGenesis' Motion for Summary Judgment

CardioGenesis moves for an order that the PLC '926 patent is invalid due to the alleged inequitable conduct of Dr. Rudko FN2 during the prosecution of the patent before the United States Patent and Trademark Office ("PTO"). In short, CardioGenesis maintains that Dr. Rudko knowingly failed to inform the patent examiner of various research papers relating to TMR experiments undertaken by Dr. Mirhoseini.

FN2. CardioGenesis does not identify any other individual as practicing inequitable conduct in front of the PTO.

A party alleging that a person practiced inequitable conduct by failing to disclose material information to the PTO must offer clear and convincing proof of the following: (1) that the prior art or information is material; (2) that the applicant could be charged with knowledge of the prior art or information; and (3) that the applicant intended to mislead the PTO as to the existence of the prior art or information. *See* FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed.Cir.1987). This proof may be rebutted in four ways: (1) showing that the prior art or information was not material; (2) assuming the prior art or information was material, that the applicant did not know of it; (3) assuming the applicant knew of the prior art or information, the applicant did not know of its materiality; or (4) showing that the applicant's failure to disclose prior art or information did not result from an intent to mislead the PTO. *See id*.

Accordingly, for CardioGenesis to prevail on its motion for summary judgment, it must prove that no reasonable factfinder could conclude anything except that CardioGenesis has proven each element of inequitable conduct by clear and convincing evidence. *See* Kingsdown Medical Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed.Cir.1988)(in banc). By contrast, summary judgment for PLC is proper if it shows that CardioGenesis cannot provide, by clear and convincing evidence, evidence sufficient to establish the existence of a single essential element of its inequitable conduct affirmative defense. *See* Celotex, 477 U.S. at 322.

1. Materiality

The first prong of the inequitable conduct test requires that the Mirhoseini references be material to the Rudko invention. When the patent application was filed in this case, information was considered material if "there [was] a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. s. 1.56(a) (1991). In 1992, shortly before the patent issued, the provision was amended to define information as "material" if it is "not cumulative to the information already of record or being made of record in the application, and ... [i]t refutes, or is inconsistent with, a position the applicant takes in: ... [a]sserting an argument of patentability." 37 C.F.R. s. 1.56(b)(2)(ii) (1992).

CardioGenesis has failed to show by clear and convincing evidence that the Mirhoseini research papers are material to the claims of the PLC '926 patent.FN3 Furthermore, to the extent the papers could be considered material, the critical point of Mirhoseini's research-that a laser should only strike a beating heart during electrically insensitive portions of the heartbeat cycle to avoid fibrillation-was in fact disclosed to the PTO in Dr. Rudko's initial patent application.

FN3. CardioGenesis first brought its inequitable conduct argument before the Court about a year ago when it moved to bifurcate the inequitable conduct issue and, as part of that motion, argued that it was likely to prevail on the issue of inequitable conduct. The Court disagreed, stressing that CardioGenesis had failed to show that the Mirhoseini research was material to the PLC '926 patent. Order Denying CardioGenesis' Motion to Bifurcate, dated February 12, 1998.

CardioGenesis urges that the Mirhoseini references are material because Dr. Rudko had characterized the point of novelty of his invention as "synchronization to avoid fibrillation," a technique first practiced by Dr. Mirhoseini. There are two problems with CardioGenesis' argument. First, CardioGenesis has failed to demonstrate that Dr. Mirhoseini did anything other than perform important foundational research in discovering the importance of firing laser pulses at moments in the heartbeat cycle when the heart is least vulnerable to fibrillation. CardioGenesis presented *no* evidence suggesting that Dr. Mirhoseini, a cardiovascular surgeon with no background in laser engineering, ever designed or produced a laser system to address the safety issue. Indeed, the evidence uniformly reveals that Dr. Mirhoseini utilized an off-the-shelf laser and, using an electrocardiogram as a reference, manually fired the laser so as to avoid the vulnerable periods of the heartbeat cycle. FN4 While Dr. Mirhoseini may have engaged in the pioneering research that helped lead to today's understanding that a TMR laser should be fired at only the safe moments during a heartbeat cycle, CardioGenesis failed to provide any evidence that Dr. Mirhoseini used a device specially tailored to fire at only the safe moments of a patient's heartbeat cycle.

FN4. Despite the lack of any evidence showing that Dr. Mirhoseini designed or developed a laser system for automatically synchronizing laser pulses with the beat of a heart, counsel for CardioGenesis Coe Bloomberg persisted at oral argument in representing that "to the best of my knowledge," Dr. Mirhoseini did in fact develop a method for automatic synchronization. Mr. Bloomberg, however, was unable to provide *any* description of this purported mechanism, two years after the commencement of this lawsuit and after months of intensive discovery. The Court can only conclude that Mr. Bloomberg misrepresented the facts in this case and warns him that further misrepresentations may result in sanctions.

In his initial patent application Dr. Rudko did in fact disclose to the examiner that prior research had revealed the importance of striking the heart at safe periods. CardioGenesis has been unable to inform the Court what in particular Dr. Rudko should have added to this disclosure.FN5

FN5. Again, the Court must emphasize that CardioGenesis presented no credible evidence showing that Dr. Mirhoseini created a device that synchronized the delivery of laser pulses with the beat of a heart.

Second, CardioGenesis' argument makes no sense as a matter of law. While it maintains that Dr. Rudko and his counsel repeatedly argued that the point of novelty of the '926 patent was simply synchronizing the laser with the heartbeat in order to avoid fibrillation, *see, e.g.,* Opening Brief at 13, Reply Brief at 6, that

innovative use by itself could not have rendered the Rudko device patentable.

The prosecution history reveals that the examiner initially found that the claims, as proposed, were unpatentable over two patents issued to Hardy and Shturman. The Hardy patent, U.S. Patent No. 4,658,817, discloses a laser specifically designed to perform TMR, but is silent as to any need for heartbeat synchronization. The Shturman patent, U.S. Patent No. 4,788,975, discloses an "aiming verification" system for the laser removal of plaque from blood vessels, and reveals a way to synchronize laser pulses with the heartbeat, but in order to facilitate aiming the laser at targets, not to avoid fibrillation (apparently blood vessels, unlike heart tissue, are not electrically sensitive). Timing of laser pulses is critical in Shturman because vessels move with the heartbeat cycle, thereby making it difficult for the laser operator to maintain his or her aim on any particular spot.

In Shturman, the operator first aims the laser at the plaque to be removed. Second, the operator collects data (images) of the vessel's targeted area at various points in the heartbeat cycle. Third, the operator reviews the data (images) to determine at which point in the cycle the laser is accurately aimed at the target area. Fourth, the operator selects the particular time or time interval during which to fire the laser in an upcoming cycle or cycles and inputs this time or time intervals and number of cycles into a computer. The computer then apparently limits the firing of the laser to those points in the cycle when the operator has determined that the laser beam is safely aimed at the target area.

CardioGenesis argues that Dr. Rudko overcame the examiner's rejection by stating that his invention's objective, unlike the objective in Shturman, was "synchronization to avoid fibrillation." FN6 However, if, in fact, all that Rudko did was to apply the Shturman technology to the problem of avoiding fibrillation, the '926 patent would not have issued. As the patent examiner himself recognized, a novel use of an old product cannot render a device patentable.

FN6. Of course, phenomena of nature are not patentable, *see* Diamond v. Diehr, 450 U.S. 175, 191, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981), and PLC has made no attempt to patent the *concept* of striking the heart only during safe intervals. PLC has instead patented a specific method and device for achieving that well-understood objective.

It is well settled that "a new use of an old thing or an old process, quite unchanged, can under no circumstances be patentable." H.K. Regar & Sons v. Scott & Williams, Inc., 63 F.2d 229, 231 (2d Cir.1933)(Learned Hand, J.). "It is not invention to perceive that the product which others had discovered had qualities they failed to detect." General Electric Co. v. Jewel Incandescent Lamp Co., 326 U.S. 242, 248-49, 66 S.Ct. 81, 90 L.Ed. 43 (1945); *see also* In re Tuominen, 671 F.2d 1359, 1361 (C.C.P.A.1982)(a difference in use, as opposed to a difference in the product, is not patentable). The patent examiner was well aware of this fundamental legal concept. He explained: "to anticipate a claimed device, a reference need only show the claimed structure, it is not necessary to have provided the structure for the same reason Applicant has done so." Office Action mailed September 9, 1991 at 4-5.

The prosecution history reveals that Dr. Rudko overcame the objection of the examiner by pointing out that Shturman taught an essentially manual system rather than an automated system incorporating a means for generating a trigger pulse, means for positioning the leading edge of the trigger pulse at a specific time during the hearbeat cycle, or means for defining the width of the trigger pulse to occur during the heartbeat cycle. Amendment "A" filed Sept. 9, 1991 at 10-11. In addition, Dr. Rudko argued that Shturman contained

no requirement "that a laser catheter would be *reliably and consistently* aimed at the target area only during the period between the R and T waves." Amendment "A" dated September 9, 1991 at 12 (emphasis added). It must have been the *mechanism* for achieving the goal of avoiding fibrillation that convinced the examiner ultimately to issue the patent.FN7

FN7. While CardioGenesis in oral argument attempted to distinguish the concept of striking a beating heart during safe portions of the heartbeat cycle from the concept of "synchronization" to avoid fibrillation, the Court perceives no meaningful distinction between the two. The heartbeat is by nature repetitive and cyclic- the idea of synchronization is hardly a stretch from the concept of striking the heart only during safe periods. The important distinction for the purposes of the present motion lies in the *implementation* of safe synchronization, not in its mere concept.

After a meeting between the examiner and the applicants, the examiner made a notation that it was "agreed that insertion of the language 'means for positioning the leading edge of the pulse *only* at a time during the expansion and contraction cycle of the heartbeat which would not cause fibrillation of the heart' would cause the claims to read over the art of record." Examiner Interview Summary dated February 19, 1992 (emphasis added). PLC asserts that the inclusion of the term "only" reinforces their position that that the circuitry of the Rudko device, which acted as an automatic safety mechanism which confined the firing of the laser to the safest possible periods, caused the claims to read over the prior art.

CardioGenesis has not proven by clear and convincing evidence that the Mirhoseini research is material under either of the tests cited above.FN8 Under the code in effect when the application was filed, 37 C.F.R. s. 1.56(a)(1991), CardioGenesis has failed to prove that the PLC '926 patent would not have issued had Dr. Rudko altered his patent application to include details surrounding Dr. Mirhoseini's research. Further, CardioGenesis has failed to show that the Mirhoseni research is "not cumulative to the information already of record ... in the application." 37 C.F.R. s. 1.56(b)(1992).

FN8. CardioGenesis argues the deposition testimony of Dr. Fisher, Dr. Ku and Mr. Nixon contain evidence that Mirhoseini's work was material to the '926 patent. The Court does not agree. That testimony confirmed the well-known fact that Mirhoseini pioneered the *general concept* of safe synchronization, but it fails to show that Mirhoseini pioneered any specific *mechanism* to achieve that objective.

CardioGenesis' motion for summary judgment must be DENIED.

B. PLC's Countermotion for Summary Judgment

PLC countermoves for summary judgment that PLC and Rudko did not practice inequitable conduct on the PTO. Summary judgment for PLC is proper if CardioGenesis cannot provide evidence sufficient to establish the existence of any single element of its inequitable conduct affirmative defense. PLC has shown, by clear and convincing evidence, that CardioGenesis cannot prove that the Mirhoseini research was material to the '926 patent. Accordingly, summary judgment on the issue of inequitable conduct in favor of PLC is warranted.

CONCLUSION

CardioGenesis' motion for summary judgment on the issue of inequitable conduct is DENIED. PLC's

countermotion for summary judgment on the issue of inequitable conduct is GRANTED.

IT IS SO ORDERED.

N.D.Cal.,1998.
CardioGenesis Corp. v. PLC Medical Systems, Inc.