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IN THE SUPREME COURT OF THE STATE OF DELAWARE

REINHARD WARNKING, and SOUND INTERVENTIONS, INC., a Delaware corporation,	:	No. 517, 2013
Defendants-below/Appellants,	:	Appeal from the Court of Chancery of the State of Delaware, in C.A. No. 7387-VCN
v.	:	
RECOR MEDICAL INC., a Delaware corporation,	:	
Plaintiff-below/Appellee.	:	

APPELLANTS' *CORRECTED* OPENING BRIEF

October 16, 2013

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NATURE OF THE PROCEEDINGS

This is an appeal from the Chancery Court's written Memorandum Opinion dated May 31, 2013 (revised July 16, 2013) (the "Opinion") and Final Judgment dated July 16, 2013, which after a two day trial of this matter, found that Defendant Reinhard J. Warnking ("Mr. Warnking"), while employed by ProRhythm, Inc. ("ProRhythm"), conceived of proprietary information that was related to the business of ProRhythm, and filed patent applications containing that proprietary information after his employment with ProRhythm ended.

Pursuant to the terms of an IAA Mr. Warnking signed while employed at ProRhythm, the Chancery Court ordered Defendant Sound Interventions, Inc. ("SII") to assign PCT Application No. WO 2011/053757 (the "'757 PCT Application") (A492–A532), U.S. Provisional Patent Application No. 61/256,429 (the "'429 Application") (A325–77), U.S. Provisional Patent Application No.61/292,618 (the "'618 Application") (A378–A432), all patent applications that claim priority from the '757 PCT Application, the '429 Application, the '618 Application, and all issued patents that claim priority from the '757 PCT Application, the '429 Application, and the '618 Application to Plaintiff ReCor Medical Inc. ("ReCor"), enjoined Defendants from using the renal denervation technology contained therein, and awarded ReCor its attorney's fees. Defendants appeal from the Chancery Court's decision in its entirety.

SUMMARY OF ARGUMENT

The parties' dispute arose out of an Asset Purchase Agreement (the "APA") wherein ReCor purchased the remaining assets of ProRhythm, Inc. ("ProRhythm"), a company engaged in cardiac mitral valve repair work. Mr. Warnking is the former CEO of ProRhythm. Mr. Warnking and certain other ProRhythm employees not retained by ReCor formed SII to engage in a different line of work – the use of ultrasound in the renal arteries to denervate nerves, through a process called renal denervation.

More than a year after the APA closed, ReCor, apparently positioning itself to move from using ultrasound for mitral valve repair to using ultrasound for renal denervation, filed a complaint in the Chancery Court seeking, *inter alia*, a declaratory judgment that it owned the renal denervation patent applications conceived of and developed by Defendants. The Chancery Court found that while he was still employed by ProRhythm, Mr. Warnking breached the IAA as he conceived of Proprietary Information [1] that was related to the business of ProRhythm.

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[1] Pursuant to Mr. Warnking's Employee Non-Disclosure, Non-Compete and Invention Assignment Agreement (the "IAA") (A34–40), Proprietary Information is defined as:

> Intellectual Property Rights (as hereinafter defined), trade secrets or proprietary or confidential information respecting inventions, products, product plans, designs, drawings, sketches, marketing and other plans, methods, know-how, techniques, technology, systems, characters, processes, strategies, software programs, works of authorship, customer lists, user lists, vendor lists, content provider lists, supplier lists,

This appeal centers primarily on the Chancery Court's factual finding that the patent applications at issue contain Proprietary Information related to the business of ProRhythm. The provisional '429 Application (the "Invention") provides the only direct evidence of Mr. Warnking's Invention, and it contains no Proprietary Information that relates to the business of ProRhythm. Accordingly, the Chancery Court's decision must be reversed in its entirety.

1. The Invention does not contain any Proprietary Information that is related to the business of ProRhythm.

The Chancery Court held that the Invention was proprietary to ProRhythm because of the independent renal denervation study conducted by University of Oklahoma employee, Dr. Hiroshi Nakagawa, on June 27, 2009 (the "June 27 study"), who conducted mitral valve research for ProRhythm pursuant to a research agreement between ProRhythm and the University of Oklahoma (the "Research Agreement"). (Opinion at 43). Had the Chancery Court conducted a

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> pricing information, project notes, memoranda, reports, lists, records, specifications, software programs, data, documentation budgets, plans, projections, forecasts, financial information and proposals in whatever form, tangible or intangible or other materials of any nature relating to any matter within the scope of the business of the Company or concerning any of the dealings or affairs of the Company. (A34).

Intellectual Property Rights are further defined as:

> all industrial and intellectual property rights, including, without limitation, patents, patent applications, patent rights, trademarks, trademark applications, trade names, service marks, service mark applications, copyrights, copyright applications or registrations, databases, algorithms, computer programs and other software, know-how, trade secrets, proprietary processes and formulas, inventions, trade dress, logos, design and all documentation and media constituting, describing or relating to the above. (A34).

more fulsome examination of the technology at issue, it would have found that Dr. Nakagawa's experiment was completely irrelevant to the Invention. In addition, the plain language of the Research Agreement provides that the renal denervation portion of the June 27 study was owned by and therefore property of the University of Oklahoma, and could not be the property of ProRhythm. As such, the Chancery Court's holding that the Invention contained ProRhythm's proprietary information was incorrect as a matter of law and must be reversed.

Further, the Chancery Court's holding that the Invention was related to the business of ProRhythm is contradicted by the evidentiary record, as there is no evidence that ProRhythm requested, authorized or paid for the renal denervation portion of the June 27 study. Thus, the study and/or its findings could not have been owned by ProRhythm. Additionally, there is no evidence in the record showing that ProRhythm ever engaged or contemplated engaging in renal denervation work; in fact, all of the evidence (including the testimony of ReCor's own witnesses) shows that no renal denervation work was performed by ProRhythm, and that ProRhythm was in fact a cardiac mitral valve company. As such, the Chancery Court's holding that renal denervation was within the scope of the business of ProRhythm was erroneous and must be reversed.

2. The Chancery Court's remedy was inequitable and not justified.

The Chancery Court's award of the Invention to ReCor was not warranted because the Invention was not conceived of by Mr. Warnking while he was at ProRhythm.[2] Even assuming, *arguendo*, that Mr. Warnking thought about using ultrasound for renal denervation while at ProRhythm, the use of ultrasound for renal denervation was in the public domain prior to his conception of the Invention and therefore could not be property of ProRhythm. (A92–120). In addition, the Chancery Court's award of the injunction prohibits Mr. Warnking from utilizing the legitimate fruits of his knowledge, skill and labor obtained in the four years after his employment with ProRhythm. Moreover, the Chancery Court determined that ReCor was contractually entitled to attorney's fees, but failed to consider that ReCor was only successful in obtaining one of the two renal denervation technologies it sought. As such, the Chancery Court's decision to award ReCor the patent applications, an injunction and reasonable attorney's fees was erroneous and must be reversed.

[2] Mr. Warnking never entered into a non-compete with ReCor; thus the only prohibition was contained in the IAA which expired after his employment with ProRhythm ended.

STATEMENT OF FACTS

SII is small start-up medical device company founded to develop an interventional, therapeutic ultrasound treatment for hypertension. Mr. Warnking is Chairman of the Board of Directors at SII and the inventor of the inventive subject matter claimed in the patent applications at issue. Mr. Warnking was also the former President, Chief Executive Officer and Director of ProRhythm, formerly Transurgical, Inc. ("Transurgical"), from February 1, 2001 to September 30, 2009.

In 2001, ProRhythm was developing a treatment for Atrial Fibrillation ("AF") which used a catheter-based system that utilizes high intensity focused ultrasound ("HIFU") to create scar tissue in the heart to block unwanted electrical impulses. Starting in 2008, due to clinical complications in its AF program, ProRhythm shifted its focus and began to develop exclusively a treatment for another heart condition, Mitral Valve Regurgitation. Mr. Warnking invented the mitral valve treatment and assigned it to ProRhythm in an effort to give ProRhythm a chance of survival after its failed AF program, and gave up a significant severance package by doing so. (A623).

After Mr. Warnking's employment with ProRhythm ended on September 30, 2009, and during his 30 day sabbatical period (A221–A236), Mr. Warnking first started reviewing certain published patent applications by Ardian, Inc. ("Ardian"). (A92–120). Ardian proposed a procedure that used catheter-based radio frequency

("RF") on renal arteries to treat high blood pressure. While affecting the renal nerves to control hypertension has been long understood, prior to this procedure physicians were only able to affect the renal nerves by medication or surgery. In conjunction with the prior art (including the Ardian patent) and Mr. Warnking's 30 years of experience, Mr. Warnking conceived of the Invention (A537). The Invention became the subject matter of the provisional applications filed on October 30, 2009. (A325–377; A433–491). The provisional applications were later assigned to SII, and became the basis of two PCT applications.

In or around May of 2009, ReCor was formed to acquire the assets of ProRhythm, specifically the mitral valve technology, ReCor's field of business at the time. On or about August 31, 2009, ReCor and ProRhythm entered into the APA for the purchase of all of ProRhythm's assets. (A237–310). Starting in 2010, ReCor began to shift its focus from mitral valve repair to renal denervation. Following news of SII's presence in the marketplace and guided by its desire to have the first position in the renal denervation space, ReCor searched old ProRhythm files and unearthed roughly 10 emails that it used to accuse Mr. Warnking of having conceived of the Invention while at ProRhythm.

On or about April 12, 2012, ReCor commenced litigation in the Delaware Court of Chancery, relying primarily on the aforementioned emails and Dr. Nakagawa's June 27 study. (A541-555).

ARGUMENT

I. THE CHANCERY COURT ERRED IN HOLDING THAT THE INVENTION CONTAINS PROPRIETARY INFORMATION THAT IS RELATED TO THE BUSINESS OF PRORHYTHM

A. Question Presented

Did the evidence presented at trial prove that Mr. Warnking's Invention contained Proprietary Information related to the business of ProRhythm?

B. Scope of Review

This Court reviews findings of historical fact subject to the clearly erroneous standard of review.[3] Questions of law must be reviewed *de novo*. *Walt Disney Co. Derivative Litig.*, 906 A.2d 27 (Del. 2006).

C. Merits of Argument

The Chancery Court's holding is founded on a single sentence in the IAA. (Opinion at 25). That sentence provides that if Mr. Warnking were to "make, conceive, discover or reduce to practice any Proprietary Information" that "relates to the business of" ProRhythm, that information became the sole property of ProRhythm. (A35). Thus, in order for ReCor to be entitled to the Invention

[3] An appeal from a bench trial is upon both the law and the facts. *Baker v. Long*, 981 A.2d 1152 (Del. 2009). In exercising its power of review, the Supreme Court has a duty to review the sufficiency of the evidence and to test the propriety of the findings below. *Levitt v. Bouvier*, 287 A.2d 671 (Del. 1972). Findings of fact must be sufficiently supported by the record and be the product of an orderly and logical deductive process. *Id.* Thus, findings of historical fact are subject to the deferential clearly erroneous standard of review. *Bank of New York Mellon Trust Co. v. Liberty Media Corp., et al*., 29 A.3d 225 (Del. 2011). However, when findings of fact are clearly wrong and the doing of justice requires they be overturned, the Supreme Court is free to make contradictory findings of fact. *Levitt*, 287 A.2d at 671.

through Mr. Warnking's contractual obligations with ProRhythm, ReCor was required to adduce sufficient record evidence to establish:

i) Mr. Warnking made, conceived,[4] discovered or reduced to practice Proprietary Information; and

ii) that the Proprietary Information related to the business of ProRhythm.

There is no evidence in the record to support the Chancery Court's affirmative finding on either requirement.

1. The Chancery Court's holding that the Invention contained Proprietary Information of ProRhythm was erroneous.

The crux of the Chancery Court's decision relies on its factual finding that the renal denervation portion of the June 27 study and the information gleaned from it were proprietary and confidential to ProRhythm. The facts and law however, prove otherwise. As demonstrated below: i) the Invention does not relate to Dr. Nakagawa's June 27 study; ii) the Invention does not reflect concepts and knowledge Mr. Warnking applied at ProRhythm; and iii) the terms of the Research Agreement demonstrate that the renal denervation portion of the June 27 study was the property of the University of Oklahoma and not the property of ProRhythm. As

[4] The Chancery Court wrote at length about when Mr. Warnking conceived of the Invention. In making its determination that Mr. Warnking conceived of the Invention while at ProRhythm, the Chancery Court relied on irrelevant statements and beliefs of non-party employees; emails exchanged by and between ProRhythm employees and researchers discussing renal denervation; Mr. Warnking's long-term and extensive experience in the ultrasound space; and the relatively short period of time it took Mr. Warnking to conceive of the Invention. None of this information describes the properties of the Invention itself, which is the only relevant issue here.

such, the Chancery Court's determination that the Invention was proprietary to ProRhythm was erroneous and must be reversed.

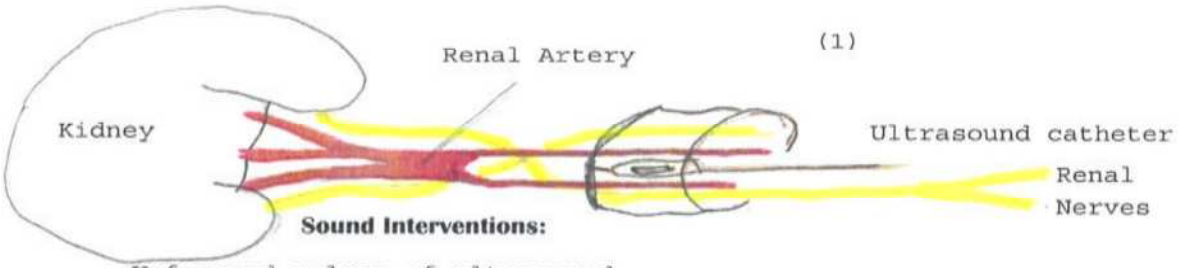
a. The Invention does not relate to the renal denervation portion of the June 27 study.

The Chancery Court ignored the differences between the technology in the Invention and the renal denervation portion of the June 27 study, and the similarities of the Invention and the prior art that existed at that time. Had the Chancery Court weighed the important and significant differences among these technologies, it could have only found that the Invention was not related to the renal denervation portion of the June 27 study. As demonstrated in the diagram below, the Invention (illustration #1), is entirely different than the Ardian ultrasound method (illustration #2), the renal denervation portion of Dr. Nakagawa's June 27 study, Ardian's RF method and the ReCor patent (illustration #3), yet all are methods of accomplishing renal denervation. Similarly, the prior art (illustration #4) demonstrates that the idea of utilizing ultrasound to necrose tissue was also in the public domain.

Yet, as the diagram demonstrates, the June 27 study has nothing to do with the Invention, except that Dr. Nakagawa used ultrasound to perform his ad hoc study. However, publically available information at the time from Ardian and the other prior art reveals that the use of ultrasound energy to perform renal denervation was already in the public domain; however, the Invention's novelty is

its method of providing a volumetric energy field that targets nerves dosimetrically without ablating tissue with a known energy level. (A325–377; A537). This is different than: i) geometrically locating the ultrasound energy as disclosed by Ardian and illustrated in #2 below; and ii) physically contacting the renal artery wall in a spiral or "corkscrew" pattern as disclosed by Ardian and attempted by Dr. Nakagawa and illustrated in #3 below. (A92–120; A635; A565; A624–26).

Specifically, during the renal denervation portion of the June 27 study, Dr. Nakagawa used an ultrasound transducer to perform the Ardian "RF method" of renal denervation (which was in the public domain), i.e. contacting the renal artery wall with the energy source and applying the energy to the renal artery wall at different locations in a spiral pattern. (A627–28; A625–26; A643). To do this, Dr. Nakagawa performed the study with a Touch-Up catheter, in which it is necessary to contact the renal artery wall to affect individual nerves or groups of nerves adjacent to the renal artery wall at the point of contact. (A627–28). Similarly, ReCor's patent application teaches applying ultrasound energy in a similar spiral pattern because ProRhythm's engineers and others skilled in the art understood that applying ultrasound energy to the entire renal artery in a ring would ablate the artery and cause it to stenose (close up), resulting in renal artery stenosis and compromised kidney blood supply. (A570–95; A647).

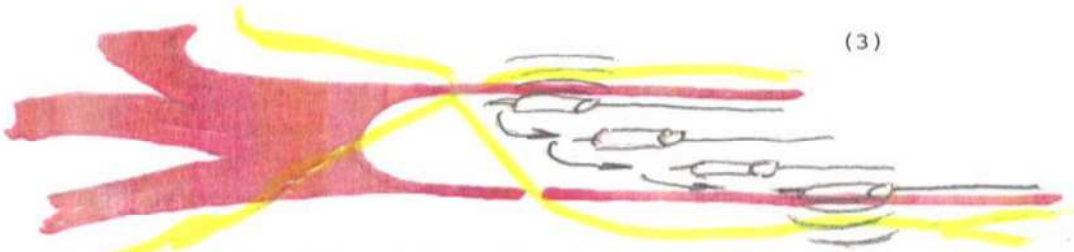


Sound Interventions:

- Unfocused volume of ultrasound.
- Energy level selected to differentially necrose nerves but not tissue (dosimetry).
- Non-occluding balloon to maintain blood flow to artery wall.

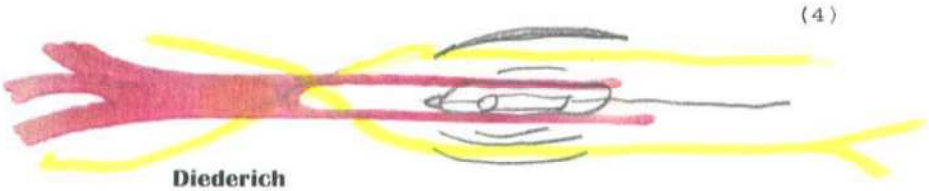
Ardian (ultrasound method):

- Focused ultrasound to geometrically target and necrose nerves.



Dr. Nakagawa's June 27 renal denervation study; Ardian (RF method); and ReCor patent:

- Each energy application is separate with a very localized volume to target individual nerves.
- "Corkscrew" pattern to distribute injury on artery wall.



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- Unfocused ultrasound, but with tissue necrosing energy level.
- Occluding balloon, no cooling of artery wall.
- This is prior art.

As shown in the diagram above, in contrast to ReCor's patent application and the June 27 study and in avoiding Ardian's patent claims, the Invention teaches the application of a volumetric field of ultrasound energy from a catheter centered in the renal artery, clearly teaching away from contacting and ablating the renal artery wall. (A346–48). The Invention replaces the geometrical focused energy application (illustration #2) and the geographic spiral energy application (illustration #3) with a volumetric field of ultrasound energy that encompasses the renal artery and accomplishes targeting of nerves through energy levels utilizing the fact that nerves are more heat sensitive than tissue (illustration #1).

Accordingly, the renal denervation portion of the June 27 study provided no information whatsoever that would have allowed Mr. Warnking to identify the specific levels of ultrasound energy needed for or the creation of a volume of ultrasound energy that would encompass all renal nerves around the renal artery and not other nearby organs. This is because the focus of the June 27 study was physically contacting the renal artery wall and not emitting the energy from the center of the renal artery. In fact, in a further departure from the Invention, the renal denervation portion of the June 27 study did not even require the use of ultrasound energy. (A643–44). As such, the Chancery Court erred in holding that the renal denervation portion of the June 27 study resembled, or had any influence on, the Invention.

Further, there is no correlation between the results of the June 27 study and the Invention because they are the product of two different methods for performing renal denervation, and therefore the facts cannot support the Chancery Court's holding because *the Invention contains no proprietary information of ProRhythm*. The results of the renal denervation portion of the June 27 study did not reveal any new or proprietary information; rather, as evidenced by illustration # 3 on the diagram above, the results demonstrate an attempt at an idea that was already in the public domain via the Ardian patents. Moreover, the results of Dr. Nakagawa's study were not available until December, 2009 (months after the patent applications were filed) and even if available in October 2009 when Mr. Warnking conceived of the Invention, would not have assisted or prompted Mr. Warnking's conception of the Invention because they were inconclusive. (A561).

Thus, the Chancery Court's holding that "the results from [the June 27 study], although not obtained until December, actually showed some ablation of the renal nerves, confirming that the use of ultrasound for renal denervation was feasible" is correct – but irrelevant. (Opinion at 36–37). Ardian confirmed and disclosed to the public that the use of ultrasound for renal denervation was feasible (A92–120); the Chancery Court itself acknowledged this. (Opinion at 32). Therefore, the Chancery Court's holding that Invention was Proprietary

Information of ProRhythm because it resembled the renal denervation portion of the June 27 study was erroneous and must be reversed.

b. The Invention does not reflect concepts and knowledge Mr. Warnking applied at ProRhythm.

The Chancery Court found that the Invention related to concepts and knowledge that Mr. Warnking applied at ProRhythm, namely the use of therapeutic devices that utilize ultrasound and the concept of dosimetry. (Opinion at 45). The Chancery Court made this finding based on an incomplete survey of the technology and a selection of ten emails among ProRhythm employees and associates discussing general notions of renal denervation.

As a fundamental matter, the use of similar devices and concepts does not prove that the Invention contains Proprietary Information of ProRhythm. The Invention is a specific dosimetry level, not the use of a device or concept. (A631). It is not disputed that ProRhythm's devices used ultrasound (A608–09), or that all energy devices rely on dosimetry, which is a specific dose of energy (which is the product of power and time). (A538). However, ProRhythm used completely different ultrasound devices and dosimetry to perform completely different procedures. The Chancery Court's decision, however, grants all inventions using ultrasound as proprietary to ProRhythm.

In fact, there is nothing about the Invention that reflects concepts and knowledge used at ProRhythm. For instance, ProRhythm's expertise and the

Invention's method of advancing a catheter into the renal artery and applying energy was already in the public domain (A632–33; A92–120), as was ProRhythm's ultrasound transducer and actuator system. (A56–65; A80–91; A144–51).

Significantly, the use of dosimetry in the renal arteries was never performed at ProRhythm, as ProRhythm's work under AF and mitral valve utilized a very different purpose and energy level targeted on a different part of the body. (A656–58). ReCor's own employee and witness, Jamie Merino ("Mr. Merino"), who is a former ProRhythm employee and would have worked on a renal denervation project at ProRhythm – if one existed – admitted that he had no experience with dosimetry with respect to renal denervation at ProRhythm. (A615–16). Moreover, it was impossible for ProRhythm to do renal denervation with its existing technology because ProRhythm's software was incapable of emitting the power levels required to perform renal denervation (A652; A616–20) which explains why ReCor, in its bid to enter the renal denervation space, asked Mr. Yong Zou ("Mr. Zou"), a current SII employee and former ProRhythm employee, to alter ReCor's software (which was ProRhythm's old software) so that it had the capabilities needed to perform renal denervation. (A650–51; A322–24).

In fact, SII had to develop new technology in order to do renal denervation. Specifically, the catheter, and all other devices currently used at SII are

significantly different from the catheter used at ProRhythm and displayed by ReCor at trial. (A654). Moreover, SII uses different hardware and software then was used at ProRhythm. (A653). Thus, had the technology at ProRhythm the ability to be used for renal denervation and the development of the Invention, there would have been no reason for SII to develop new technology and no reason for ReCor to hire Mr. Zou to modify ProRhythm's old software so that ReCor could start to do renal denervation. (A322–24).

Additionally, the email correspondence relied on by the Chancery Court is not evidence of the knowledge and concepts applied by Mr. Warnking at ProRhythm. In fact, a majority of the emails do not even include Mr. Warnking (A142; A143; A152–53; A156; A210; A211–13; A217-20; A321), and to the extent they do, Mr. Warnking is simply a recipient (A130; A131–33; A141; A207; A318–20). The Chancery Court erred in relying on those emails for any basis of what Mr. Warnking had in his mind while at ProRhythm. To the extent Mr. Warnking participated in the email correspondence, his comments *only* expressed his general thoughts about renal denervation and not the inventive subject matter that would later form the basis for the Invention. (A154–55; A157; A214–16; A311–17). In fact, there is not one single email in the record that contains, references, or even insinuates the inventive subject matter of the Invention. The emails discuss the business potential of renal denervation. Thus, the emails are

irrelevant and should have had no bearing on the Chancery Court's ultimate task – determining whether the Invention contains Proprietary Information of ProRhythm.

c. The renal denervation portion of the June 27 study was not the property of ProRhythm.

The Chancery Court held that the "weight of the evidence compels the finding" that the renal denervation portion of the June 27 study was the property of ProRhythm. (Opinion at 14). The Chancery Court's holding is erroneous in two respects. First, pursuant to the Research Agreement, which the Chancery Court held governed the June 27 study, it is clear that the University of Oklahoma, and not ProRhythm, is the owner of any intellectual property derived from that study. Second, there is no evidence in the record to support the Chancery Court's holding that anyone from ProRhythm requested, required or paid for the renal denervation portion of the June 27 study.

i. Pursuant to the terms of the Research Agreement, the renal denervation portion of the June 27 study was not the property of ProRhythm.

The Chancery Court did not apply the plain terms of the Research Agreement, which the Chancery Court held governed the study and the results derived thereof. (Opinion, at n. 52). A review of the Research Agreement shows that the Chancery Court erroneously held that the June 27 study and its results were the sole property of ProRhythm.

The Research Agreement was entered into in 2001, by and between the Board of Regents of the University of Oklahoma (the "University") and Transurgical, Inc. (the predecessor to ProRhythm). (A41). Under the Research Agreement, Dr. Nakagawa was to conduct certain research and studies relating to AF for ProRhythm. (A48). The unambiguous language of the Research Agreement provides for three (3) possible owners of the intellectual property derived under the Agreement:

> Rights to University Intellectual Property, whether or not patentable or copyrightable, relating to Project, made solely by employees of University, shall belong to University and shall not be subject to the terms and conditions of this Agreement.
>
> Rights to inventions, improvements and/or discoveries, whether or not patentable or copyrightable, relating to Project, made solely by employees of [ProRhythm], shall belong to [ProRhythm] and shall not be subject to the terms and conditions of this Agreement…
>
> Rights to Joint Intellectual Property shall belong to both the University and to [ProRhythm]. Ownership will be determined by mutual agreement based on the contributions of each party. (A-43).

The Chancery Court's decision, however, does not apply the terms of the Research Agreement or even mention the three possible ownership scenarios. In fact, the Opinion is devoid of any application of the Research Agreement other than a cursory mention of one of the Defendants' related arguments. (Opinion at 13-14). Thus, the Chancery Court erred by holding that the June 27 study was governed by the Research Agreement without actually applying the terms of the

Research Agreement to determine which party, ProRhythm or the University, possessed the legal rights to the renal denervation portion of the study.

Had the Chancery Court applied the plain language of the Research Agreement, it would have determined that there was no evidence in the record to support a conclusion that the renal denervation portion of June 27 study and the inventions, improvements and/or discoveries conceived from it were made solely by employees of ProRhythm, which it was required to do in order to make such a finding. (A43). In fact, it is undisputed that Dr. Nakagawa, an employee of the University, requested and conducted the June 27 study. (Opinion at 12). Thus, the June 27 study and its results could not have been made "solely by employees of [ProRhythm]" and therefore cannot be the property of ProRhythm under the terms of the Research Agreement. (A43).

Moreover, and as discussed further below, the renal denervation portion of the June 27 study was initiated by and conducted under the direction of Dr. Nakagawa, a University employee. (A636). Dr. Nakagawa even testified that the renal denervation portion of the June 27 study was his "personal stuff." (A640). ProRhythm never requested or knew about the renal denervation portion of the study until Mr. Zou arrived for the scheduled mitral valve study.(A655). Thus, the plain language of the Research Agreement mandates the conclusion that the renal

denervation portion of the June 27 study was the University's intellectual property, and not as the Chancery Court held, ProRhythm's proprietary information.

ii. ProRhythm never requested, required or paid for the renal denervation portion of the June 27 study; therefore, the study and its results cannot be the property of ProRhythm.

On June 27, 2009, pursuant to the Research Agreement, Dr. Nakagawa conducted two separate studies, a mitral valve study pursuant to a ProRhythm protocol and a renal denervation study pursuant to his own hypothesis, independent of the mitral valve study and independent of ProRhythm. It is not disputed that ProRhythm paid the University for the mitral valve portion of the June 27 study. (A641–42). However the Chancery Court erroneously held that because ProRhythm paid for the mitral valve portion of the June 27 study, this payment was consideration for the renal denervation portion of the experiment. (Opinion at 14). There is no evidence showing that a separate payment was made by ProRhythm for the renal denervation portion of the June 27 study, nor is there any evidence that the payment made by ProRhythm in connection with the June 27 study was in consideration for both a mitral valve and renal denervation portions of the study.

In fact, Dr. Nakagawa's actions on June 27 and testimony show that the two studies were not related. Dr. Nakagawa completed the two studies and submitted *only* the mitral valve related specimen to an independent lab for a histology report, as he had done with prior ProRhythm studies, and the results of the mitral valve

histology were delivered to ProRhythm within a few weeks thereafter. However, with respect to the renal denervation portion of the study, Dr. Nakagawa stored that specimen at his facility until September 30, 2009, at which point he decided to give it to the University of Oklahoma's in-house lab to obtain a histology report. (A564).The results were not received by Dr. Nakagawa until December 14, 2009. (A564; A568–69), and he thereafter shared the results with Messrs. Warnking, Smith and Zou, as Dr. Nakagawa had by then discussed the possibility of starting a renal denervation company with them. Dr. Nakagawa is a very successful and well-known electrophysiologist and having him and his experiments connected to a small startup medical device company was beneficial to SII in helping it find investors. Thus, this explains why Mr. Smith would later refer to the renal denervation portion of the June 27 study as the "one animal experiment that we did." (A321).

To the extent ProRhythm was involved with the renal denervation portion of the June 27 study, such involvement was at the periphery of the experiment, a favor to assist Dr. Nakagawa, and in no way critical to its performance or results. Additionally, the Chancery Court did not get the facts straight and/or appreciate the insignificance of Dr. Nakagawa's use of ProRhythm's Touch-Up catheter during the renal denervation portion of the June 27 study. There is no evidence that ProRhythm brought the Touch-Up catheter to the June 27 study. In fact, the exact

catheter used by Dr. Nakagawa was immaterial to the purpose of his study. (A643). The testimony in the record shows that Dr. Nakagawa "took the liberty" to use the catheter out of convenience. (A637; A643). Thus, there was absolutely no significance to Dr. Nakagawa in using ProRhythm's Touch-Up catheter. (A643).

The Chancery Court also erred in holding that the data sheet and notes from the renal denervation portion of the June 27 study were kept together by ProRhythm. (Opinion at 14) The data sheet referenced by the Chancery Court was not ProRhythm's. It was the data sheet used by the University's engineer, Dr. Ikeda. (A166–97). As such, the data sheet was not ProRhythm's record, and ProRhythm did not have any control or input into the notes contained therein. The only data sheet kept by ProRhythm was the HIFU Animal Case Report dated June 27, 2009, which does not contain *any* renal denervation data. (A158–65). ProRhythm did not keep any records or data sheets relating to the renal denervation portion of the June 27 study, and no such evidence is in the record, despite ReCor having full access to all ProRhythm's books and records.

This directly contradicts the Chancery Court's finding that Mr. Zou collected and maintained data from the renal denervation portion of the June 27 study to prepare a report.[5] (Opinion at 15). The emails between Mr. Zou and Dr. Ikeda, which the Chancery Court relied on to support its holding, are actually evidence

[5] The Chancery Court likely confused the descriptions by Dr. Nakagawa (at his deposition) of deposition exhibit 26 (A166–97) and exhibit 27 (A158–65).

that the renal portion of the June 27 study was not owned by ProRhythm. (A208–09; A210). Dr. Ikeda emailed Mr. Zou shortly after the June 27 study to ask for the time and power levels used during the renal denervation portion of the June 27 study because it was Dr. Nakagawa's experiment and Dr. Nakagawa wanted the results. (A636). Thus, it was natural that Dr. Ikeda contact Mr. Zou to ensure that he had the correct power and time levels. (A659). Mr. Zou, who was present at the study and set the power levels on the controller, despite not having the results written down, happened to remember the power and time levels and provided such to Dr. Ikeda. (A660). Had it been ProRhythm's study, there would have been no reason for Dr. Nakagawa to confirm the power levels; and ProRhythm would have had all the documents and records, not Dr. Nakagawa.

There is also no evidence that Dr. Ikeda prepared for the renal denervation portion of the June 27 study on the orders or instructions of ProRhythm; rather, Dr. Ikeda prepared for the renal denervation portion of the June 27 study at the direction of Dr. Nakagawa – his boss. (A645). Thus, the Chancery Court's finding that the renal denervation portion of the June 27 study was planned ahead of time (Opinion at 15), while theoretically possible, it is absolutely unsupported by the evidence to hold that it was planned ahead of time by ProRhythm employees or under the direction of ProRhythm. The record is devoid of any evidence that

supports the Chancery Court's conclusion that ProRhythm was involved in the planning or preparation for the renal denervation portion of the June 27 study.

Lastly, the Chancery Court incorrectly considered Dr. Nakagawa's testimony at his deposition that the histo-pathology results were ProRhythm's "top secret" information. (Opinion at 15-16). (A638–39; A566). As an initial matter, the histo-pathology results Dr. Nakagawa was likely referring to was the histo-pathology for the mitral valve portion of the June 27 study, which is it not disputed was the property of ProRhythm, and not the histo-pathology for the renal denervation portion of the study.

Further, the Chancery Court relied on Dr. Nakagawa's testimony when it found that the Research Agreement governed the June 27 study. (Opinion at 13–14). The Research Agreement was entered into by the University and ProRhythm. (A41). The Director of the University executed the Research Agreement on behalf of the University. Dr. Nakagawa was not a party to it. Therefore, Dr. Nakagawa's personal opinion as to which person or entity the information from the June 27 study belonged to is irrelevant as he is legally incompetent to draw such a legal conclusion. Dr. Nakagawa is in no way qualified to make a legal determination based on the terms of the Research Agreement and the Chancery Court erred in permitting him to do so. Thus, to the extent the Chancery Court construed Dr.

Nakagawa's seemingly confused deposition testimony as undermining his credibility at trial, such construction was erroneous.

As such, based on the foregoing, there is no evidence in the record to support the Chancery Court's holding that the renal denervation portion of the June 27 study was proprietary to ProRhythm.

2. The Chancery Court erred when it concluded that the Invention related to the business of ProRhythm.

In order for ReCor to prevail at trial, it needed to show that the Proprietary Information conceived of, made or developed by Mr. Warnking while at ProRhythm was Proprietary Information and it must be *related to the business* of ProRhythm. (A35, emphasis added). There is no evidence in the record to support the Chancery Court's holding that the Invention was related to the business of ProRhythm.

In fact, this is supported by the testimony and statements of two of ReCor's key witnesses: Mr. Merino, a former ProRhythm employee who is now employed by ReCor, and Mano Iyer ("Mr. Iyer"), President and CEO of ReCor, whose testimony concerned Dr. Bonan, a former ProRhythm investigator who is currently a ReCor investor, equity holder and scientific advisor. Specifically, Mr. Merino testified at trial that "[d]uring my time at ProRhythm I was not aware of any work that was being done in the renal space." (A613–14). Similarly, Dr. Bonan, told Mr. Iyer that he did not perform any renal denervation work for ProRhythm. (A605–

07). Neither Dr. Bonan nor Mr. Merino performed renal denervation work for ProRhythm because ProRhythm was a mitral valve company. In fact, Antoine Papiernik, the Chairman of the Board at ReCor at the time of the APA, testified that ReCor was interested in ProRhythm for its mitral valve assets. (A596-97).

Moreover, as discussed above, there is no evidence that ProRhythm ever engaged in renal denervation work.[6] In fact, the Chancery Court acknowledged that renal denervation likely was not within the scope of the business of ProRhythm prior to the June 27 study. (Opinion at 43). Thus, the Chancery Court's conclusion that the renal denervation portion of the June 27 study "certainly made [renal denervation] part of the 'dealings or affairs' of [ProRhythm]" was erroneous. (Opinion at 43).

As discussed above, there is no evidence in the record showing that ProRhythm requested, consented to or paid for the renal denervation portion of the June 27 study. In fact, in response to the question "[w]ere you asked or directed by anyone at ProRhythm to conduct this renal experiment," Dr. Nakagawa answered "no." (A567). Nor is there any evidence that ProRhythm maintained any records or data sheets from the renal denervation portion of the June 27 study. (A158–65). Therefore, the Chancery Court erred when it concluded, that a single 30 minute

[6] Significantly, ProRhythm's software was incapable of producing the energy levels necessary for renal denervation. This was confirmed by ReCor's decision to hire Mr. Zou, nearly a year after the APA, as a consultant to modify ProRhythm's old software so that the software would be capable of producing energy levels necessary for renal denervation. (A322–24).

study conducted by an independent researcher brought the entire space of renal denervation within the scope of the business of ProRhythm.

Accordingly, because there is no evidence that renal denervation was within the scope of ProRhythm's business and there is no evidence supporting the Chancery Court's conclusion that the renal denervation portion of the June 27 study brought renal denervation within the scope of ProRhythm's business, the Chancery Court's finding that the Invention belonged to ProRhythm was erroneous. As such, the Final Judgment must be reversed in its entirety.

II. THE CHANCERY COURT'S REMEDY WAS INEQUITABLE AND NOT JUSTIFIED

A. Question Presented

Did the Chancery Court err in awarding the patent applications, an injunction prohibiting Defendants from making any further use of the renal denervation technology disclosed in the patent applications that was not already in the public domain, and attorney's fees to ReCor?

B. Scope of Review

This Court reviews questions of law *de novo*. *Walt Disney Co. Derivative Litig.*, 906 A.2d 27. Findings of historical fact are subject to the clearly erroneous standard of review. *Bank of New York Mellon Trust Co.*, 29 A.3d 225.

C. Merits of Argument

Based on the foregoing, the Chancery Court had no basis upon which to find that the Invention contained Proprietary Information related to the business of ProRhythm. However, even if this Court agrees with the Chancery Court, the remedy awarded must be reversed. While a court of equity has broad discretion to shape and adjust the remedy to best achieve justice under the facts of a particular case, *Agilent Technologies, Inc. v. Kirkland*, 2010 Del. Ch. LEXIS 34, *32 (Del. Ch. Feb. 18, 2010), the award granted by the Chancery Court to ReCor was inappropriate and inequitable. In essence, based on a thirty minute study by an independent researcher, the Chancery Court awarded significant patents that cost millions of dollars and years of development to reduce to practice, and a broad sweeping injunction. This holding should be reversed.

1. The Chancery Court's award of the patent applications was not warranted.

Even if the Chancery Court correctly found that ReCor was entitled to a remedy, the remedy did not rise to the award of the patent applications. The information and knowledge contained in the patent applications did not contain Proprietary Information of ProRhythm. As fully explained above, the Invention was not, in any way, related to or representative of the work that was performed at ProRhythm. The Invention is the concept of providing an energy field that targets nerves without ablating tissue with a known energy level. (A346–48). There is no

evidence in the record that shows that Mr. Warnking conceived of the Invention while at ProRhythm. In fact, the only evidence linking Mr. Warnking to renal denervation while he was at ProRhythm were the emails in which renal denervation as a potential business endeavor was discussed – there was nothing introduced at trial showing that Mr. Warnking conceived of the actual Invention while at ProRhythm.

It is important to note that SII further developed the ‘429 provisional patent application twice, in the ‘618 application and the ‘757 PCT application. Specifically, the ‘429 application described dosimetry within an unfocused field of ultrasound energy for targeting nerves and not tissue. (A346–48). The ‘618 application was further developed to include centering the catheter in the renal artery so that the ultrasound energy field encompassed the entire renal artery. (A396–99). The ‘757 PCT application was even further developed to more accurately describe the energy field’s impact volume, the balloon for centering the transducer, and a real-time adjustment of the impact volume to accommodate different sized renal arteries. (A501–13). Thus, the ‘757 PCT application contains developments and technology that were not in Mr. Warnking’s mind in October 2009.

Moreover, there is no evidence in the record, nor are there any allegations that, Mr. Warnking or the former ProRhythm employees took any physical data,

information, files, tools or the like from ProRhythm. In fact, Mr. Warnking purposefully tried to move away from mitral valve work[7] because he was contractually prohibited from further development of mitral valve technology under the Consulting Agreement he entered into with ReCor. (A221–36; A604; A-600–01). It was perfectly reasonable for Mr. Warnking to move in the direction of renal denervation, which he was not violating any agreement, as there was no indication whatsoever that ReCor was interested in that space. This is evident by the fact that ReCor did not see a conflict when it engaged Mr. Zou, an employee of SII, for consulting work in October 2010, after Mr. Zou specifically disclaimed that he was doing renal denervation work for SII and asked ReCor to confirm "that there is no confliction." (A322–24).

2. The injunction granted by the Chancery Court was inequitable.

The standard for issuing a permanent injunction requires proof of: (1) actual success on the merits; (2) irreparable harm; and (3) the harm resulting from failure to issue an injunction outweighs the harm befalling the opposing party if the injunction is issued. *ID Biomedical Corp. v. TM Techs, Inc.*, 1995 Del. Ch. LEXIS 34, *42 (Del. Ch. March 16, 1995). The Chancery Court's award of an injunction prohibiting Mr. Warnking and SII from making further use of the renal denervation

[7] Use of ultrasound for mitral valve repair is totally different than the Invention; in mitral valve repair work you look to damage the tissue; the Invention does not.

technology disclosed in the patent applications that was not already in the public domain was in clear error. Specifically, the Chancery Court failed to consider that the harm befalling SII and Mr. Warnking due to the issuance of the injunction was severely outweighed by any harm that ReCor would have experienced without the issuance of the injunction.

Specifically, it was inequitable for the Chancery Court to award the ‘429 Application, the ‘618 Application and the ‘757 PCT Application and an injunction prohibiting the use of the technology contained therein to ReCor when the facts show that the knowledge and information contained in the ‘757 PCT Application was not in Mr. Warnking’s mind at the time he was employed by ProRhythm.

Moreover, SII has spent millions of dollars reducing the Invention to practice, including the development of roughly six iterations of the device and over forty animal studies. (A661). ProRhythm did not spend a dime on renal denervation or incur any additional liabilities in connection with renal denervation. (A644). Therefore, the prohibition of the use of the technology contained in the Invention and the award of intellectual property worth millions of dollars that was developed by SII and paid for by SII’s shareholders to ReCor under the guise of ProRhythm’s apparent right to the underlying “thought” is excessive and inequitable.

As discussed above, the injunction has effectively prohibited Mr. Warnking from working in the field of ultrasound renal denervation, notwithstanding the fact that the patent applications awarded to ReCor are not approved patents with valid claims. Since there is no misappropriation of trade secrets claim, only an allowed patent with valid claims and a showing of a likelihood of infringement of the allowed claims should be used to stop continued innovation of the technology by experts in a field. Whether the patent applications will be allowed and whether the claims will be of similar scope is unknown at this time. (A538).

The Chancery Court should have balanced the benefit to ReCor against the detriment to the Defendants and society. *ID Biomedical Corp. v. TM Techs, Inc.*, 1995 Del. Ch. LEXIS 34 at *42. Had the Chancery Court done so, it would have recognized that the benefit to ReCor is to eliminate a competitor, while the detriment to Defendants is the loss of their jobs and company. A balance of the equities shows that the benefit to ReCor was undeserved. As such, the Chancery Court's award of an injunction to ReCor was inequitable and must be reversed.

3. The Chancery Court's award of attorney's fees to ReCor was improper.

The Chancery Court erred in awarding ReCor its reasonable attorney's fees as the prevailing party under the fee shifting provision of the IAA. Pursuant to the APA, ReCor acquired the right to assert "[a]ny claims, lawsuits or rights to recovery" ProRhythm had at the time of the APA. (A245–46). Under the terms of

the IAA, the prevailing party to a litigation arising under the terms of the IAA had a right to recover his or its attorney's fees. (A38). Thus, ProRhythm must have had a claim to assert at the time of the APA for ReCor to have acquired the right to assert it. Because there is no evidence to support the Chancery Court's holding that Mr. Warnking breached his obligations under the IAA, ProRhythm did not have any rights to Mr. Warnking's Invention and therefore, ReCor has no basis to assert a claim on behalf of it.

4. The Chancery Court's determination that Mr. Warnking conceived of the Invention for '429 Application but not his invention for the '455 Application is clearly erroneous.

The Chancery Court found that Mr. Warnking conceived of the Invention for the '429 application while still at ProRhythm, but that ReCor did not satisfy its burden of establishing that Mr. Warnking conceived of the invention for the noninvasive patent application (the '455 application) while employed by ProRhythm. (Opinion at 39). The Chancery Court's conclusion is not supported by the evidence. The core invention of the '455 Application and the '429 Application are identical. (Opinion at 1). Both the '455 and the '429 Applications' point of novelty is the use of dosimetry with volumetric energy field. The only difference is that the '455 Application used an external ultrasound transducer applied to the body while the '429 Application used an internal cylindrical ultrasound transducer inserted in the renal artery. (A325–77; A433–91). It is therefore erroneous for the

Chancery Court to conclude that Mr. Warnking conceived of one of the inventions while at ProRhythm and not the other.

CONCLUSION

Based on the foregoing, the judgment of the Chancery Court should be reversed in its entirety.

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