IN THE FIFTH DISTRICT COURT OF APPEAL
FOR THE STATE OF FLORIDA

MEDTRONIC, INC. AND
MEDTRONIC RESPONSE, ETC.,

Petitioners,

vs.

ROBERT GRAHAM AND TAMMY GRAHAM, ETC., ET AL.,

Respondents.
_____/

CASE NO: 5D08-414

L.T. Case No. 48-2006-CA-3989
(Orange)

RESPONSE TO PETITION FOR WRIT OF CERTIORARI

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Citations to the Appendix that accompanied the Petition will be in the format (A nn) where nn is the page number stamped in the lower right corner of the Appendix pages, while citations to the Appendix accompanying this Response will be in the format (AA nn).

STATEMENT OF FACTS

While coaching a high school basketball game, Plaintiff Robert Graham suffered a sudden cardiac arrest. (A 81, ¶22). An officer from the Tavares Police Department was the first emergency-responder and attempted to revive Plaintiff Graham with a Lifepak 500 automated external defibrillator that was designed, manufactured, and sold by Defendants Medtronic, Inc. and Medtronic Emergency Response System, Inc. (collectively referred to herein as "Medtronic"). (A 81, ¶23; A 79). The defibrillator failed to accurately detect and assess Plaintiff Graham's heart rhythm and failed to administer an electrical charge sufficient to restart his heart. (A 81-82, ¶24). A second defibrillator had to be located and used to restart Plaintiff Graham's heart, by which time he had suffered catastrophic brain injury. (A 82, ¶25).

Medtronic had recalled the first defibrillator used on Plaintiff Graham weeks earlier because a defect prevented it from detecting the heart rhythms of certain patients and, therefore, it could not reasonably be expected to properly defibrillate someone suffering a life-threatening cardiac arrest. (A 80-81, ¶18). Medtronic notified its customers of the defibrillator defect, but failed to inform them that the defibrillators had been recalled, instead advising its customers to continue using the defibrillators until Medtronic could update them. (A 81, ¶20). The City of Tavares, who owned the defective defibrillator used on Plaintiff Graham, received this letter,

but failed to remove the defibrillator from the use of its emergency personnel. (A 81, ¶¶ 21 & 23).

Plaintiffs, Robert Graham and his wife Tammy, sued Medtronic for strict liability product defect as well as negligence for failing to properly design, manufacture, distribute, and recall the defective defibrillators. (A 82-87; 90-95). Plaintiffs also alleged Medtronic was negligent because it failed to exercise reasonable care in warning consumers of the defibrillator defect. (A 83, ¶29b; 86, ¶36b). Plaintiffs recently amended their complaint to allege Medtronic failed to timely act on information it had regarding the defects in the defibrillator prior to the recall and failed to notify the FDA of these defects at the time it submitted the defibrillator for pre-market approval. (AA 45; 51, ¶ 25; 51-53, ¶28; 54-55, ¶35).

In a motion for summary judgment that has yet to be heard by the trial court, Medtronic contends that data downloaded from the defibrillator shows that an electrical charge was successfully administered to Plaintiff Robert Graham. (A 137). Medtronic therefore claims in its Petition for Writ of Certiorari that it is "undisputed that the subject device functioned according to its specifications…." (Petition, p. 3). In opposition to a motion for summary judgment filed by the City of Tavares, however, Plaintiffs presented the testimony of Kevin Thoni, M.D., who was present at the time of Plaintiff Robert Graham's cardiac arrest. (AA 1-44).

Dr. Thoni, who participated in the attempted resuscitation of Plaintiff Graham with the defibrillator, (AA 20-38), determined, "[b]ased on [his] personal and

professional observations, the subject automated external defibrillator never transmitted an electrical current to Robert Graham." (AA 20, ¶ 4). And he "did not observe any evidence whatsoever of an electrical current passing through Robert Graham's body." (AA 20, ¶ 5; AA 24). In deposition, Dr. Thoni testified that he saw the defibrillator connected to Robert Graham, powered on, and operated in order to provide a shock to Robert Graham, but he "did not see any shock delivered to" Robert Graham. (AA 21-38). Nor did the defibrillator restore Robert Graham's pulse. (AA 36-37). This evidence is directly contrary to any evidence indicating the defibrillator administered a shock to Plaintiff Robert Graham.

In an effort to prove their case against Medtronic, Plaintiffs propounded their Sixth Request for Production in which they asked Medtronic to produce complaint files for certain complaints described in attached exhibits. (A 75-76). Medtronic objected to Plaintiffs' request on the following grounds: 1) the request is impermissible in that it seeks information about complaint files on defibrillators that are not the same model as the defibrillator used on Plaintiff Graham; 2) the request is burdensome because the complaint files cannot be "easily" located by Medtronic; and 3) the request seeks information that, pursuant to 21 U.S.C. 360i(b)(3), cannot be used in civil litigation. (A 10-11). Medtronic did not support its objections with any evidence.

Plaintiffs filed a motion to compel Medtronic's responses to their Sixth Request for Production. (A 12-20). In support of their motion, Plaintiffs filed the

affidavit of Edward Reese, Ph.D., an expert in the medical device field. (A 21-28). Dr. Reese averred that the complaint files on different model defibrillators are relevant to the defect in the defibrillator used on Plaintiff Robert Graham because Medtronic itself represented to the FDA that these devices are substantially equivalent. (A 24, ¶¶5-6). By doing so, Medtronic was able to avoid undergoing a vigorous premarket approval process and place its new model defibrillators on the market right away. (Petition, p. 17). Dr. Reese also averred that the "Complaint Files maintained by the Defendants that relate to the biphasic Lifepak 500 [defibrillator] and the Lifepak 12 . . . contain essential information regarding the defects, labeling, mechanics and specifications of the referenced devices [which] is relevant to the Plaintiff in its investigation into this matter, including its investigation of Medtronic's notice and its response to the defects of its similarly situated medical devices." (A 24, ¶8).

At the hearing on Plaintiffs' motion to compel, Plaintiffs explained to the trial judge that the requested complaint files consist of Medtronic's investigations of complaints provided to it regarding the use of its devices. (A 33). Plaintiffs provided Medtronic with documents describing the device involved, the date of the report, and a description of the events resulting in the complaint. (A Exhibits 1-475). Medtronic argued that it would be a "massive" endeavor for it to locate these complaint files and that producing them would amount to more than 10,000 pages of paper. (A 46-47).

Medtronic did not produce any evidence, affidavit or otherwise, to support these assertions.

The trial court overruled Medtronic's objections to Plaintiffs' Sixth Request for Production and ordered it to respond to the request within 60 days. (A 75). Instead, Medtronic filed the instant petition for writ of certiorari.

ARGUMENT

The Court should deny Medtronic's petition for writ of certiorari because the trial court acted within its discretion when compelling Medtronic to reply to Plaintiffs' Sixth Request for Production as the trial court's order does not depart from the essential requirements of law and does not subject Medtronic to irreparable harm.

I. STANDARD

"A petition for certiorari to review a discovery order is appropriate 'when a discovery order departs from the essential requirements of law, causing material injury to a petitioner throughout the remainder of the proceedings below and effectively leaving no adequate remedy on appeal.'" *O'Neill v. O'Neill*, 823 So. 2d 837, 839 (Fla. 5th DCA 2002). When considering whether a trial court's order departs from the essential requirements of law, it must be remembered that "[t]rial courts have broad discretion in discovery matters and discovery orders will only be overturned where the court has abused that discretion." *Tanchel v. Shoemaker*, 928 So. 2d 440, 441-42 (Fla. 5th DCA 2006). And, as for having no adequate remedy on appeal, compelling the production of irrelevant discovery rarely amounts to such irreparable harm. *Colbert v. Rolls*, 746 So. 2d 1134, 1135 (Fla. 5th DCA 1999); *Liberty Mut. Ins. Co. v. Lease America, Inc.*, 735 So. 2d 560, 562 (Fla. 4th DCA 1999) ("Production of irrelevant material does not rise to the level of irreparable harm for certiorari to lie."). Nor does being compelled to engage in burdensome discovery

amount to irreparable harm unless a party will suffer destructive or ruinous consequences by complying with the discovery request. *See Topp Telecom, Inc. v. Atkins*, 763 So. 2d 1197, 1199-1200 (Fla. 4th DCA 2000) ("An erroneous order compelling discovery when the cost and effort to do so is burdensome but not destructive is simply not 'sufficiently egregious or fundamental to merit the extra review and safeguard provided by certiorari.'") (quoting *Haines City Community Dev. v. Heggs*, 658 So. 2d 523, 531 (Fla. 1995)).

II. THE TRIAL COURT'S ORDER IS NOT A DEPARTURE FROM THE ESSENTIAL REQUIREMENTS OF LAW AND DOES NOT CREATE IRREPARABLE HARM

The trial court acted within its discretion when compelling Medtronic to produce documents in accordance with Plaintiffs' Sixth Request for Production without requiring Plaintiffs to first post a cost bond. Medtronic failed to demonstrate that complying with Plaintiffs' request would be unduly burdensome or that the documents requested by Plaintiffs are irrelevant to this action. Furthermore, even if the requested documents are wholly irrelevant to the subject matter of this litigation and would be burdensome to produce, Medtronic's compliance with the trial court's order will not amount to the irreparable harm necessary for the granting of Medtronic's petition for writ of certiorari.

A. MEDTRONIC FAILED TO DEMONSTRATE BELOW THAT PLAINTIFFS' DISCOVERY REQUEST IS UNDULY BURDENSOME AND, EVEN IF IT IS BURDENSOME, COMPLYING WITH THE REQUEST WILL NOT SUBJECT MEDTRONIC TO IRREPERABLE HARM WARRANTING CERTIORARI RELIEF.

It was incumbent upon Medtronic to present evidence to the trial court sufficient to demonstrate that compliance with Plaintiffs' Sixth Request for Production would be unduly burdensome such that Medtronic would suffer disastrous or ruinous effects by providing the discovery. Medtronic failed to provide any evidence to the trial court and failed to even allege any burden greater than a general unwanted effort and expense. The trial court, therefore, acted within its discretion when overruling Medtronic's objection that complying with Plaintiffs' discovery request would result in an undue burden.

Responding to any discovery is somewhat burdensome. The onus is on the party objecting to discovery to present evidence demonstrating that complying with the discovery request will be *unduly* burdensome. *See Topp Telecom, Inc. v. Atkins*, 763 So. 2d 1197, 1199 (Fla. 4th DCA 2000). "[I]t is incumbent upon [the objecting party] to quantify for the trial court the manner in which such discovery might be overly broad or burdensome by showing the volume of documents, or the number of man-hours required in their production, or some other quantitative factor that would make it so." *Caterpillar Indus., Inc. v. Keskes*, 639 So. 2d 1129, 1131 (Fla. 5th DCA 1994). Without an affidavit or other record evidence demonstrating an undue burden,

the trial court is within its discretion to overrule such an objection. *Topp Telecom*, 763 So. 2d at 1199.

In order to be entitled to certiorari relief, the party objecting to discovery on the ground that it is unduly burdensome must also demonstrate that complying with the discovery request will "effectually ruin the objector's business" or otherwise cause the objector "financial ruin." *Topp Telecom*, 763 So. 2d at 1200. It is not enough for the objector to allege merely that the "discovery involved . . . would simply require unwarranted effort and expense to comply with the request. . . ." *Id.*; *see also Megaflight, Inc. v. Lamb*, 749 So. 2d 594, 595 (Fla. 5th DCA 2000) (noting that "erroneous orders that require overbroad discovery of nonprivileged documents should be subjected to certiorari review more cautiously than erroneous orders requiring discovery of confidential or privileged matters").

Here, Medtronic did not provide any evidence to the trial court to quantify the manner in which Plaintiffs' discovery request is unduly burdensome. In its objection to Plaintiffs' Sixth Request for Production, Medtronic states that the requested "complaint files could not be located easily." (A 10). It then claims that it would take a Medtronic employee "several hundreds of hours" to attempt to locate the complaint files and then "hundreds of additional hours" to review and copy the files. (A 10). Medtronic did not, however, provide any evidence, affidavit or otherwise, to support these claims.

Nor did Medtronic provide any such evidence at the hearing on Plaintiffs' motion to compel Medtronic to respond to their Sixth Request for Production. Medtronic represented to the trial court that complying with Plaintiffs' discovery request would be "a massive effort," but it never provided the trial court with any evidence or even any specific allegations as to why compliance would be unduly burdensome. (A 46-47).[1] For this reason alone, the trial court acted within its discretion (and, thereby, did not violate the essential requirements of law) when compelling Medtronic to respond to Plaintiffs' Sixth Request for Production. *See Topp Telecom*, 763 So. 2d at 1199 ("There is obviously no error in overruling [a burdensomeness] objection when it is not supported by record evidence, such as an affidavit detailing the basis for claiming that the onus of supplying the information or documents is inordinate.").

Furthermore, Medtronic failed to even allege, much less prove, sufficient facts below to demonstrate that compliance with Plaintiffs' discovery request will result in irreparable harm. It is not enough that Medtronic's compliance will "require unwarranted effort and expense," *id*., which is all that Medtronic claimed when it represented to the court that compliance would take a single employee hundreds of hours. Medtronic did not even advise the court of the number of people it employs—

[1] Nor does Medtronic point to any such evidence in its petition for writ of certiorari. Medtronic claims that complying with Plaintiffs' request "could literally bring Defendants' 'business activities to a halt,'" but it does not cite to any evidence, in the record or otherwise, to support this assertion. (Petition, p. 10).

Is that a single employee out of a handful of employees; a hundred employees; a thousand? In order to amount to the kind of irreparable harm that warrants certiorari review, a party's compliance with a discovery request must be destructive or ruinous to the party. *See id*. at 1200 ("[T]he mere fact of unwarranted effort and expense is not, by itself, synonymous with a 'departure from the essential requirements of law' [e.s.] for which immediate review is necessary."). Otherwise, burdensome discovery can be remedied by the trial court with the reallocation of costs at the end of a case. *Id*. at note 5.

Because Medtronic failed to present evidence to demonstrate to the trial court that compliance with Plaintiffs' Sixth Request for Production will be unduly burdensome such that it will be destructive or ruinous, Medtronic has failed to demonstrate that the trial court's order departs from the essential requirements of law or will cause Medtronic irreparable harm. *See id*. at 1199 ("If a trial judge has no record factual basis-apart from a mere claim or contention of undue burden-to conclude that requested discovery is oppressively excessive, there can be no error and therefore no necessity for any immediate appellate remedy.").

B. PLAINTIFFS' DISCOVERY REQUEST IS RELEVANT TO THE ISSUES IN THIS LITIGATION AND, EVEN IF IRRELEVANT, DOES NOT SUBJECT MEDTRONIC TO IRREPERABLE HARM WARRANTING CERTIORARI RELIEF.

Plaintiffs presented the trial court with evidence demonstrating that the complaint files sought in their request for production are relevant to the subject matter of this litigation. But, even if the requested information was completely irrelevant to this action, such irrelevance would not warrant certiorari relief because the production of irrelevant discovery does not amount to irreparable harm. *See Liberty Mut. Ins. Co. v. Lease America, Inc.*, 735 So. 2d 560, 562 (Fla. 4th DCA 1999).

In opposition to Medtronic's claim that the complaint files Plaintiffs requested in their Sixth Request for Production are not relevant to this litigation, Plaintiffs presented the trial court with the affidavit of Edward Reese, Ph.D., an expert in the medical device field. (A 21-28). According to Dr. Reese, the complaint files on the different model defibrillators included in Plaintiffs' request are relevant to the defect in the defibrillator used on Plaintiff Robert Graham because Medtronic itself represented to the FDA that these devices are substantially equivalent. (A 24, ¶¶5-6). Dr. Reese states in his affidavit that the "Complaint Files maintained by the Defendants that relate to the biphasic Lifepak 500 [defibrillator] and the Lifepak 12 . . . contain essential information regarding the defects, labeling, mechanics and specifications of the referenced devices [which] is relevant to the Plaintiff in its

investigation into this matter, including its investigation of Medtronic's notice and its response to the defects of its similarly situated medical devices." (A 24, ¶8).

Although it had ample time to present evidence in opposition to Dr. Reese's affidavit prior to or at the hearing on Plaintiffs' motion to compel, Medtronic failed to do so. Instead, counsel for Medtronic merely represented, as it does in its petition for writ of certiorari, that "substantially equivalent" by FDA standards is not the same thing as "substantially similar" by legal standards. (A 48-49; Petition, p. 16-17). While substantial equivalency and substantial similarity may not be identical concepts, the fact remains that the trial court had evidence before it that the discovery requested by Plaintiffs on different defibrillator models is relevant to this litigation because the devices are all so similar that the FDA does not require an independent investigation of the devices before they are put onto the market. Because one defibrillator model is so similar to another, Medtronic has been able to avoid subjecting each defibrillator to "further regulatory analysis" by the FDA before marketing each new model. (Petition, p. 17). Thus, it stands to reason that the problems with a particular model are also problems with the other similar models, making information about those other models relevant.

But, even if the discovery requested by Plaintiffs regarding Medtronic's other defibrillator models is completely irrelevant to the instant litigation, the Court should still deny Medtronic's petition for writ of certiorari or, better yet, dismiss the petition

for lack of jurisdiction,[2] because the "[p]roduction of irrelevant material does not rise to the level of irreparable harm for certiorari to lie." *Liberty Mut. Ins. Co. v. Lease America, Inc.*, 735 So. 2d 560, 562 (Fla. 4th DCA 1999) (citing *Coyne v. Schwartz, Gold, Cohen, Zakarin & Kotler, P.A.*, 715 So. 2d 1021, 1023 (Fla. 4th DCA 1998); *Eberhardt v. Eberhardt*, 666 So. 2d 1024 (Fla. 4th DCA 1996), *approved by Allstate Ins. Co. v. Boecher*, 733 So. 2d 993, 998-99 (Fla. 1999)); *see also Argus Fire & Cas. Ins. Co. v. Winn*, 854 So. 2d 829 (Fla. 5th DCA 2003) (denying certiorari because, although the information requested in discovery appeared to be "largely irrelevant," production of the information would not cause irreparable harm). For this reason, "appellate courts in certiorari proceedings are reluctant to review relevancy issues by certiorari." *Colbert v. Rolls*, 746 So. 2d 1134, 1135 (Fla. 5th DCA 1999).

The Florida Supreme Court explained the type of harm that is necessary to quash a discovery order on a petition for writ of certiorari in *Martin-Johnson, Inc. v. Savage*, 509 So. 2d 1097 (Fla. 1987):

> In certiorari proceedings, an order may be quashed only for certain fundamental errors. In *Kilgore v. Bird*, this Court recognized the distinction between discovery orders that merely violate rules of evidence and may be corrected by a reversal, and those that violate fundamental rights causing harm that cannot be remedied on appeal. In that case, involving a ruling on objections to interrogatories, this Court said:

[2] "In considering a petition for certiorari the reviewing court's first duty is to assess whether the petitioner has made a prima facie showing that the order creates irreparable harm. If the petitioner does not make such a showing, the court lacks jurisdiction and will dismiss the petition." *Morgan, Colling & Gilbert, P.A. v. Pope*, 798 So. 2d 1, 3 (Fla. 2d DCA 2001).

[R]equiring a witness to answer some questions may constitute error which may or may not warrant reversal on appeal and inflict no injury on the witness, while requiring the witness to answer other questions might so violate his civil rights as to make review on appeal entirely inadequate and would constitute such a departure from the essential requirements of the law as to make a ruling requiring the answer reviewable on certiorari to adequately protect the constitutional or lawful rights of the witness....

Many of the questions, *supra*, which witness has been required to answer are so framed as to violate the rules of evidence and it appears that some of the others may require a violation of the lawful rights of the witness which may not be mended by review on appeal. Before we can determine the extent of the illegality of the question as distinguished from the impropriety thereof, we must have before us the pleadings on which questions are based.

149 Fla. at 582, 6 So.2d at 547-78 (emphasis added).

Thus, not every erroneous discovery order creates certiorari jurisdiction in an appellate court. Some orders entered in connection with discovery proceedings are subject to adequate redress by plenary appeal from a final judgment. See *City of Miami Beach v. Town*, 375 So. 2d 866 (Fla. 3d DCA 1979).

We recognize that discovery of certain types of information may reasonably cause material injury of an irreparable nature. Illustrative is "cat out of the bag" material that could be used by an unscrupulous litigant to injure another person or party outside the context of the litigation. *See e.g. Bridges v. Williamson*, 449 So. 2d 400 (Fla. 2d DCA 1984) (irreparable injury due to possible republication of libelous statement); *City of Miami Beach v. Town*, 375 So. 2d 866 (Fla. 3d DCA 1979) (question concerning ongoing police investigation may compromise the investigation as well as cause actual physical danger to those involved).

We cannot characterize the information requested here in this same vein. We are not dealing with material protected by any privilege. Nor can we say petitioner's privacy interest rises to the level of trade secrets, work product, or information about a confidential

> **informant. We cannot view the harm suffered by this disclosure as significantly greater than that which might occur through discovery in any case in which it is ultimately determined that the complaint should have been dismissed.**

Martin-Johnson, 509 So. 2d at 1099-1100 (emphasis added).

Here, Medtronic has not claimed that the complaint files requested by Plaintiffs are protected by privilege or are protected trade secrets or work product and that it will be forever harmed if "the cat is let out of the bag." Nor has Medtronic demonstrated why complying with the trial court's order compelling it to respond to Plaintiffs' Sixth Request for Production will result in harm that cannot be remedied on plenary appeal. Medtronic's disclosure of the complaint files in discovery does not mean that whatever is in those files will be admissible at trial. And, "[i]f an error is made at trial concerning the admissibility or use of that information, there can be adequate redress through a plenary appeal." *Morgan, Colling & Gilbert, P.A. v. Pope*, 798 So. 2d 1, 3 (Fla. 2d DCA 2001).

As the trial court's order does not depart from the essential requirements of law and Medtronic will not suffer irreparable harm by complying with the trial court's order, the Court should deny Medtronic's petition for writ of certiorari.

C. THE TRIAL COURT DID NOT ERR IN FAILING TO REQUIRE PLAINTIFFS TO POST A COST BOND.

Just as it precludes a finding that the trial court abused its discretion in entering the motion to compel, Medtronic's failure to present evidence below that

demonstrates it will undergo an undue burden by producing the requested complaint files precludes a finding that the trial court erred in failing to require Plaintiffs to post a cost bond.

"It is appropriate for a court to require a party to post a bond to indemnify the producing party against the costs of discovery **when the cost is unreasonable and unduly burdensome**." *Allstate Ins. Co. v. Hodges*, 855 So. 2d 636, 642 (Fla. 2d DCA 2003) (citations omitted) (emphasis added). As Medtronic made only general allegations regarding the burden of complying with Plaintiffs' discovery request and failed to demonstrate what the cost of its compliance would be, much less that the costs would be unreasonable and burdensome, the trial court acted within its discretion when ordering Medtronic to produce the requested cost files without Plaintiffs first posting a cost bond. *See id*. (finding that the trial court may have determined that discovery costs would not be unreasonable and unduly burdensome and, therefore, it did not depart from the essential requirements of law when denying the motion for a cost bond).

CONCLUSION

The Court should dismiss or deny Medtronic's petition for writ of certiorari because the trial court's order compelling Medtronic to reply to Plaintiffs' Sixth

Request for Production does not depart from the essential requirements of law or subject Medtronic to irreparable harm.

Dated: April 21, 2008 By: _____

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true and correct copies of the foregoing Response to Petition for Writ of Certiorari were served by overnight delivery, postage prepaid, this 21st day of April, 2008, upon: **Michael J. Wiggins, Esq., Bianca G. Liston, Esq.**, Cabaniss, Smith, Toole & Wiggins, PL, Post Office Box 4924, Orlando, FL 32802-4924; **Gregory A. Page, Esq.**, Page, Eichenblatt, Bernbaum & Bennett, P.A., 214 E. Lucerne Circle, Orlando, FL 32801; **Don Roper, Esq.**, 116 N. Park Ave., Apopka, FL 32703.

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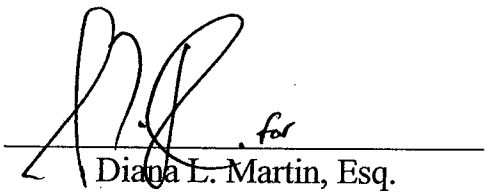

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