IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION, et.al.	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Civil Action No. 00-958-MPT
	:	
ATRIUM MEDICAL CORPORATION,	:	
	:	
Defendant.	:	

MEMORANDUM OPINION

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Wilmington, Delaware
April 22, 2004

Thynge, U.S. Magistrate Judge

I. INTRODUCTION

In July 2002, this court issued a claim construction opinion following a *Markman* hearing[1] held in May 2002. In November 2002, a trial was held on the patent infringement dispute between Genzyme and Atrium regarding pulmonary drainage devices. Genzyme alleged damages caused by the marketing and sale of Atrium's "OASIS" and "EXPRESS" devices, which allegedly infringed Genzyme's "Elliot patents" (U.S. Patent Nos. 4,544,370; 4,715,856; 4,747,844 and 4,822,346) and its "D'Antonio patent" (U.S. Patent No. 4,899,531). Both parties reserved the right after the verdict for the court to decide certain issues of law and fact. After the eight day trial, the jury found that Atrium did not infringe any claims of the patents-in-suit and that claims in issue in the '531 and '844 patents were invalid.

II. PROCEDURAL AND FACTUAL BACKGROUND

The technical overview and procedural history that follows is drawn from the trial record, the court's claim construction, the evidence presented to the jury and the patents themselves. These sections address factual findings and procedural issues associated with each of the patents individually, and discuss the specific issues raised in the post trial motions before the court.

A. The D'Antonio Patent

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[1] *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995). For a more complete review of the asserted claims of the D'Antonio and Elliot patents, see the court's claim construction opinion, *Genzyme v. Atrium*, 212 F. Supp.2d 292 (D. Del. 2002). The description of the claims in this opinion cover only those claim limitations that are germane to the current motions addressed by the court.

Technology and Claims

The D'Antonio patent is directed toward a medical device used during surgical procedures to clear fluids and air from the body cavity. Chest drainage devices that used water columns as one-way valves to prevent the flow of fluid back into the patient also act to regulate the suction applied to the patient by preferentially allowing air from the atmosphere into the suction and collection chambers. Medical personnel would regulate the suction by varying the amount of water in U-shaped tubes within the device. Instead of employing a water-based control mechanism, the D'Antonio patent utilizes a mechanical valve that "preferentially applies suction pressure" to regulate the pressure between the chambers. This is accomplished, in part, by a gas port closing member positioned between the vacuum and collection chambers within the device.

The specific D'Antonio patent claims in dispute at trial were 1, 16, 17 and 18 of the '531 patent. These claims provide for a "closing means" that functions to regulate the pressure between two chambers in the device.

The '531 patent recites[2]:

A system for draining fluids from a portion of the body comprising an inlet port, a suction chamber, a suction regulator consisting of two chambers (one connected to suction and the other to the atmosphere) with an opening and a closing means between the chambers, and a biasing means for adjusting the position of the closing means in order to regulate the pressure between the chambers (claim 1). It also claims

[2]The claim language used here and in the recitations below has been abbreviated as needed for clarity and brevity. For the specific claim language presented to the jury, refer to the trial transcript, D. I. 263 at 22 - 27.

a system similar to that in claim one where the closing means can be set to a predetermined position by applying a force to the closing means and that force dampened by a dampening means (claim 16). The dampening means is described as a dash pot (claim 17). The closing force applied in claim 16 to the closing means is determined by a biasing means (claim 18).

Procedural History

As a result of the *Markman* hearing and opinion, claim language in the '531 patent was defined and subsequently included in the instructions to the jury. Relevant to the arguments before the court, a suction regulator "closing means" was defined as a mean-plus-function element of the claim. The functions set forth were opening and closing and the corresponding structure was "a ball that is disposed within the opening in the dividing means, or a hinged door, and structural equivalents thereof." This definition was consistent with the construction that Genzyme proposed and was not subsequently disputed by Genzyme prior to or during the course of the trial, or as included in the jury instructions.

Throughout this case, including at trial, Genzyme contended that Atrium's manufacture, use, offer for sale, and/or sale of its EXPRESS and OASIS chest drainage devices infringed claims of the D'Antonio patent. Before trial, Atrium pursued a motion for summary judgment for non-infringement of the D'Antonio patent, contending that its accused devices did not contain the disclosed "spherical ball" limitation defined by the "closing means" as specified in the patent. The court ruled in favor of Genzyme holding that the structural equivalence of "a ball disposed within the opening in the dividing

means or a hinged door" was a disputed issue of material fact. Concomitantly, the issue of structural equivalents was the thrust of the dispute between the parties.

At trial, expert testimony distinguished Genzyme's device from the prior art and established its functional equivalence to Atrium's device. Testimony was also offered suggesting that a ball and flat plate were interchangeable structures. In addition, testimony revealed that other structures were present in the Atrium devices that had equivalent functions to the "closing means" described in the D'Antonio patent. Finally, expert testimony explained how the Atrium devices potentially infringed.

In contrast, testimony for the defense revealed that a weighted ball is not equivalent to a flat disk. Other evidence showed that Atrium invested in the research and development of its suction regulator and found that the use of a "ball" in its design was not commercially available nor economically feasible at the time. Under cross examination, Genzyme's witnesses testified that Deknatel (a predecessor company of Genzyme) did not, nor did any commercial chest drainage device, use a ball within an opening or a hinged door as a suction regulator closing means. The prosecution history revealed that in distinguishing the '531 patent from Willwrath et al.,[3] D'Antonio argued that Willwrath's spherical element was not disposed within the opening, and he claimed that his "closing means was responsive to slight variations in pressure on the opposite sides thereof . . . providing a preferential draw from the patient." This feature also distinguished his claims from the Akiyama.[4] However, Dr. D'Antonio testified on cross-

[3]German Patent No. 2,500,993 (issued 1/11/75) to H.H. Willrath, et al.

[4]U.S. Patent No. 4,533,353 (issued Aug. 6, 1985) to Sueshiro Akiyama.

examination that a ball within an opening is equivalent to a flat plate because "one could cut the top and bottom off the ball."

B. The Elliot Patents

Technology and Claims

These patents disclose devices that remove fluid and air from a patient's chest cavity through the use of vacuum suction. Body fluids are drained through a tube into a collection chamber within the device. Proper operation requires the use of one-way "valves" to prevent the reverse flow of collected fluids due to negative inhalation pressure. Prior art devices used a water column to act as a one-way valve or "water seal" to prevent reverse flow. The Elliot patents disclose a "waterless" or "dry" device that replaces water seals with a mechanical one-way valve. The patents further disclose a number of pressure relief and control valves to allow for accurate pressure regulation and reverse flow protection.

The Elliot patent claims in dispute were claims 1 and 6 of the '370 patent; claims 5, 6, 12, 13, 16 and 21 of the '844 patent; claims 5 and 11 of the '346 patent; and claims 2, 3, and 4 of the '856 patent. These claims primarily disclose structures within a device that provide for waterless operation and leak detection.

The '370 patent recites:

A non-water seal thoracic drainage system comprising: a collection bottle, a fluid chamber, a one-way waterless valve in the flow path from the chamber to the outlet, which is the sole means to prevent reverse flow, unaided by water-based seals and a U-tube leak detector (claim 1). The patent further claims an air chamber in the

device that is large enough to dampen leak detector fluctuations in response to positive pressure surges (claim 6).

The ‘844 patent recites:

> A non-water seal thoracic drainage apparatus comprising a negative pressure relief valve vented to the atmosphere (claims 5 and 6). It claims inlet and outlet tubes to a collection chamber that contains a one-way waterless valve means along the flow path between the inlet and outlet tubes (claim 12), and includes a high negative pressure relief valve, connected to a source of increased pressure or the atmosphere (claim 13) and designed to open when the pressure in the flow path exceeds a predetermined value. In addition, it claims a positive pressure relief valve to vent to the atmosphere (claim 16) and also claims the apparatus in claims 17-20 with a fluid filled air leak detector and high negative pressure relief valve (claim 21).

The ‘346 patent recites:

> A non-water seal thoracic drainage apparatus containing a high negative pressure relief valve which opens at a predetermined value and is connected to a source of high pressure (claims 5 and 11).

The ‘856 patent (a continuation of the ‘370 patent) recites:

> An apparatus according to claim 1 (a device for draining a patient’s chest cavity) which includes a flow control valve connectable to a source of external suction which can control the suction to the upstream one-way valve seal (claim 2). It also claims the apparatus in claim 2 containing a positive pressure relief valve (claim 3) and a high negative suction relief valve (claim 4).

Procedural History

As noted previously, several terms in the Elliot patents were defined for the jury as a result of the *Markman* hearing. A "one-way" and "one-way waterless valve means" was defined as a "type of valve, also known as a check valve, that allows the flow of fluid in one direction but prevents flow in the reverse direction." In addition, a "water seal" was defined as "a fluid filled structure that allows air to escape from a patient, but prevents back flow of air to the patient." Finally, an "air leak detector" or "U-tube" was defined as an "air leak detector or U-tube that does not act as a water or fluid seal." Similar to the D'Antonio claims, these definitions were consistent with the constructions Genzyme proposed throughout litigation, and were not subsequently disputed by Genzyme prior to or during the trial, including in the jury instructions.

At trial, Genzyme contended that Atrium's manufacture, use, offer for sale, and/or sale of its EXPRESS chest drainage device infringed claims of the Elliot patents. The focus of the alleged infringement centered on Atrium's one-way waterless valve and "U-tube" air leak detector. These structures were specified in patents '370, '346, '856 and '844. Expert testimony was presented to demonstrate how Atrium's EXPRESS device met the claim limitations by including both structures. Evidence was also presented that air leak detectors could optionally be filled with fluid or left empty during normal operating conditions. Testimony also revealed that when the one-way valve in the EXPRESS device was working properly, under normal operating conditions, its fluid filled air leak detector could not act as a water seal.

Evidence, including test results and expert testimony, demonstrated that Atrium's

EXPRESS device, modified to simulate the failure of a one-way valve, would allow the U-tube air leak detector to function as a water seal and prevent reverse flow to the patient. In addition, the air leak detector could not act as a water “safety” seal, nor could it act as a “seal” or an air leak detector when it was not fluid filled.

Further, testimony was presented that the Elliot patents exclude a water seal and that a water seal is present in the EXPRESS model as a structure carried over from previous designs.

Moreover, the evidence showed that Dr. Elliot distinguished his invention from the prior art, which contained either mechanical or water seals, by explicitly requiring a “one-way waterless” valve means unaided by water seals. Finally, expert testimony was presented that a “one-way waterless valve means” requires that a mechanical check valve (a waterless valve) is the sole means for preventing reverse flow to a patient. At the conclusion of the evidence, Genzyme moved pursuant to Fed. R. Civ. P. 50(a) for judgment as a matter of law (JMOL) that Atrium infringed the claims of the D’Antonio and Elliot patents in question. That motion was denied and the issue of infringement was decided by the jury.

III. STANDARD OF REVIEW

A. Motion For Judgment As A Matter Of Law

Genzyme requests judgment as a matter of law to reverse the jury’s finding of non-infringement of the Elliot and D’Antonio patents, or in the alternative, seeks a new trial on infringement. In moving for JMOL, Genzyme seeks relief from an adverse jury verdict. To prevail on a renewed motion for JMOL following a jury trial, a party "must

show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998), quoting *Perkin-Elmer Corp. v. Computervision Corp*., 732 F.2d 888, 893 (Fed.Cir.1984), accord *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 345, 350 (D. Del 2000).

The inappropriateness of entering judgment as a matter of law "solely" on the basis of inconsistent verdicts is evident in the procedural requirements under Fed.R.Civ.P. 50(b), which requires a motion prior to the return of the verdict. See *Mosley v. Wilson*, 102 F.3d 85, 90 (3d Cir. 1996). In addition, Fed. R. Civ. P. 49(b) instructs courts facing a jury's inconsistent answers to special interrogatories to either return the question to the jury or to order a new trial. *Id*. On this point, *Mosley* references the dissenting opinion of Justice Stevens in *Los Angeles v. Heller*, 475 U.S. 796, 804-06 (1986). Justice Stevens commented that the court has the option to let the verdict stand, attempt to read the verdict in a manner that will resolve inconsistencies, resubmit the question to the jury, or order a new trial where the evidence might support either of the "inconsistent" verdicts. *Mosley*, 102 F. 3d at 90.

Substantial Evidence

The substantial evidence standard is established "if that minimum quantum of evidence" from which a jury might reasonably afford relief exists to support the jury's verdict. In that circumstance "a motion for JMOL must be denied." *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938) ("Substantial evidence is more than a mere

scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion"). In contrast, JMOL was granted where "reasonable jurors" could not have found otherwise because "the record before the jury contained *no* evidence to rebut the substantial evidence of infringement." *LNP Eng'g Plastics*, *Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353, 1357 (Fed. Cir. 2001). (emphasis added). In assessing the sufficiency of the evidence, the court must give the non-moving party the benefit of the doubt, resolve all conflicts in the evidence in his favor, and in general, view the record in the light most favorable to him. *Lifescan*, 103 F. Supp. 2d at 350. A court may not substitute its view of the evidence for the jury's view. Rather, the court must determine whether the evidence reasonably supports the jury's verdict. See *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998).

The Federal Rules of Evidence (FRE) require that the evidence presented be relevant to the matter in dispute and free from unfair prejudice. According to FRE 401-403, admissible evidence must be relevant, or tend to make a fact more or less probable. The trial judge is obligated to act as a "gatekeeper" and has broad discretion to balance the probative value of the evidence against its potential prejudicial harm. *See Magnivision*, *Inc. v. Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997). Further, error in the admission of evidence is not grounds for granting JMOL or a new trial, if its admission was harmless error. Fed.R.Civ.P. 61. The factors guiding the courts in determining harmless error are well documented.[5] Statements made about prior art and

[5]"A number of factors have guided the courts in their determinations of whether error is harmless, including (1) whether erroneously admitted evidence was the primary evidence relied upon, (2) whether the aggrieved party was nonetheless able to present the substance of its claim, (3) the existence and usefulness of curative jury instructions, (4) the extent of jury argument based on tainted evidence, (5) whether erroneously admitted evidence was merely cumulative, and (6) whether other evidence was

infringement in closings that accurately reflected evidence, which has been admitted without objection, are not improper. See *Loral Fairchild Corp. v. Victor Co. of Japan, LTD.*, *et al.*, 208 F. Supp. 2d 344, 360 (E.D. New York 2002). Ultimately, it is within the trial court's discretion to exclude evidence when the "probative value is outweighed by the danger of unfair prejudice, confusion of the issues or misleading the jury." *Fed. R. Evid. 401* and *403.*

B. Motion For A New Trial

Federal Rule of Civil Procedure 59(a) provides that a "new trial may be granted . . . for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States." *Fed.R.Civ.P. 59(a*). New trials should be granted "when the record shows that the jury's verdict resulted in a miscarriage of justice or where the verdict, on the record, cries out to be overturned or shocks our conscience." *Applera Corp. MDS., Inc. v. Micromass UK Ltd.*, 204 F.Supp.2d 724 (D. Del. 2002) quoting *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344, 1353 (3d Cir.1991). However, the decision to grant or deny a new trial is "committed to the sound discretion of the district court." *Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980). Although the Federal Circuit has reviewed whether irrelevant and prejudicial evidence was presented at trial, this issue is not unique to patent law and Third Circuit law applies. See *Union Carbide v. Shell*, 308 F.3d 1167 (F. Cir. 2002).

"Among the most common reasons for granting a new trial are the following: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be

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overwhelming." *ATD Corp. v. Lydall Inc.*, 159 F.3d 534, 549 (Fed. Cir. 1998).

granted to prevent a miscarriage of justice; (2) newly discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent." *Lucent Techs., Inc. v. Newbridge Networks Corp*., 168 F. Supp. 2d 181 (D. Del. 2001). In determining whether to grant a motion for a new trial, the court "need not view the evidence in the light most favorable to the verdict winner." *Id.* at 251. Similar to a motion for JMOL, a court cannot grant a new trial "merely because the court would have weighed the evidence differently and reached a different conclusion." *Id.* citing *Markovich v. Bell Helicopter Textron, Inc*., 805 F.Supp. 1231, 1235 (E.D.Pa), *aff'd*, 977 F.2d 568 (3d Cir.1992). On a motion for a new trial where a party contends that the jury's verdict was against the weight of the evidence, a new trial should "be granted to prevent a miscarriage of justice," but a court should "proceed cautiously" since such a decision would necessarily substitute the court's judgment for that of the jury. *MLMC, Ltd. v. Airtouch Communic's, Inc*., 215 F. Supp. 2d 464, 470 (D. Del. 2002); *Klein v. Hollings* 992 F.2d 1285, 1290 (3d Cir. 1993).

IV. GENZYME'S MOTION FOR JMOL THAT THE D'ANTONIO '531 PATENT AND ELLIOT '844 PATENT ARE VALID

A. Legal Standard

Anticipation

Patents are evaluated under a statutory presumption of validity. See 35 U.S.C. § 282. Nonetheless, patent claims may be invalidated when it is proven that a prior art reference "anticipates" the invention. *Applied Medical Resources Corp. v. U.S. Surgical Corp*., 147 F.3d 1374, 1378 (Fed.Cir.1998). A patent is anticipated by prior art

and invalid if the invention was "described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Determinating anticipation is a two step process of construing the claim and comparing the claim to prior art. The latter is a matter of fact for the jury and includes determining what a reference teaches by clear and convincing evidence. *In Re Baird*, 16 F.3d 380 (Fed. Cir. 1994). Evidence offered to defeat the presumption of validity must always be clear and convincing. *Ryco, Inc., v. Ag-Bag Corp.*, 857 F.2d 1418 (Fed. Cir. 1998) (a patent is presumed valid, and the party attacking validity has the burden of proving facts supporting a conclusion of invalidity by clear and convincing evidence). Ultimately, the teachings of the prior art must place the invention claimed in possession of the public. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983).

For a patent to be anticipated, every element of a patent claim must appear in a single reference. Other references and opinion may be used to reveal what the reference would have meant to those skilled in the art at the time of the invention. *Studiengesellschaft Kohle, m.b.H. v. Dart Indus., Inc.*, 726 F.2d 724, 727 (Fed.Cir.1984). A trier of fact must identify the claimed elements, determine their meaning in light of the specification and prosecution history and identify those same elements in the anticipating reference. It is error to treat the claims as a mere catalog of parts, disregarding the part-to-part relationships set forth that give the claims their meaning. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984). Experts often use the same words to describe the same device and a prior art reference. However, whether the terms are being used in different ways to connote different

intended functions is the issue. The "prior art cannot anticipate a patent simply by possessing identically named parts, unless these parts *also* have the same structure or otherwise satisfy the claim limitations, and were understood to function in the same way by one skilled in the art." *Applied Med. Res. Corp.*, 147 F.3d at 1380. (emphasis added).

For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art. Presumed knowledge of one skilled in the art does not allow an expert to read into the reference elements that are not there. See *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997). An expert's "conclusory testimony, unsupported by documentary evidence, cannot supplant the requirement for anticipatory disclosure in the prior art reference itself." *Id*. Where no reasonable jury could find that the defendant has met its burden establishing that each and every limitation of the claim has been disclosed, the Federal Circuit will uphold a district court's finding of validity on a motion for JMOL. *Structural Rubber Prods. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984).

Obviousness

"Invalidity based on obviousness is a question of law based on the underlying facts. The relevant facts relate to (1) the scope and content of the prior art, (2) the level of ordinary skill in the field of the invention, (3) the differences between the claimed invention and the prior art, and (4) any objective evidence of nonobviousness, such as, long felt need, commercial success, the failure of others, or copying." *C.R.*

Bard, Inc., v. M3 Systems, Inc.,157 F.3d 1340, 1351(Fed. Cir. 1998), quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). The subject matter of the claim constitutes what is "sought to be patented" and that is, therefore, the sole object of the court's concern in determining obviousness. *In re Sovish*, 769 F.2d 738 (Fed. Cir. 1985).

Where there is a new combination or arrangement of mechanical components, a conclusion of obviousness requires that there be "some suggestion, motivation, or teaching in the prior art whereby the person of ordinary skill would have selected the components that the inventor selected and used them to make the new device." *Id.* Similar to the analysis under anticipation, there is a presumption of validity, and a "party seeking a judgment that a patent is obvious bears the burden of demonstrating by clear and convincing evidence that the teachings of the prior art would have suggested the claimed subject matter to one of ordinary skill in the art." *Union Carbide v. Shell Oil*, 308 F.3d 1167, 1186 (Fed. Cir. 2002). Concomitantly, substantial evidence must support the factual findings necessary to support that legal conclusion. *Bard*, 157 F.3d at 1362.

A single prior art reference may be used to render a claim obvious, but there must be a suggestion or motivation to modify its teachings to the claimed invention based on the reference itself, the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved to support the obviousness conclusion. *Sibia Neurosciences Inc. v. Cadus Pharm. Corp.*, 225 F. 3d 1349 (Fed. Cir. 2000). In contrast "where a reference discloses the *exact element* at issue and discloses the *motivation* for using the element to improve the properties of the invention," obviousness in light of that reference alone is clear. *In re Inland Steel Co.*, 265 F.3d 1354, 1361 (Fed. Cir. 2001). (emphasis added).

In determining whether the clear and convincing evidence standard is met, the court must consider secondary factors of nonobviousness. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1986). While not conclusive, secondary factors of nonobviousness are an important part of the determination and must be given appropriate weight in the analysis. Factors, such as, commercial success, filling an unmet need, competitive copying, and licensing can contribute to that determination. Conclusory statements of success, for instance, are generally not enough. A nexus must exist between the invention and the commercial activity. That burden, through evidence of, such as, market share, growth of market share and replacement of earlier sales by others, must be met by the patentee and weighed against the challenger's rebuttal. *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 320 (Fed. Cir. 1985)

B. Validity of the '531 Patent Claims

The Zuhdi-Kimmel Reference[6]

Claims 1, 16, 17 and 18 of the '531 were found to be both invalid as anticipated and obvious by the Zuhdi-Kimmel regulator. The Zuhdi-Kimmel regulator is described as a device that is approximately 13 cm in height, having a central knob to adjust vacuum pressure. The knob is connected to a spring and a seat disc that reacts to vacuum, which, in turn, modifies the influx of air to control the amount of vacuum in the line connected to a collection vessel. The figures in the reference show the regulator connected via a "T-type" tubing junction to a source of vacuum and to either a collection or return reservoir.

[6]Vacuum Regulator for Cardiotomy Return and Chest Drainage Systems by Nazih Zuhdi, et. al., *Journal of Thoracic and Cardiovascular Surgery*, Vol. 39, No. 2, Feb. 1960.

As an expert for the defense, Dr. Kamm testified that Atrium's "closing means" was similar to the "closing means" in the Zuhdi-Kimmel regulator, but "quite different" from the ball in the D'Antonio patent. In reference to the closing means, he stated that if the D'Antonio and Zuhdi-Kimmel regulators were the same, then the D'Antonio claims are invalid.

Testifying for Genzyme, Dr. McDonald believed that Messrs. Hochberg[7] and D'Antonio represented during the prosecution of the patent that the Zuhdi-Kimmel regulator appeared to be different. However, he was uncertain whether such representation was necessary for the issuance of the patent. Dr. McDonald testified that there were features in D'Antonio's invention that were not in Zuhdi-Kimmel, specifically a unitary system configuration and a suction chamber. He also testified that the closing means in the Zuhdi-Kimmel regulator was structurally equivalent to the closing means in the D'Antonio patent.

D'Antonio also testified that there was no suction chamber in the Zuhdi reference. He stated that tubes could not operate as a suction chamber because a certain volume is required for the chamber to function properly, and tubes do not satisfy that requirement. Further, his testing indicated that sufficient chamber volume is needed to equilibrate the two flows; otherwise, the device would be inoperable.

Discussion

Anticipation of the '531 patent by the Zuhdi-Kimmel Reference

The Zuhdi-Kimmel reference does not anticipate claims 1, 16, 17 and 18 of

[7]Patent counsel during the prosecution of the D'Antonio patent.

the ‘531 patent. At trial, Atrium did not present clear and convincing evidence that this reference had each and every component of the ‘531 patent claims. Specifically, substantial evidence was not proffered that the Zuhdi-Kimmel reference contains a suction chamber. For a finding of invalidity, Atrium bears the burden to support such a conclusion by clear and convincing evidence. Atrium relies primarily on a single statement – Dr. McDonald’s answer to a hypothetical question on cross examination – as its proof of invalidity. This response alone does not meet the standard required to render claims 1, 16, 17 and 18 invalid.

In addition, Atrium’s post trial argument that a "T" tubing junction meets the court’s definition of a vacuum chamber is without merit. No adequate evidence substantiating this argument was presented.

Substantial secondary indicia of validity shows that Genzyme was successful at increasing market growth and licensing products based on this technology. As a result, the Zuhdi-Kimmel reference does not anticipate and render the claims of the ‘531 patent invalid.

In response to Genzyme’s post trial motion, Atrium argues that "expert opinion on ‘the ultimate issue of *infringement*’ even without detailed explanation created a prima facie showing that the fact finder was free to accept or reject." *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1574-76 (Fed. Cir. 1991). (emphasis added). However, meeting the clear and convincing standard is still required for *invalidity*. In *Symbol Techs*, there was competent evidence to uphold the trial court’s finding of patent validity. There, expert testimony of a co-inventor was sufficient when supported by the charts and drawings used by that inventor to demonstrate and explain infringement of means-plus-

function claims. *Id*. at 1574. Unlike Dr. McDonald's answer,[8] the charts in *Symbol Techs* showed and described each asserted claim and the corresponding structural parts of the accused devices depicted in the drawings. Testimony described how each claim limitation was met by the corresponding structure of the device in the drawings. In addition, the co-inventor explained the bases for his conclusion. *Id.*

The thorough *Symbol Techs* point-to-point examination of the Zuhdi-Kimmel article, and how it meets each of the claims of the D'Antonio patent, did not occur at trial. Specifically absent from the analysis was reference to the suction chamber element in the '531 patent. Rather than proving that the Zuhdi-Kimmel device satisfied this claim element, Atrium focused on comparing its regulator with the closing means in the D'Antonio device. In contrast, witnesses for Genzyme explained how tubing in the Zuhdi-Kimmel reference could not possibly function as a suction chamber. Further, those witnesses testified that the Zuhdi-Kimmel reference would not invalidate the D'Antonio patent due to a number of differences, including the lack of a suction chamber. No directly contrary evidence was presented by Atrium. Similar to the finding that Opticon failed to prove invalidity by clear and convincing evidence in *Symbol Techs*., Atrium has failed to do the same here.

Obviousness of the '531 Patent by the Zuhdi-Kimmel Reference

The Zuhdi-Kimmel reference does not render the '531 patent claims obvious since there is no evidence that this reference alone is enough to motivate,

[8]Atrium's attorney asked Dr. McDonald (after having him compare the "closing means" in each device) to assume that the D'Antonio regulator and the Zuhdi-Kimmel regulator were the same. He answered, "Since the Zuhdi-Kimmel article was published back in 1960, . . . I think the claims would be invalid."

suggest or teach the combination of the elements in the D'Antonio patent. Atrium argues that the burden of clear and convincing evidence of obviousness was implicitly met since there were suggestions to combine a suction chamber and regulator in several prior art references other than Zuhdi-Kimmel. In adherence to the special verdict form, the jury's determination required a finding based on a single reference. Therefore, a reasonable jury could not have found that the D'Antonio claims were obvious in light of the Zuhdi-Kimmel reference alone, since the reference lacks the element of a suction chamber.

According to Atrium, sufficient evidence exists to sustain a verdict of obviousness because the motivation or teaching implicit in the prior art *as a whole* would suggest the combination of the elements in the '531 patent claims, specifically the teachings of the Akiyama and Willrath patents which suggest suction chambers in chest drainage devices. That evidence would support modifying the Zuhdi-Kimmel device to include a suction chamber. Atrium, however, did not meet its evidentiary burden on obviousness based on the Zuhdi-Kimmel reference alone. Although multiple references may be used to establish the knowledge of one skilled in the art at the time of the invention, here, pursuant to the verdict form, the jury was directed to make its decision on a single reference. The standard previously set forth herein that requires both *disclosure* of the missing element and *motivation* for using an element as a property of the invention, is not met by the evidence at trial. *In re Inland Steel Co.*, 265 F.3d at 1361. Under similar circumstances, the court in *Motorola* found that evidence of obviousness from other sources, such as the teachings from other references not identified by the jury, could not

be used to infer the disclosure of a missing claim limitation. *Motorola,* 121 F. 3d at 1473**.**

Atrium also relies on its expert's testimony that substituting a flat plate for the closing means would render the '531 patent obvious in light of the Zuhdi-Kimmel reference. However, no testimony was elicited from that expert as to why it would be obvious to one skilled in the art to add the missing element of a suction chamber to the Zuhdi-Kimmel reference. Neither disclosure of the element nor the motivation for using that element in the invention is found or suggested by the Zuhdi-Kimmel reference or by the testimony at trial. Without the missing claim limitation or evidence of the motivation by one skilled in the art to combine elements from other sources, Atrium failed to meet its burden of proving obviousness by clear and convincing evidence.

C. Validity of the '844 Patent Claims

The Delta Medical Reference

Claims 12, 13 and 16 of the '844 patent were determined to be both anticipated and obvious in light of the Delta Medical Reference and device described therein. This reference by Dr. Siposs describes a "triple-action" or three-way cardiotomy device (VRV-200B) for "left ventricle decompression." The reference describes and depicts an 8 cm long "in-line" device, placed in tubing to drain the left ventricle of the heart of blood and air during cardiac surgery. Downstream from the device, is a peristaltic pump and, downstream from this pump, is a collection/return vessel or cardiotomy reservoir. The problem solved is maintaining "adequate suction without introducing air into the ventricle during bypass surgery." It suggests that the device can be included in the sump line at any point between the heart and the pump. The three-way action of this device is 1) limiting the vacuum in the line to a safe efficient value, 2)

preventing flow toward the heart and 3) automatically venting downstream pressure to the atmosphere.

On cross examination, Dr. Elliot testified that the thoracic cavity included the chest and all of the organs within the chest. When asked to identify the elements of the Delta Medical reference device, he confirmed that three of the elements contained in the ‘844 patent were included in the reference. Specifically, he identified a check valve, a positive pressure relief valve and a negative pressure relief valve as components of both his patent and the device. Further, he was aware of Dr. Siposs’ 3-way device (valve) and had used it in cardiac surgery. Although he concluded that the device would not work in his invention, Dr. Elliot contacted Dr. Siposs to learn if similar manufacturing techniques could be used to produce one that would. Dr. Elliot testified that the device in the Delta Medical reference "vented blood" and did not normally operate in the absence of liquid. Moreover, according to Dr. Elliot, although the Delta Medical device did not depend on an aqueous environment to function, because of its high opening pressure and small diameter, it could neither effectively nor safely be used in a chest drainage device. He agreed that the reference cited a one-way "check-valve" similar to the type described in his invention. With regard to the cardiotomy reservoir shown, he testified that a vent at the top of the reservoir exists to relieve trapped air.

Dr. Kamm testified that he agreed with Dr. Elliot that the components in the Delta Medical reference were in the ‘844 patent claims. He also testified that the reference described a thoracic drainage device. By pointing out each component, he concluded that the reference disclosed each and every limitation of claims 12, 13 and 16 of the ‘844 patent. He also confirmed that every cardiotomy reservoir was vented to release air.

The Tamada References [9] [10]

Two references attributed to Tamada et. al. were chosen by the jury as rendering the '844 patent claims obvious. The Tamada I reference describes the use of a Heimlich[11] valve to prevent the back-flow of air into a patient's pleural cavity during aspiration. In describing the novelty of the invention, Tamada I compares this valve to prior devices, including waterseal type valves. Tamada I points out that waterseals are susceptible to being breached if collection bottles tip over, and suggests that inserting a Heimlich flutter valve, or dry valve, ensures the effectiveness of the device. The Tamada I reference describes a negative pressure safety device that utilizes differences in water pressure to prevent hyper-negative intrathoracic pressures. Its stated purpose is to control an extrinsic pneumothorax, which may occur when a patient coughs strongly. Such forceful coughing may overcome the vacuum and exert excessive pressure on the one-way valve. The negative safety pressure device also allows adjustment of the suction pressure to compensate for air leakage within the system.

Tamada II explains that the water level of the safety pressure device in Tamada I may indicate intrathoracic pressure, without causing the pressure to fluctuate. Tamada II teaches that the pressure can be modified by adjusting the submerged depth of the hollow tube in the safety pressure device. Tamada II suggests monitoring the water level

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[9]Jiro Tamada and Shigeki Hitomi, *Improvements on the Low-Pressure Continual Pleural Aspirator - The Development of an Aspiration Device with a Unidirectional Valve and a Safety Pressure Device*, Journal of the Japan Society of Pulmonary Surgery, Vol. 25 No. 11 (November 1977).

[10]Jiro Tamada and Shigeki Hitomi, *A New Low-Pressure Continual Pleural Aspriator - The Development of an Aspiration Device with a Unidirectional Valve, a Safety Pressure Device, and an Air Leakage Indicator*, Journal of the Japan Society of Pulmonary Surgery, Vol. 31 No. 12 (December 1978).

[11]A one-way mechanical valve invented by Dr. Heimlich.

in the safety pressure device to prevent lung failure. It also depicts a one-way “dry" Heimlich valve added to the system to relieve positive pressure.

Dr. Kamm testified that the Tamada references contained all of the elements of claim 12, except they use a water column as a high negative pressure relief valve. The jury heard from him that other inventions exist which use a dry-type valve with an aspiration jar to relieve negative pressure.[12] Dr. Kamm suggested that since mechanical negative pressure relief valves had been used in a number of other medical devices and patents, he would have been very surprised if one of ordinary skill in the art would not have made the combination. He further commented that the combination is suggested in a paper by Enerson.[13] Moreover, Dr. Kamm testified that a positive pressure relief valve was present in the Tamada II reference and that it would have been obvious to insert the valve, along with the other elements of claims 12, 13, and 16, into a chest drain.

Under cross examination, Dr. Kamm confirmed that one of ordinary skill in the art would know that the water column in the Tamada references could be replaced with a mechanical check valve. He found support for this conclusion in the Puderbaugh and Enerson references. However, when specifically asked, Dr. Kamm neither confirmed that the Tamada references alone suggested using a dry valve as a high negative pressure relief device, nor the motivation for that substitution. He did not agree that mechanical valves operated differently than water columns.

Discussion

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[12] U.S. Patent No. 4,013,076 (issued March 22, 1977) to Puderbaugh, et al.

[13] Enerson & McIntyre, *A Comparative Study of the Physiology and Physics of Pleural Drainage Systems*, 52 J. Thoracic and Cariovascular Surgery 40 (July 1966).

Claims 12, 13 and 16 of the '844 patent were found anticipated by the Delta Medical reference. These claims were also found to be obvious in light of the Tamada I and Tamada II references. Claims 1, 16, 17 and 18 of the '531 patent were held anticipated and obvious in light of the Zuhdi-Kimmel regulator.

On a motion for JMOL, substantial evidence is required to support the jury's finding under the clear and convincing standard that each and every element of the contested claims in the '844 and '531 patents is present in the prior art. The same evidentiary standard applies when determining obviousness. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir.1986).

Anticipation of the '844 patent by the Delta Medical Reference

The Delta Medical reference, and the device described therein, does not anticipate the claims of the '844 patent, since a reasonable jury could not have found by the clear and convincing standard that the reference contained each and every claimed element with the same structure and functioned in the same way.

Atrium argued that the Delta Medical device has similarly named components as those in the '844 patent claims. The device arguably is a thoracic drainage apparatus since it provides for drainage of the heart, an organ in the thoracic cavity.[14] Atrium demonstrated that the device has a check valve to stop the return of blood and air to the

[14]Both parties offered extensive argument as to whether the preamble of claim 12, "A thoracic drainage apparatus comprising," should be limiting. By normal human anatomy and medical definition, the heart is contained in the thoracic cavity, and thus, this prior art may be considered a thoracic drainage apparatus. However, the preamble only operates to limit claim language in circumstances to "breath life into the claim" or where the claim is indefinite without it. See *Schumer v. Lab Computer Sys., Inc.*, 308 F.3d 1304, 1310 (Fed. Cir. 2002). There is no basis to limit the claim to either "pleural" or thoracic" cavity since claim 12 recites a device that is "connectable to receive fluid and air from a patient's *chest* cavity." (emphasis added). This language is unambiguous and definite.

heart, and another structure which relieves both positive and negative pressure. However, in light of the part-to-part relationships that give the claims in question their meaning, the Delta Medical device does not contain the same components which function similarly to those in the ‘844 patent.

Dr. Elliot’s invention, a "dry-suction apparatus," is an improvement over systems with water-based valves and designed to work in the absence of water to assist a patient’s breathing. The Delta Medical device, on the other hand, is designed to remove blood and air from the heart. Dr. Elliot testified the Delta Medical device “vented blood," and although possibly is "waterless" relative to his invention, it is not interchangeable or a substitute for the waterless valves in his invention.

Dr. Elliot, as a thoracic surgeon, was familiar with and used the Delta Medial device. He considered the mechanical characteristics of the Delta Medical device and felt they were unusable and unsuitable in his invention. While Dr. Elliot confirmed that the device has a negative pressure relief valve, he never stated, nor was he asked, whether this valve is structurally or functionally the same in both devices. The negative pressure relief valve of the ‘844 patent is designed to allow air back into a patient’s chest cavity when needed. However, the *same* valve described in the Delta Medical device automatically limits the vacuum in the "line" downstream between the device and the reservoir. It does not reintroduce air to the heart or thoracic cavity. Even if it could do so in sufficient volume to be effective, the reference describes this potential occurrence as a "tragic mistake" that the device is intended to prevent.

Claim 16 of the ‘844 patent has a positive pressure relief valve "operatively associated with" and designed to vent the air space above the fluid collection chamber.

Testimony was elicited by both parties that the cardiotomy reservoirs in the Delta Medical reference have built-in vents, but not positive pressure valves, to the atmosphere. Atrium points to the Delta Medical reference as suggesting that a positive pressure relief valve could prevent the problem of reservoir pressure. In fact, the reference states that the check valve prevents the tragic effects caused by reservoir pressure by preventing air or blood flow towards the heart. It does not provide that a positive pressure relief valve can be used to vent the cardiotomy reservoir. Rather, the Delta Medical reference teaches away from venting the cardiotomy reservoir by suggesting that a surgeon can place the device at any point in the sump line between the heart and pump[15], since its principle use is as a safety device to prevent blood or air from flowing into the patient due to inadvertent pump reversal.

Considering the differences between the design and function of the Delta Medical device and the Elliot patent, a reasonable jury could not have found that the reference anticipated the '844 patent claims by clear and convincing evidence. Atrium's treatment of the claims as a catalog of parts ignored the part-to-part intra relationship of the claims and their relationship to the specification. Since the court is responsible to ensure that the patents are properly evaluated by the jury under the statutory presumption of validity, the verdict finding that the '844 patent is invalid as anticipated is reversed.

Obviousness of the '844 patent by the Tamada I and Tamada II References

The jury held that claims 12, 13 and 16 of the '844 patent were obvious

[15]In the suggested configuration the pump would act to restrict the flow of air (and pressure) between the reservoir and the valve.

under the Tamada I and Tamada II references. The jury selected *only* these two references from a list of four possibilities. However, the Tamada references do not render the '844 patent claims obvious since they do not suggest any motivation to replace a water based multi-function high negative pressure relief valve with a mechanical valve. Expert testimony provides no evidence that the Tamada references alone would render the claims obvious. The fact that the Tamada references suggest the use of a mechanical valve in one part of their inventions, and not in another, inherently teaches away from the '844 invention. Although other prior art references in evidence indicate the knowledge of one skilled in the art at the time of the invention, the jury did not select those as rendering the '844 patent obvious. This limited selection by the jury evidences that Atrium did not meet the clear and convincing standard.

The parties agree that the elements of the '844 patent claims are met by the Tamada references, except that these publications describe a drainage device containing a water column-based high negative pressure relief valve instead of a mechanical valve. Atrium argues that the motivation existed to replace the water column-based, high pressure valve with a mechanical valve. Specifically, Dr. Kamm testified that one of ordinary skill in the art would have had the knowledge and motivation to modify the Tamada references. He indicated that the Puderbaugh reference suggests that mechanical check valves exist and the Enerson reference suggests that the substitution could be made, thereby insinuating that one skilled in the art would have had the invention in his possession. Atrium argues that Dr. Kamm's testimony, combined with the Tamada references, is enough to meet the standard of clear and convincing evidence obviousness. However, contrary to Atrium's argument, by *only* choosing the

Tamada references, the jury explicitly concluded that teachings of these other references, despite being within the knowledge of one skilled in the art, were not helpful or relevant.

Atrium points to *B.F. Goodrich* as an example of where the Federal Circuit upheld a verdict of obviousness in light of a single prior art reference. *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). In contrast to *B.F. Goodrich*, where the court determined that the differences between the claimed and prior art inventions were minor, in the present matter the ‘844 patent specifies a waterless high negative pressure valve, while the Tamada references recite a water-based valve. This distinction is clearly evident in the ‘844 patent specification which details a "waterless" system for thoracic drainage. Atrium’s expert testified to an implicit suggestion or motivation to combine the understanding of one skilled in the art at the time of the invention with the Tamada references to render the ‘844 patent claims obvious. The test for an "implicit showing" of obviousness is "what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In Re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000)

Kotzab requires that "broad conclusory statements standing alone are not ‘evidence’." *Id*. Moreover, *Kotzab* overturned the PTO’s rejection due to obviousness. In *Kotzab*, a PTO examiner concluded that the term "one system" was the same as a limitation of "one sensor." The court rejected the examiner’s decision, finding that there was no evidence on the record to support such a conclusion. The court determined that both the examiner and the Board fell into the "hindsight trap," by comparing element by

element, instead of, considering the invention in the context of the teaching of the entire reference. *Id.* Rather, the analysis must be based on the "reason [that] the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *Id.* Atrium's implicit motivation is refuted by the jury's limited selection.

The mere conclusory testimony elicited from Dr. McDonald regarding the Tamada references and the knowledge of one skilled in the art do not render the '844 claims obvious by a clear and convincing standard. No evidence was presented as to why the Tamada references alone provide the motivation to replace the water-based negative pressure valve with a mechanical valve. No suggestion exists in the Tamada references motivating a skilled artisan to select a mechanical valve as a replacement for the water-based multi-function valve. In fact, the Tamada references, by implication, teach away from this substitution because, despite suggesting the use of a mechanical valve to prevent back flow to a patient, they do not suggest its application as a high negative pressure relief device as the '844 patent requires.

Atrium cannot now argue that the jury made its determination based on the prior art references in evidence or the testimony of knowledge of one skilled in the art at the time of invention. *Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d at 467. In *Motorola*, the Federal Circuit affirmed the reversal by the trial court of a verdict of obviousness, since no motivation was evident to combine the elements from the two references selected, particularly in the absence of any evidentiary support from one skilled in the art. Neither conclusory testimony regarding the knowledge of one skilled in the art, nor the other prior art references in evidence, but not relied upon by the jury, can be used to

bootstrap the references selected.

Genzyme demonstrated long felt need and commercial success as secondary considerations of nonobviousness. Although these elements are never conclusive, they support the court's finding of nonobviousness. Genzyme points to the testimony of Dr. McDonald, specifically, his review of seven secondary factors as indicia of nonobviousness. He discussed the commercial success of the patented products, selling over three million units, while competitors struggled to capture a tiny share of the market. The contrast was compelling. The technology at issue was licensed extensively prior to Genzyme's purchase of the '844 patent with payments in royalties to Dr. Elliot of several million dollars. Genzyme offered evidence that Atrium analyzed the features of the dry/dry devices under the Elliot patent and included them in its products. Thus, the evidence in support of the secondary considerations in conjunction with the other evidence of nonobviousness demonstrates the validity of the '844 patent.

V. GENZYME'S MOTION FOR JMOL ON INFRINGEMENT OF THE '531 AND '844 PATENTS

A. Legal Standard

Infringement

A patent is directly infringed when a person "without authority makes, uses, or sells any patented invention, within the United States during the term of the patent . . . ." 35 U.S.C 271(a). *Novartis Pharmaceuticals Corp., v. Eon Labs Mfg., Inc*., 234 F. Supp. 2d 464, 467 (D. Del. 2002). A patent owner may prove infringement by literal infringement or the doctrine of equivalents. Literal infringement occurs where each element of at least one claim of the patent is found in the alleged infringer's product. *Id*.

At trial, Genzyme did not proceed on the basis of the doctrine of equivalents, but solely on direct infringement.

Determining infringement is a two step process. First, the court must construe the asserted claims to ascertain their meaning and scope and then the claims are compared to the accused device. *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 163 F. Supp. 2d 426, 437 (D. Del. 2001). Genzyme had to prove, by a preponderance of the evidence, that every claim limitation was met by the accused device. Unlike the analysis of infringement under a motion for summary judgment, where a court compares the accused products with properly construed claims, or when the Federal Circuit reviews an appeal *de novo*, the review of a jury's decision of non-infringement via a JMOL motion should be limited to whether substantial evidence supports the verdict under the appropriate jury instruction. *Hewlett Packard Co. v. Mustek Systems, Inc.*, 340 F.3d 1314, 1320 (Fed. Cir. 2003).

A number of the asserted claims of the patents-in-suit include limitations drafted in "means-plus-function" form, where the limitation does not describe a specific structure, but instead describes a function and claims a "means" for accomplishing that function. Pursuant to 35 U.S.C. § 112, ¶ 6, limitations drafted in means-plus-function form are construed to "cover the [functionally] corresponding structure, material, or act described in the specification and equivalents thereof." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1266-67 (Fed. Cir. 1999). Section 112, ¶ 6 provides a compromise: patentees may express a limitation in their patent claims "as a means or a step for performing a specified function without the recital or structure . . . in support thereof." Such a claim, however, will not be interpreted to cover all structures which would perform that function, but only

"the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6; *see also J&M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1367 (Fed. Cir. 2001) ("the scope of such [means-plus-function] claim language is sharply limited to the structure disclosed in the specification and its equivalents"). *J&M v. Harley-Davidson* also reminds that comparing equivalents under literal infringement is a question of fact.

"Literal infringement of a claim containing a means clause requires that the accused device perform the identical function as that identified in the means clause and do so with structure which is the same as or equivalent to that disclosed in the specification." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1547 (Fed. Cir. 1997). The duty to link or associate structure to a claimed function is the *quid pro quo* for the convenience of employing the means-plus-function claiming technique of § 112, ¶ 6. *B. Braun Medical Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997). However, the word "equivalents' under § 112, ¶ 6 should not be confused with the doctrine of equivalents. When applying the means-plus-function paragraph of § 112, ¶ 6 the "sole question is whether the single means in the accused device which performs the function stated in the claim is the same as or an equivalent of the corresponding structure described in the patentee's specification as performing that function." *Intel Corp. v. ITC,* 946 F.2d 821, 842 (Fed. Cir. 1991), quoting *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1575 (Fed. Cir. 1985). Further, paragraph 6 of § 112 limits a claim "from every possible means to those which are 'equivalent.'" *Id.*

> Properly understood section 112 ¶ 6 operates more like the reverse doctrine of equivalents than the doctrine of equivalents because it restricts the scope of the literal claim

language.

Johnston v. Ivac Corp., 885 F.2d 1574, 1580 (Fed. Cir. 1989). As a result, § 112, ¶ 6 "rules out the possibility that any and every means which performs the function specified in the claim *literally* satisfies that limitation." *Pennwalt Corp. v. Durand-Wayland, Inc.,* 833 F.2d 931, 934 (Fed. Cir. 1987) (en banc). (emphasis in the original).

Discussion

The D'Antonio Patent

Are a flat plate and a spherical ball equivalent structures?

In its post trial motion, Genzyme begins by arguing that no reasonable jury could find that a biased, pressure-regulating flat plate is not equivalent to a biased pressure-regulating ball within an opening, or a hinged door, if it achieves the same result. Genzyme maintains that each is equivalent and that Atrium's chest drains literally include all elements of the asserted claims. Genzyme employs doctrine of equivalents language when expressing that the closing means in each device "operates in substantially the same way to perform the same function to achieve the same result."[16] Alternately, Atrium contends that there is no legally sufficient basis to find in favor of Genzyme under JMOL, since there is substantial evidence to support the jury's verdict, citing *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) and *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998). Atrium emphasizes the prosecution history of the D'Antonio patent in which the "biased regulating ball" was distinguished over "flap-type" valves in the prior art. Atrium argues

[16]See D.I. 289 at 7.

that the court must consider such evidence in a light most favorable to the non-moving party and disregard evidence that the jury was not "required to believe," relying on *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133 (2000).

Here, the issue is whether there was substantial evidence presented during the trial that a flat plate and spherical ball are structural equivalents when placed between the dividing means and used to regulate the pressure between the chambers of a thoracic drainage device. Where substantial evidence of equivalents is found, the court then determines if the verdict of non-infringement would be a reasonable conclusion supported by the findings. Even if there is doubt that evidence existed to challenge equivalents, this court must still provide the benefit of doubt to Atrium, and resolve the motion in its favor. It is Genzyme's burden to prove that there was little evidence to substantiate the verdict of non-infringement. Genzyme has not met that burden. Accordingly, this court concludes that substantial evidence was presented to the jury, and the jury came to the reasonable verdict of non-infringement as a result.

Genzyme's argument that, as a matter of law, Atrium's device is "the same as" the D'Antonio patent and that it is entitled to JMOL of infringement based on the claims construction provided to the jury, must fail for two reasons. First, it uses doctrine of equivalents "language" to convince the court that, in defining the closing means at issue, both devices are the same. Genzyme exclusively argued (and the court only instructed the jury on) literal infringement.

At trial, there was significant evidence for the jury to consider regarding the structural equivalents of a spherical ball and flat plate as described within a suction regulator. Testimony from expert witnesses, the patent holder and opinions of

representatives from both parties were presented. Numerous exhibits were provided to the jury to view and inspect, for example, DX 993 and PTX 1047, along with the patents and claim definitions to assist in its determination. Both sides presented extensive evidence on the issue of equivalents – clearly, more than a "mere scintilla" – and certainly enough that a reasonable mind would accept as adequate to support a conclusion. In reviewing the '531 patent, its patent prosecution history and the claim construction of a "closing means," the finding of non-infringement was reasonable.

The '531 patent claims a suction regulator with a "closing means between the chambers and a biasing means for adjusting the position of the closing means." The court's construction of a "closing means" as a "ball that is disposed within the opening in the dividing means, or a hinged door, and structural equivalents thereof," allowed the jury to determine that a flap was not structurally or functionally equivalent to the ball or hinged door as described in the '531 patent. The burden was on Genzyme to demonstrate that Atrium's flap-type valve would perform the required function with a similar structure to its claimed "ball" or "door". It did not.

Distinguishing the '531 patent was the description of how a ball disposed within the opening of a dividing means operates to allow air flow around it in order to respond to slight variations in pressure on opposite sides . During prosecution, D'Antonio argued that the suction regulator's design, which included the spherical ball, allowed for preferential removal of fluids from the thoracic cavity. Although Genzyme now argues that other valves present in the specification could substitute for the closing means in the suction regulator, in its trial presentations, it failed to sufficiently demonstrate that Atrium's flap-type valve could either respond to slight variations in pressure or allow for

the preferential removal of fluids. Ultimately, Genzyme failed to prove literal infringement, since Atrium's flat flap valve was not shown to perform the identical "means" or function with a structure which is the same as or equivalent to that disclosed in the specification. Although Atrium's device as a whole may act in a similar manner to Genzyme's device, that alone is not enough. Therefore, the claims at issue in the '531 patent, as examined and determined by the jury, were reasonably found not infringed.

Should the court broaden the construction of "closing means" to include any flap, hinged plate or valve?

For the first time, Genzyme asks the court to review its claim construction decision and broaden the patent claims to allow a ball to be equivalent to *any* flap, hinged plate or valve. In making this request, Genzyme now asserts that the court inadvertently narrowed the definition of a "closing means," in claims 1 and 16, by not allowing "other gas port closing means." [17] If allowed, then Atrium's OASIS and EXPRESS clearly infringe on the biased pressure-regulating ball. Genzyme relies on a broad interpretation of *Budde v. Harley-Davidson*, 250 F.3d 1369 (Fed. Cir. 2001) and *Serrano v. Telular Corp.*, 111 F.3d 1578 (Fed. Cir. 1997), contending that "the Federal Circuit held that broad generic disclosures in a patent of alternative embodiments meant that the claimed 'means for' element must be construed to cover such alternative embodiments, or their equivalents."

Atrium, on the other hand, asserts that Genzyme should be barred from, or has

[17]Language in the '531 patent description of the preferred embodiment states that the technique of suction regulation could be accomplished with other (referring to the described seated ball) gas port closing means, such as, a hinged door.

waived its right to challenge the court's construction of a "closing means" relying on the equitable doctrines of waiver, judicial estoppel and invited error.[18] It relies on a case where a defendant first advocated a certain claim construction to support invalidity, and then contended on appeal that the construction by the lower court was erroneously too narrow. See *Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709, 115 (Fed Cir. 1998) (where the Federal Circuit found it "highly questionable" for a party to appeal on the basis that the trial court committed error in claim construction by adopting the position that the party advocated at trial). Atrium contends that the court provided the jury with the proper claim construction of "closing means." According to Atrium, a broader definition, in particular the construction now propounded by Genzyme, would negate the requirement for *any* structure. A means-plus-function element does not include "all means" for doing the same function. *J&M Corp. v. Harley-Davidson, Inc.*, 269 F.3d 1360, 1367 (Fed. Cir. 2001).[19]

Issues regarding claim construction are properly raised prior to the end of the trial proceedings and before a decision by the jury. "It is improper to adopt a new or more detailed claim construction in connection with the JMOL motion when issues have not

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[18]Doctrine of waiver generally does not allow a plaintiff to argue a point which he has previously opposed. In relation to claim construction, the doctrine has been applied to preclude a party from adopting a new claim construction position on appeal. *Interactive Gift Exp., Inc. v. Compuserve Inc.*,256 F.3d 1323, 1345 (Fed. Cir. NY 2001). Judicial estoppel is "where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position." *New Hampshire v. Maine*, 532 U.S. 742 (U.S. 2001). Invited error "prevents a party from inducing action by a court and later seeking reversal on the ground that the requested action was error." *John Zink Co. v. Zink*, 241 F.3d 1256, 1259 (10th Cir.2001).

[19]"An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure . . . in support thereof, and such claim shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2000). Limitations drafted in means-plus-function form are construed to "cover the [functionally] corresponding structure, material, or act described in the specification and equivalents thereof." *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1266-67 (Fed. Cir.1999).

been properly raised prior to jury instructions." *Hewlett-Packard*, 340 F. 3d at 1321. After providing the jury with the claim language, "it is too late at the JMOL stage to argue for or adopt a new interpretation and test the jury verdict by that new interpretation." *Id*. Where claims are in dispute after trial, a party cannot "wait until after the jury returned a verdict against it and then on JMOL request a different construction, deleting a portion that the party previously agreed to." *Abbott Laboratories v. Syntron Bioresearch, Inc*., 334 F. 3d 1343, 1352 (Fed. Cir. 2003)

Genzyme's argument for broadening the court's *Markman* construction of a closing means to include a flat valve and a one-way valve is without merit. It points to the court's finding that the corresponding structure in the patent specification "includes the most general structures disclosed that satisfy the claimed function, and that it would be in error to incorporate structure from the written description beyond what is necessary to perform the claimed function." Thus, the ruling supports its argument. See *Micro Chem. v. Great Plains Chem. Co. Inc*., 194 F.3d 1250 (Fed. Cir. 1999). Genzyme also emphasizes Federal Circuit principles of applying generalized structures to describe the "means" and are not limited to parts of the specification. See *Budde v. Harley-Davidson*, 250 F.3d 1369 (Fed. Cir. 2001) and *Serrano v. Telular Corp.*, 111 F.3d 1578 (Fed. Cir. 1997). In both cases, since the embodiments were "detailed" in the specifications, the claims were defined by those details. However, these cases do not require that a "means for" element in a patent, including alternative embodiments, *must* be construed broadly to cover the embodiments or their equivalents.

This court recognized that the specification should be taken as a whole to determine the structure corresponding to a means-plus-function element. It determined

that, *any* "other gas port closing means" or a generic "closing member" was too broad. This court noted that "the only specific structural examples of such means in the specification are the spherical ball and a hinged door. Moreover, the corresponding structure of a means-plus-function element cannot be circularly described to include all means for doing the claimed function."

Similarly, in *Budde*, the Federal Circuit rejected Harley-Davidson's argument that the Summary of the Invention and the Objectives sections of the specification should be viewed in isolation. In contrast to Genzyme's argument to *generally* broaden, *Budde* relied upon a *detailed* description in the specification that disclosed the "means" (sensors) in question, directly linking the disclosed structure to the "electronic sensing means" limitation in the claims.

In *Serrano*, the Federal Circuit determined that an inventor's definition and explanation of the word "determining" in the specification, controlled the interpretation of that claim term. It, thus, found that the disclosed structure included what was described in the patent specification and any alternative structures *identified*. Thus, in *Serrano*, a discrete logic chip and a microprocessor were both specified in the patent and, therefore, were functional equivalents.

The operative words in these decisions are "detailed" and "identified." Contrary to Genzyme's assertions, neither decision allows the inclusion of structures that were not detailed or identified to perform the specific function in question, such as, valves included in other parts of the invention that are not related in the specification to the "specified" spherical ball or "suggested" hinged door. Genzyme asks the court to incorporate a broader interpretation of the patent claims based on language either

eluded to tangentially, or not related within the specification to the disclosed structures. Such a request is contrary to the intent of § 112, ¶ 6.

Is Genzyme barred from obtaining a broader construction?

During claim construction, Genzyme and Atrium were in "point to point" dispute over the terms defining the ‘531 patent’s suction chamber, dividing means, closing means, second chamber, biasing mean and damping means. Genzyme sought to ascribe broad general meanings to the claim terms. Not surprisingly, Atrium sought to limit the meaning of the claim terms to the specific disclosures in the patent. Genzyme contended that claims should be given their ordinary meaning and not be limited to the preferred embodiments set forth in the specification. In contrast, Atrium argued that certain claim limitations should be narrowly drawn, because they were means-plus-function claims, whose corresponding structures are limited to those structures disclosed in the specification. It maintained that Genzyme narrowed the meaning of the claim terms by distinguishing its closing means from both the Willrath and Zuhdi-Kimmell references during prosecution.

To a substantial extent, Genzyme succeeded in its claim construction position. For example, the court decided in Genzyme’s favor to accept a broader definition of "dividing means" as either a partition or divider. It denied Atrium’s request to limit construction to only horizontal partitions, similar to structures found in the prior art. Genzyme contended that the term "closing means" referred to a closing member, such as a ball, hinged door, or other gas port closing means, which can open or close an opening in a suction regulator, while Atrium, again, sought to further limit the definition relative to prior art. The court’s interpretation resulted in a definition that generally

favored Genzyme, and did not limit structures based on prior art as suggested by Atrium. Apparently, Genzyme agreed with the court since it issued a press release that the claim construction decision was "overwhelmingly positive" and "fully consistent" with its own position.

This court cannot countenance allowing a party to defend one point of view at trial, and argue another after receiving an adverse verdict. The doctrine of waiver, as discussed in *Interactive Gift Express*, applies. Genzyme is not allow a “second bite” at claim construction and a new trial due to an unfavorable decision by the jury. In accord with *Key Pharmaceuticals*, Genzyme cannot argue that the court committed error in its claim construction when a very similar construction was advocated by it throughout the litigation.

The Elliot Patents

Genzyme’s position is that it presented clear and undisputed evidence that Atrium infringes the asserted claims of the Elliot patents, and further, Atrium’s argument for non-infringement is insufficient to prevent a granting of JMOL. The Elliot patent claims describe a leak detector, and Genzyme argues that the Atrium device infringes directly on these claims because its EXPRESS device contains a leak detector. For the claims which do not require a leak detector, Genzyme maintains that the issue of infringement should be decided as a matter of law because the evidence simply does not exist to rebut infringement. Atrium responds that all of the Elliot patents, regardless of the limitation of an air leak detector, are limited by a “one-way waterless valve means,” and therefore, devices containing water-based valves or seals cannot infringe. According to Atrium, evidence was presented that the EXPRESS device contains a

chamber, that is an air leak monitor and water-based valve when filled with liquid. Atrium contends that its device is not covered by the Elliot patents, and thus does not infringe.

Evidence was presented that the EXPRESS device was designed with, and contained, a functional "water-based" chamber that was both a water-seal and leak detector. Testing by experts representing both parties indicated that the structure functioned as a seal when filled with water. In addition, the unambiguous language of the Elliot patents (specifications, prosecution history and claims) specifically excludes water based seals as part of the invention. In viewing the record in the light most favorable to Atrium, the jury's verdict should not be overturned under a motion for JMOL since substantial evidence supports its finding of non-infringement.

Genzyme's initial argument simply states that claims 12, 13 and 16 of the '844 patent are infringed because these claims do not require an air leak detector and therefore, JMOL should be granted, since there is no legally sufficient evidentiary basis for a reasonable jury to find for Atrium. Further, according to Genzyme, Atrium's expert, Dr. Kamm, did not present a non-infringement analysis with respect to these claims. Genzyme states that Dr. McDonald clearly explained how Atrium's EXPRESS device infringes each of the asserted claims. It contends that the factual foundation for the legal conclusion of infringement is based on the structure of the EXPRESS device. Genzyme urges the court to reject Atrium's argument that a "one-way" waterless valve means requires the absence of a water seal in "any" part of the EXPRESS device. Genzyme contends that this would be a new construction that the court did not consider. Genzyme reminds the court that "words in a claim should be given their

ordinary meaning" and that the court should "take care in not reading limitations into claims that are not there." Finally, the court would have to improperly rely on extrinsic evidence in its interpretation of these claims in order to require the absence of a water based seal for infringement.

Genzyme continues by maintaining that the "second set of asserted claims"[20] are also infringed by the EXPRESS device because it was reasonably capable of operating either with or without water in the air leak monitor. Thus, it was reasonably capable of satisfying the claim limitations, even though it was capable of non-infringing modes of operation as well. To support its argument, Genzyme relies on the finding that "the sale of a device may induce infringement of a method claim, even if the accused device is capable of non-infringing modes of operation in unusual circumstances." *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1337, 1343-44 (Fed. Cir. 2001).

Genzyme asserts that when the EXPRESS device is not filled with water, its air leak monitor cannot act as a water seal, and would ultimately infringe on the Elliot patents in that mode of operation. Genzyme suggests that this court must compare the asserted claims in both modes of operation, because, as a matter of law, infringement occurs if the claims are met under "foreseeable operating conditions." *Canon Computer Sys., v. Nu-Kote Int'l, Inc.,* 134 F.3d 1085, 1089 (Fed. Cir. 1998). Genzyme asserts that this limitation is met because either mode of operation would require the basic structure to be present and that *Intel Corp. v. ITC*, 946 F.2d 821 (Fed. Cir. 1991) held that the limitation can be met by the presence of the structure "alone." Genzyme further argues

[20]Claims 5, 6 and 21 of the '844 patent; claims 5 and 11 of the '346 patent; claims 1 and 6 of the '370 patent; and claims 2, 3 and 4 of the '856 patent

that Atrium's reliance on test reports by Dr. Kamm and Dr. McDonald, which indicate that the EXPRESS device's air leak monitor can act as a water seal, is improper because these tests were performed under abnormal operating conditions. Genzyme concludes that Atrium's reliance is unfounded since evidence of non-infringement under abnormal test (operating) conditions has no probative value. See *Hilgraeve*, 265 F.3d at 1343.

Atrium responds that the jury found that Genzyme had not met its burden by proving infringement of claims 12, 13 and 16 of the '844 patent. Atrium's argument relies primarily on the evidence presented that the EXPRESS device contains a water based seal, and thus removes its device from any claim of infringement under the Elliot patents. Atrium points to several instances where the trial testimony and evidence support this conclusion. Specifically, the prosecution history distinguished the Elliot patents from the prior art references of Kurtz and Nehring by explicitly requiring that the "one-way waterless valve means [is] operative to prevent reverse flow *unaided* by underwater seals and comprising the *sole means* thereof."[21] (emphasis added). Atrium points to the '844 patent which describes "overcoming the alleged shortcomings of prior art chest drainage devices by eliminating *all* underwater seals." (emphasis added). On direct and cross examination, in three separate instances, Genzyme's infringement expert testified that a "one-way waterless valve means" is a limitation requiring that the device in claims 12, 13, and 16 not have a water seal. Atrium concluded by adding that Dr. Kamm's testimony confirmed that the EXPRESS device contains a water seal.

[21]U.S. Patents 3,830,238 - 4,453,937 to Kurtz et. al, as referenced in the '844 patent and U.S. Patent No. 4,289,158 (issued Sept. 15, 1981) to J. Nehring.

As to the second set of asserted claims,[22] requiring both a leak detector and waterless valve means, Atrium argues that the jury found none infringed because it concluded that each of the claims required both the presence of an air leak detector and the absence of a water seal. Atrium argues that it is impossible for the EXPRESS device to meet both of these limitations under any operating conditions, and thus, the device cannot infringe upon the Elliot patents. Atrium cites testimony from Drs. Kamm and McDonald to support that the EXPRESS device prevents the back flow of air to the patient when filled with water. According to Atrium, the mere presence of a leak detector cannot infringe. Rather, a filled and functioning air leak detector is defined in the Elliot patents. Atrium points to testimony from Dr. Elliot that his invention contained U-tube air leak indicators that do not function as water seals. Atrium contends that *Hilgraeve* is not on point, since it involved overturning a motion for summary judgment concerning inducement to infringe on a method claim. Atrium further distinguishes the present matter from *Hilgraeve* in that its EXPRESS device is not "reasonably capable" of infringing because its fluid filled air leak detector acts like a water seal. *Hillgraeve*, 265 F.3d at 1343 (where “a device may infringe if it is reasonably capable of satisfying the claim limitations”).

Atrium asserts that the tests conducted by both Drs. Kamm and McDonald are valid in establishing the ability of the EXPRESS device to prevent back flow of air into a patient when filled with fluid. It argues that Dr. Kamm by-passed the one-way mechanical valve in the device in order to simulate a range of normal operating conditions and pressures. It contends such testing concluded that the EXPRESS water

[22]See footnote No. 20.

seal was "effective over the entire range of clinically possible suction pressures, whether the mechanical valve would be working or not." Dr. McDonald performed some tests under unusually high "non-clinical" suction pressures and confirmed the results Dr. Kamm performed within normal clinical conditions. Both Drs. Kamm and McDonald provided testimony to support the functionality of the water seal to the jury.

Finally, Atrium suggests that the jury heard testimony from an Atrium executive that the water seal in the EXPRESS device was virtually the same structure as the water seal in Atrium's prior (wet/wet and dry/wet) products and its design was carried over intentionally; the decision to keep the water seal as an aid to the mechanical valve was to provide patients with an additional safety measure upon failure of the dry valve.

Under the necessary analysis, Atrium is not required to prove non-infringement, but needs only to convince the court that substantial evidence of non-infringement was provided to the jury to rebut Genzyme's arguments. At trial, Genzyme had the burden of proving that Atrium infringed one or more of the claims in the Elliot patents. The jury determined that Genzyme did not prove such infringement. Similarly, under the present motion, the burden rests with Genzyme to show that this determination was made without substantial evidence or legally sufficient proof to support the verdict, with the benefit of doubt flowing to Atrium.

Genzyme's argument that there was no contradictory evidence to infringement is patently incorrect. Nor is it accurate that no legally sufficient evidentiary basis exists for a jury to find for Atrium on this issue. From the expert testimony and other evidence at trial, both parties presented substantial evidence to support the verdict. Testimony from Drs. Elliot, Kamm and McDonald established a framework for the jury to consider and

evaluate the claims and their scope. Evidence was presented regarding the design and manufacture of the devices. The record provides enough evidentiary support for both parties to support a reasonable conclusion.

The court is equally unconvinced by Genzyme's argument that claims 12, 13, and 16 of the '844 patent should read on a device that could contain a water based seal. The jury heard testimony that the a "one-way waterless valve means" was a limitation requiring that the device be absent of water-based valves. In addition, it heard that Dr. Elliot distinguished his patents over prior art by purposefully and repeatedly claiming "a non-water seal thoracic drainage apparatus" in his patents. Further, the opening paragraph under the Summary of the Invention in the '844 patent specifically disclaims underwater seals.[23] Although the words of a claim should be given their ordinary meaning, from the evidence presented, and in the context of the '844 patent itself, it was reasonable for the jury to determine that the claims incorporating a "one-way *waterless* valve means" excluded other *water-based* seals or valves. In accord with *Pannu v. Iolab*, this court will not overturn a jury's verdict on motion for JMOL absent lack of substantial evidence, or where the evidence is legally sufficient to establish the verdict. Sufficient evidence is clearly present.

The second set of asserted claims in the Elliot patents describe a device that contains both an air-leak monitor and specifically excludes water-based seals. Genzyme argues that it is the presence of both an air-leak monitor and water-based

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[23]"The teachings of the instant invention that this and other shortcomings of the prior art chest drainage systems can be overcome by the simple, yet unobvious, expedient of *eliminating all underwater* seals and pressure regulating systems *predicated upon fluid head* and *replacing* them *with* suitable *fluidless valve* mechanisms that provide accurate pressure regulation . . . " (emphasis added).

seal, whether operable or not, that will read upon Elliot patents. It implies that either mode (wet or dry) could be a foreseeable operating condition. Atrium contends that the modes are mutually exclusive states of operation, and thus cannot infringe on the patents. When the device is filled with water, it would contain a water-seal, and would not infringe. Without water, Atrium's device would not provide leak monitoring.

Genzyme argues that the test results by both parties' experts should be disregarded because they were based on erroneous operating conditions. The court disagrees. The jury had evidence to determine that under clinically relevant operating conditions, the EXPRESS air leak monitor functioned as a water-based seal. In addition, testimony from Drs. Kamm and McDonald supports this conclusion. It is a matter for the fact finder to conclude whether the test conditions and results were reasonable, credible and probative. In addition, the jury considered testimony that the water seal structure present in past Atrium thoracic drainage devices was purposefully carried over into the EXPRESS device.

The court must give the non-moving party the benefit of the doubt and resolve all conflicts in the evidence in Atrium's favor. Here, the substantial evidence reasonably supports the jury's finding of non-infringement.

VI. GENZYME'S MOTION FOR A NEW TRIAL BASED ON IMPROPER INTRODUCTION OF EVIDENCE, INCONSISTENT VERDICTS, AND PREJUDICIAL ARGUMENT

A. Alleged Improper Introduction of Prosecution History Evidence

Genzyme argues that, throughout the trial, Atrium introduced evidence which improperly influenced the jury to find that D'Antonio disclaimed a flat plate as a closing means in his '531 patent suction regulator. Genzyme claims to have repeatedly warned

during pre-trial hearings and under a motion in limine, that statements made about prosecution history would have a prejudicial effect. Specifically, Genzyme references the defense's statements made during opening arguments, a single comment during the closings,[24] and two statements by defense witnesses comparing Atrium's device to prior art.[25] The commentary during opening and closing statements related to D'Antonio's representations during the patent prosecution that his invention was distinct from a specific prior art reference. Genzyme claims that Atrium disregarded the court's instructions to limit such evidence, and argues that the now "tainted" verdict requires a new trial. In response, Atrium claims that any evidence it presented was limited to the direct evidence that Genzyme introduced, and only pertained to equivalents, under § 112, ¶ 6 which was in issue at trial.

Contrary to Genzyme's argument, substantial evidence supports the jury's verdict. Further, when reviewing the evidence as a whole, the jury has not reached a "seriously erroneous result or that the verdict is a miscarriage of justice that warrants a new trial." *Loral Fairchild Corp. v. Victor Co. of Japan, LTD.*, *et al.*, 208 F. Supp. 2d 344, 360 (E.D. New York 2002). The rules of evidence, generally, allow the admission of relevant evidence under a Rule 403 analysis. The court determines whether there is any prejudicial effect of the evidence which outweighs its probative value and determines whether the jury was "unfairly" prejudiced. After the required analysis, the

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[24]Those statements consisted of D'Antonio's representation, during the prosecution, that his invention "appeared to be different" from the prior art. During closing, Atrium's counsel remarked that "if the Zuhdi-Kimmell flat plate is substantially different from the D'Antonio's invention, it's undisputed that Atrium has a flat plate, just like Zuhdi-Kimmel, then Atrium is substantially different . . ."

[25]The testimony of Atrium's Vice President and its expert witness comparing Atrium's device to the Zuhdi-Kimmell regulator were not made before the PTO and, therefore, do not technically fall within the prosecution history or within the operation of prosecution history estoppel.

court finds that neither the evidence nor the comments were unfairly prejudicial to Genzyme.

Genzyme argues that claim construction and estoppel are matters of law, with the court instructing the jury on the scope of the claims. Genzyme points to *Wenger Manufacturing Inc. v. Coating Machinery Sys., Inc.*, 239 F.3d 1225 (Fed Cir. 2001) arguing that the "doctrine of prosecution history estoppel is 'irrelevant' to the determination of the literal claim scope." *Wenger* establishes a "line of distinction" between using prosecution history to construe disputed claim language and applying the doctrine of prosecution history estoppel to prevent a patentee from obtaining coverage under the doctrine of equivalents of the subject matter that was relinquished during prosecution. However, the court also found that "clear assertions made in support of patentability may affect the *range of equivalents* under § 112, ¶ 6." *Id.* at 1239. (citing *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457 (Fed. Cir. 1998)) (emphasis added).

According to Genzyme, the Federal Circuit has concluded that "prosecution history may not be used to infer the intentional narrowing of a claim absent clear disavowal of claim coverage." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2001). In *Amgen,* the appellate court was referring to "claim construction" when it addressed intentional narrowing. The court also determined that prosecution history is "always relevant to claim construction" and that a "narrowing amendment to satisfy any requirement of the Patent Act may give rise to an estoppel." *Amgen*, 314 F.3d at 1327. Thus, the holding in *Amgen* does not prevent examination at trial of the representations made by the patentee concerning prior art during prosecution

of the patent. Such questions are not automatically prejudicial. Further, Genzyme has not shown that comparisons by the defense of Atrium's products to the prior art in relation to the "closing means" unfairly prejudiced the jury.

These comparisons go to the issue of equivalents under §112, ¶ 6 and distinguish whether the equivalents of the structure in question is present in Atrium's device. In contrast to *Magnivision*, *Inc. v. Bonneau Co.*, 115 F.3d 956, 961 (Fed. Cir. 1997) where the defendant's "assertions and innuendos of impropriety were magnified by repetition," Atrium referred to the similarity between its invention and the prior art briefly during its opening and closing statements and during very limited questions on cross examination.[26] Moreover, in *Magnivision*, the combined effect of improper and erroneous jury instructions and prejudicial advocacy, when viewing the proceedings as a whole, was the basis for remand for a new trial. In the present matter, the adequacy of the jury instructions are not at issue.

Prior to the closing statements, the court limited argument which referenced the closing means in the Zuhdi-Kimmell article. Similar to *Loral Fairchild Corp. v. Victor Co. of Japan, LTD.*, *et al.*, 208 F. Supp. 2d 344, 360 (E.D. New York 2002), where a curative instruction was given to reduce any prejudice potentially introduced during closing argument by the comparison of the accused process to prior art, Genzyme raised its concern and a jury instruction directed to that concern was provided.[27] As a

[26]Atrium referred to the Zuhdi-Kimmel article twice in its opening and once in its closing arguments, representing that its device is similar to the flat plate in Zuhdi-Kimmel. Atrium mentioned that Genzyme distinguished its invention as "different" than the flat plug in Zuhdi-Kimmel. Such commentary comprised approximately one-half of a page in over 2500 pages of the trial transcript.

[27]The jury was instructed that practicing the prior art is not a defense to infringement.

result, the brief comments by Atrium in its opening and closing arguments, and its cross examination of Genzyme's expert did not result in unfair prejudice or error that would require a new trial as a remedy.

B. Inconsistent Verdicts

Genzyme argues that because of the inconsistencies between the verdicts of invalidity and non-infringement, the court should grant a new trial. Specifically, it contends that the finding of anticipation under the Zuhdi-Kimmel article (using a flat plate as a closing means) requires a finding that Atrium's device, which uses a flat plate, infringes upon the closing means of the '531 patent. Accordingly, the inconsistent findings of anticipation and non-infringement imply that the jury made its decision on an emotional, rather than rational basis. Genzyme primarily relies on *Mosley v. Wilson*, 102 F.3d 85, 90 (3d Cir. 1996) in support of this argument.

Atrium maintains that inconsistent verdicts do not support a motion for a new trial and are an "unfortunate fact of life in law" quoting *Boyanowski v. Capital Area Intermediate Unit*, 215 F.3d 396, 407 (3d Cir. 2000) and emphasizes Justice Stevens dissenting opinion in *Los Angeles v. Heller*, 475 U.S. 796, 804-06 (1986). Atrium stresses that the jury need not, nor is required to, believe all of the facts offered by each expert witness. Further, Atrium contends that the jury need not evaluate the issues of invalidity and infringement as a combined analysis. Finally, it points to *Union Carbide Chemicals v. Shell Oil Co.*, 163 F. Supp.2d 426 (D. Del. 2001), where upon review of the special interrogatories, the verdicts appeared internally inconsistent and the court opted to set aside the invalidity verdicts and not require a new trial on the issues.

Since the court has found that Genzyme's patents are valid, the issues of alleged

inconsistencies between the verdicts of invalidity and non-infringement and the need for a new trial are moot.

C. Use of Alleged Irrelevant and Prejudicial Evidence

Genzyme urges the court to grant a new trial because Atrium's counsel "deliberately chose to seek a verdict based on irrelevant and prejudicial evidence and argument."[28] Specifically, Genzyme claims that Atruim appealed to the jury's prejudice against monopolies, higher prices and injunctive relief and improperly argued that 50% of the patents are invalidated in litigation. Genzyme points to three allegedly objectionable themes used by Atrium, which were designed to sway the emotions of the jury. While counsel for both parties masterfully presented their respective client's positions with zealous advocacy, the comments by Atrium's attorney's did not rise to the level of unfair prejudice or misconduct. Nor was the trial unfairly prejudiced since both parties presented arguments that had emotional underpinnings. Curative instructions were offered or provided when Genzyme objected to the Atrium's questions or comments.

Use of the terms "monopoly", "product pricing" and "injunctive relief"

Genzyme suggests that the following emotional themes were at the heart of Atrium's defense: Genzyme is a billion dollar company which purchased the patents-in-suit to obtain a monopoly and raise prices, and Genzyme initiated the action for injunctive relief and not for damages.

"In the case of alleged attorney misconduct, the party seeking a new trial must

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[28]See D.I. 285 at 10.

demonstrate that the attorney's conduct constitutes misconduct, and not merely aggressive advocacy, and that the misconduct is prejudicial in the sense of affecting a *substantial right* in the *context of the entire trial record*." *Lucent Techs.*, 168 F. Supp. 2d 181 at 260. (emphasis added). Moreover, a court must determine that it is "reasonably probable" that the verdict was influenced *by the misconduct* such that a "miscarriage of justice would result if a new trial were not granted:" that is, the error must be so "grievous as to have rendered the trial unfair." *Id.*

In its opening statement, Atrium used the word monopoly to describe Genzyme's conduct in enforcing its patent rights in the marketplace and in reference to a report used by Genzyme to evaluate its position in the chest drainage market.[29] Genzyme contends that word "monopoly" is pejorative based on the holding in *Jamesbury Corp. v. Litton Indus. Prods*., Inc., 756 F.2d 1556, 1559 (Fed. Cir. 1985). Atrium also suggested that it was Genzyme's intention to raise prices as a result of its market position.[30] Finally, Atrium described a patent as giving "someone the right for (sic) try to exclude others and to have a monopoly" and explained that "when someone has a monopoly, prices can be high."[31] Genzyme sites to two other instances where Atrium used the term "100% market share" in reference to Genzyme's position in the chest drainage

[29]"Genzyme buys Deknatel, . . . because it thinks it can maintain a monopoly in a specific market. They say so in black and white. You will see in this Goldman Sachs document that the purpose of the acquisition is to maintain a monopoly and to raise prices." D.I. 268 at 278.

[30]"What you will learn is, this case is about a large corporation that tried to buy its way into a market. You will see in the documents from the time of purchase, that they entered hoping they could bar competitors from the market and raise prices to doctors, patients and hospitals." D.I. 268 at 229.

[31]See D.I. 268 at 236.

market.[32]

Genzyme argues that Atrium repeatedly asked Mr. Collier, Genzyme's Biosurgery Division President, if Genzyme wanted to either charge higher prices or to keep prices elevated. Genzyme contends that such questions emphasized that Atrium's absence from the market would mean higher prices for chest drainage devices. Further, Atrium referred to Genzyme's cost models and pricing initiatives during cross-examination no less than 21 times. In closing argument, Atrium suggested that because of its market presence, the cost of health care was less and millions of dollars were saved.

Genzyme further contends that Atrium prejudiced the jury with questions which suggested that Genzyme wanted it "out of the marketplace."[33] For example, during the cross examination of Mr. Collier, it asked why Genzyme never offered Atrium a cross-licensing arrangement, thereby implying an improper motive.[34] While cross-examining another Genzyme witness about a press release authored by a Genzyme employee, Atrium referred to the article's stated goal to stop the sale of the current EXPRESS and

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[32]Specifically, Genzyme references certain comments made during the closings and a question on cross examination of Mr. Connolly, Genzyme's Executive Vice President of Biosurgery.

[33]"What is at stake here is Genzyme's request that you take Atrium out of the marketplace." D.I. 268 at 227

[34]Q: Now, no one from Genzyme ever called Atrium and suggested that you would be willing to enter into a cross-license, did they?
A: No.
Q: And the reason is because your intention from the day this lawsuit was filed was to take Atrium off the market; isn't that true?
A: Absolutely not. D.I. 268 at 389.

OASIS chest drainage devices.[35] During closing argument, it suggested that the verdict is important to Atrium's founders, employees and the 5,000 patients treated daily with its chest drainage products.[36]

In response, Atrium notes that Genzyme introduced the issues of monopoly, higher prices and the right to exclude in its opening argument.[37] Atrium further points to Mr. Collier's comment that it is not "morally wrong to have a monopoly based on a patent that you have earned . . . ." One of Genzyme's exhibits is a due diligence evaluation by Goldman Sachs, which noted that Deknatel (a predecessor of Genzyme) had "virtually a 100% share of the dry suction segment of the chest drainage category."[38] Moreover, under *direct* examination, Mr. Collier read a similar passage to the jury.[39] Finally, Atrium argues that Genzyme moved for a curative instruction on the use of the word "monopoly" at the end opening arguments, but later withdrew that request.[40]

Atrium argues that Genzyme could have properly moved *in limine* or objected to questions and evidence during trial which it felt were irrelevant or prejudicial. Rather, it

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[35]Q: Mr. Valerio, isn't it true that as of July 23, 2002, it was Genzyme's stated goal to stop Atrium from selling current Express and Oasis chest drainage devices? True?
A: That's what it states here. (referring to the press release) D.I. 269 at 634.

[36]See D.I. 274 at 2504.

[37]". . .[T]here was only one person selling dry units in 1996. But when Atrium came into the marketplace with a competing model, when there is two players in the market versus one, price is going to suffer and the price, in fact, went down. . . ." D.I. 268 at 221.

[38]See PTX 1107 at 44.

[39]See D.I. 268 at 318.

[40]Genzyme withdrew its request for a curative instruction stating "[w]e don't want a curative instruction with the jury." D.I. 274 at 2354

directly offered evidence of its multi-billion dollar status and questioned its own witnesses about charging higher prices no less than eighty times during direct examination. As a result, on cross-examination, Atrium claims that it was simply following up on what Genzyme had begun. Moreover, no objections were raised against Atrium's cross examination of Mr. Connolly on the matters presently in contention. Further, Atrium points to Genzyme's prejudicial accusations – stealing patent protected technology, unlawful copying, corporate wrongdoing and theft. [41]

In its preliminary instructions, the court advised the jury about the patentee's right to exclude. Genzyme reiterated that right in its opening statement.[42] Further, Genzyme emphasized that it was forced to reduce its workforce by 15%[43] due to price erosion and lost profits resulting from infringement by Atrium.

Atrium's use of the word monopoly was inappropriate, since the use of this word may be pejorative. *See Jamesbury Corp.,* 756 F.2d at 1559. Genzyme objected to it, and other terms that might imply a similar meaning. After the openings, Atrium did not use the word, and employed the terminology "right to exclude" when questioning Genzyme's witnesses. Both parties agreed that this legal concept could be used when referring to past actions, but not to a prospective outcome.[44] Although Genzyme

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[41]"This is also a case about the dark side of what is going on in too many corporations today – corporate wrongdoing spawned by fear of failure. It's about unlawful copying – taking patent protected technology from another company without permission . . . and about what happens in the United States when a company's protected technology is stolen." D.I. 268 at 193.

[42]"The patent system achieves this purpose by granting the owner of a patent the right for the term of the patent to exclude any other person from making, using, offering for sale or selling the invention covered by the patent in the United States." D.I. 268 at 224.

[43]Genzyme showed a photo of the Genzyme Biosurgery staff when discussing the "loss of people" due to infringement by Atrium. D.I. 268 at 222.

[44]See D.I. 269 at 633.

requested a curative instruction, it withdrew its motion as unnecessary.[45] The circumstances in the present matter differ dramatically from *Jamesbury.* In that case, it was the combination of the use of the word monopoly, the failure to admonish defense counsel for that characterization and the same characterization in the jury instructions that concerned the Federal Circuit. *Jamesbury Corp*., 756 F.2d at 1559. Further, in closing, the defense undermined any presumption of patent validity by implying that the jury had to determine if, in fact, the patent was valid.

In the present case, 100% market dominance was initially introduced by Genzyme in support of its claim for damages for infringement. Thus, the concept was used both as a sword and a shield before the jury. Its use in this manner does not rise to misconduct. Further, there is no prejudice affecting a substantial right based upon the entire trial record. Where, the record is "replete with examples of counsel repeatedly arguing with the court about its rulings," complaining of the court's unfair treatment in the jury's presence, and during closing argument, referring to backdated documents not in the record*,* a new trial due to attorney misconduct is warranted*.* *Blanch Road Corp. v. Bensalem*, 57 F.3d 253, 264 (3d Cir. 1995). A "pattern of misconduct from opening statement through final argument" that proves "beyond any doubt" the "reasonable probability that the jury's findings were influenced by counsel's highly improper conduct," which effectively nullifies any instructions to cure unfair prejudice, justifies a new trial. *Id.*

Each party attempted to persuade the jury of the correctness of its position. Genzyme explained that the case was about "corporate wrongdoing" and the "dark side"

[45]See D.I. 269 at 804; D.I. 274 at 2354.

of corporate America. Atrium employed the David and Goliath theme – the "little guy" trying to compete with the "big guy." Both eluded to the impact that an adverse judgment would have on their respective workforces. However, neither approach rises to the level of misconduct, affecting a substantial right in the context of the entire trial record. Unlike the facts in *Blanche Road* where counsel openly disagreed with the court, Atrium generally complied with the court's instructions and kept its questions relevant and with the bounds of direct examination. Genzyme's motivation to file suit was relevant to Atrium's laches defense. Questions posed to Genzyme's executives about Genzyme's market share and pricing were relative to the ultimate question of damages.

Genzyme cites *United States v. Zehrbach*, 47 F.3d 1252 (3d Cir. 1995) for the proposition that "irreparable harm may be inflicted in a moment" and that prejudicial comments do not have to be endemic. *Id.* at 1267. However, *Zehrbach* also notes that while " irreparable harm may be inflicted in a moment, the comments at issue were but two sentences in a closing argument that filled forty pages of transcript." Similar to *Zehrbach*, Atrium mentioned the word monopoly twice in the 56 pages of its opening statement. As in *Zehrbach*, the court offered an instruction to disregard Atrium's comments, and previously had advised the jury about counsel's statements, arguments and questions.[46] Atrium was also cautioned about such comments. Thus, viewing the record as a whole, and in light of the curative instructions, the court cannot conclude that Atrium's remarks were "so egregious as to make it reasonably probable that the

[46] "Lawyers' statements and arguments are not evidence. The content of their questions and objections is not evidence. It is the witness' response that is evidence." D.I. 272 at 2417.

jury was improperly influenced" to warrant a new trial. *Lucent Techs.*, 168 F. Supp. 2d 181 at 260.

The 50% invalidation comment

During cross examination of Dr. McDonald, Atrium asked whether he knew that 50% of licensed patents were invalidated by juries in Federal courts.[47] Genzyme contends that the question misrepresents the facts and law relevant to the jury's consideration of invalidity issues. Genzyme immediately objected to the question, and a curative instruction was provided to the jury which satisfied both parties. Although this question is improper, the nature and extent of its impact, considering the record as a whole, is not enough to require a new trial. Atrium's unsupported comment is similar to the "isolated incident" described in *Lucent Techs*. *Id*. at 260.

Since Genzyme's motions for JMOL on validity of both the Elliot and D'Antonio patents have been granted, this issue has been remedied. *Lucent Techs.*, 168 F. Supp. 2d 181 at 258. See also *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*, 308 F.3d 1167 (Fed. Cir. 2002) (where the Federal Circuit agreed with the lower court that even if improper statements had influenced the jury's verdict, the issue was remedied through the granting of JMOLs on validity). Accordingly, Genzyme's motion for a new trial is denied.

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[47] Q: Dr. McDonald, I think you just told the jury that you can't imagine anyone paying a license on a patent that is invalid; correct?
A: Yes, sir.
Q: You know, based upon your experience, that people have taken licenses under patents; correct?
A: Yes, I do.
Q: In fact, those patents have then been litigated in Federal Court before juries, have they not; correct?
A: I am not familiar with any that have been declared invalid.
Q: Would it surprise you to learn that as many as 50 percent have been declared invalid?

VII. GENZYME'S MOTION SEEKING INJUNCTION AND DAMAGES

Genzyme's motion seeking an injunction and damages is rendered moot since the court has determined that the patents at issue are not infringed. As a result, neither injunctive relief nor damages may be awarded.

VIII. CONCLUSION:

For the reasons contained herein, Genzyme's motion for a new trial is DENIED. Genzyme's motion for JMOL that claims of the '844 patent are not invalid is GRANTED. Genzyme's motion for JMOL that the Elliot patents are infringed is DENIED. Genzyme's motion for JMOL that claims of the '531 patent are not invalid is GRANTED. Genzyme's motion for JMOL that claims of the '531 patent are infringed is DENIED. Genzyme's motion seeking injunction and damages is DENIED.