United States District Court, D. Massachusetts.

NOMOS CORPORATION,

Plaintiff. v. **ZMED, INC,** Defendant.

No. 01-CV-10765-MEL

June 28, 2002.

Order Correcting Opinion Aug. 26, 2002.

Patentee brought infringement action against competitor, alleging infringement of its patent for system of locating organs and lesions inside the human body to improve effectiveness of radiation treatment. The District Court, Lasker, J., held that: (1) claim preamble limited claim to a system that functioned with a radiation therapy device and a radiation therapy plan; (2) claim specification, by only disclosing the means as "a conventional, commercially available ultrasound probe," limited the claim to such a device and its equivalent; and (3) claim which referred to "disposing" the patient "on" a treatment table of a radiation therapy device, meant placing the patient so he was supported by and in contact with a treatment table of a radiation therapy device.

Ordered accordingly.

5,411,026, 5,447,154. Construed.

Clarence E. Eriksen of Jackson Walker LLP, Houston, TX, for Plaintiff.

Michael J. Bettinger of Preston Gates & Ellis LLP, San Francisco, CA, for Defendant.

MEMORANDUM AND ORDER

LASKER, District Judge.

This patent case concerns competing devices designed to increase the accuracy with which organs and lesions inside the human body can be located, and in turn, improve the effectiveness of radiation treatment.

NOMOS Corporation ("NOMOS"), a Pennsylvania corporation, is the owner of United States Letters Patent 5,411,026 (the " '026 patent") and the manufacturer of a commercial embodiment of the '026 patent known as the BAT System. ZMED, Inc. ("ZMED"), a California corporation with headquarters in Ashland, Massachusetts, produces a device called the SonArray System, a commercial embodimentof United States

Letters Patent 5,447,154 (the " '154 patent"). The '154 patent is owned by the Universite Joseph Fourier, a French educational body, which licensed the patent to Praxim, which licensed it to ZMED. NOMOS sues ZMED, claiming the SonArray System infringes the '026 patent; ZMED countersues NOMOS, claiming the BAT System infringes the '154 patent, all of which sounds simple enough.

Not simple, however, is determining the meaning of the language contained in the claims of the '026 and '154 patents. Construing the claims is a question of law for the Court's decision. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). I have adopted a common format for addressing each provision of the two patents, which lays out in order the text of the claim, the proposed construction of the patent owner/licensee, the proposed construction of the alleged infringer, my construction, and any commentary that is appropriate. In an unsuccessful attempt at brevity, I have not recounted the arguments of counsel for each claim, which have been exhaustively presented in the briefs and at the oral argument held on March 4, 2002.

I. Construction of NOMOS's '026 Patent

1. Claim 1: Preamble

Text:

A lesion position verification system for use in a radiation therapy plan, for use with a radiation therapy device, for treating a lesion within a body of a patient, comprising:
 '026 Patent, col. 12, ll. 7-10.
 NOMOS's Proposed Construction:

NOMOS indicates that the preamble should be given the effect of a claim limitation:

Thus, the lesion position verification system of claim 1 should be construed as a system that functions with a radiation therapy device and a radiation therapy plan.

Pl. NOMOS Corp.'s Br. in Supp. of its Proposed Construction of the Claims of U.S. Patent No. 5,411,026 and of U.S. Patent No. 5,447,154 ("NOMOS Opening Brief") at 9.

ZMED's Proposed Construction:

A "system" which would be one or more components working together for a particular result or functionality. This system must be useable in a radiation therapy and must be useable with a radiation therapy device. The radiation therapy plan identifies the position of the target lesion. ZMED, Inc.'s Mem. in Supp. of its Proposed Construction of the Claims of U.S. Patent No. 5,411,026 and U.S. Patent No. 5,447,154 ("ZMED Opening Brief") at 16. *Construction:*

[1] The preamble to claim 1 is a claim limitation, limiting the claim to a system that functions with a radiation therapy device and a radiation therapy plan.

Commentary:

[2] Although claim preambles are to be construed as all other parts of claims, they have a special status:

If, after reviewing the patent as a whole, the claim preamble is "necessary to give life, meaning, and vitality to the claim then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999) If, on the other hand, the body of the claim sets forth the complete invention and the preamble offers no distinct definition of any of the claim invention's limitations, "but rather merely states ... the purpose or intended use of the invention, then the preamble is of no significance to claim construction." [Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995)].

L'Oreal S.A. v. Revlon Consumer Prods. Corp., 2000 WL 291480, at (D.Del. Feb. 24, 2000) (some quotation marks omitted).

Although the preamble recites the purpose and intended use of the invention, there are two countervailing reasons why the preamble is a limitation: (1) elements (a) and (b) of claim 1 both refer back to the preamble, using the phrases " *the* lesion," " *the* radiation therapy plan," and " *the* radiation therapy device;" and, (2) the prosecution history of the preamble reveals that it was amended to add that the system was for use with a "radiation therapy device." When looking at the patent as a whole, I find that the preamble is essential for understanding elements (a) and (b) of claim 1.

2. Claim 1: Element (a)

Text:

(a) a means for generating at least one ultrasound image of the lesion in the patient's body; and '026 Patent, col. 12, ll. 11-12. *NOMOS's Proposed Construction:*

An ultrasound probe and its equivalent. NOMOS Opening Brief at 9. ZMED's Proposed Construction:

The means for generating must be a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image to show the position of the lesion in the patient's body. The ultrasound probe must be mounted to the treatment table by means of a bracket. The probe is mounted so it can be moved upwardly or downwardly with respect to the bracket.

ZMED Opening Brief at 17. *Construction:*

[3] "The means for generating at least one ultrasound image of the lesion in the patient's body must be a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image (and its equivalent), mounted to the treatment table by means of a bracket or fixation device."

Commentary:

[4] [5] This claim is the first of several "means plus function" claims, governed by 35 U.S.C. s. 112, para. 6. The statute provides:

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, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. s. 112, para. 6. A means plus function claim limitation is construed in a two step fashion.

The first step in construing a means-plus-function limitation is to identify the function explicitly recited in the claim. The next step is to identify the corresponding structure set forth in the written description that performs the particular function set forth in the claim.

Asyst Techs., Inc. v. Empak, Inc., 268 F.3d 1364, 1369 (Fed.Cir.2001) (citation omitted); *see* Valmont Indus., Inc. v. Reinke Mfg. Co., Inc., 983 F.2d 1039, 1042 (Fed.Cir.1993). Accordingly, courts must look to the specification to determine the structurecovered by the patent, but must be careful not to "import into the claim structural limitations from the written description that are unnecessary to perform the claimed function." Acromed Corp. v. Sofamor Danek Group, Inc., 253 F.3d 1371, 1382 (Fed.Cir.2001). Importantly, means plus function claims are "limited to the corresponding structure disclosed in the specification and its equivalents." Kahn v. General Motors Corp., 135 F.3d 1472, 1476 (Fed.Cir.), *cert. denied*, 525 U.S. 875, 119 S.Ct. 177, 142 L.Ed.2d 144 (1998).

Here, it is undisputed that the function of this limitation is to create an ultrasound image of a lesion in a patient's body. Therefore, what the '026 patent discloses in the specification with regard to this function determines what structure, and its equivalents, are covered.

The specification provides in pertinent part:

A means for generating an ultrasound image is disposed on treatment table. Preferably the means for generating an ultrasound image is a conventional, commercially available ultrasound probe. Ultrasound probe can generate two-dimensional ultrasound images of the portion of the patient's body containing lesion, while patient is on treatment table. Ultrasound probe is disposed upon, and mounted to treatment table as by a bracket which is preferably fixedly secured to treatment table. Ultrasound probe, by means of any suitable conventional connection is mounted so that it can be moved upwardly and downwardly with respect to bracket, so that ultrasound probe may be brought into contact with the patient's body, in order to generate ultrasound images.

'026 Patent, col. 7, ll. 6-22 (figure numbers omitted).

[6] The language of the specification is written in a "preferred means" style, yet the language only identifies one preferred structure, not any others. It is true that "[i]dentification of corresponding structure may embrace more than the preferred embodiment." Micro Chemical, Inc. v. Great Plains Chemical Co., Inc., 194 F.3d 1250, 1258 (Fed.Cir.1999). In *Micro Chemical*, the patent contained several proposed preferred embodiments. Closer to the situation at hand, however, are cases which hold that when there is only one proposed embodiment (the preferred one), the claim is limited to that embodiment. *See, e.g.*, Fonar Corp. v. General Elec. Co., 107 F.3d 1543, 1551 (Fed.Cir.), *cert. denied*, 522 U.S. 908, 118 S.Ct. 266, 139 L.Ed.2d 192 (1997); Faroudja Labs., Inc. v. Dwin Electronics, Inc., 76 F.Supp.2d 999, 1010-1013 (N.D.Cal.1999).

Accordingly, since the specification only discloses the means as "a conventional, commercially available

ultrasound probe," the claim is limited to such a device and its equivalent. Since the only conventional, commercially available ultrasound probes at the time of the patent created two-dimensional images, Tr. of *Markman* Hr'g ("Oral Argument") at 18, this probe must generate only two-dimensional images. *See* Wiener v. NEC Electronics, Inc., 102 F.3d 534, 539 (Fed.Cir.1996), *overruled on other grounds by*, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed.Cir.1998) ("Ultimately, a court must construe the claim language according to the standard of what those words would have meant to one skilled in the art *as of the application date*." (emphasis added)).

The next issue is whether the patent requires a bracket or fixation device. A device using a bracket is the only one disclosed (in the preferred means style), and therefore it would be reasonable to construe the claim to require one. *See, e.g.*, Fonar Corp., 107 F.3d at 1551; Faroudja Labs., 76 F.Supp.2d at 1010-1013. Despite this disclosure, NOMOS argues that a bracket is an unnecessary limitation because a probe without a bracket will also create an ultrasound image. *See* Acromed Corp., 253 F.3d at 1382.

It is true that the probe is mentioned as "mounted to treatment table *as by* a bracket which is preferably fixedly secured to treatment table," '026 Patent, col. 7, ll. 15-16 (figure numbers omitted and emphasis added), and the use of the words "as by" could be construed to indicate that a bracket is only one possible permutation, not a requirement. Nonetheless, taken as a whole, the specification undermines the alleged superfluity of the bracket by repeatedly describing the probe as being "mounted" or "secured" to either a radiation therapy device or a treatment table, which emphasizes the importance of the bracket in obtaining useful images. *See*, *e.g.*, '026 Patent, col. 3, ll. 39-42; col. 7, ll. 17-22 and 27-31; col. 10, ll. 48-52. Therefore, I construe the means for generating at least one ultrasound image of the lesion in the patient's body to require a bracket or fixation device.

3. Claim 1: Element (b): Part (I)

Text:

(b) a means for indicating the position, with respect to the radiation therapy device, of the means for generating the at least one ultrasound image when the ultrasound image is generated, '026 Patent, col. 12, ll. 13-16. *NOMOS's Proposed Construction:*

[E]lement (b) of claim 1 should be construed to cover: (1) a position sensing system aligned with the radiation therapy device; or (2) in the alternative, a position sensing system which is aligned with the radiation therapy device and which includes a camera system which looks at position markers that are affixed to the ultrasound probe. Element (b) of claim 1 does not require that the position sensing system directly measure the position of the ultrasound probe with respect to the radiation therapy device. Finally element (b) of claim 1 should be construed to cover the equivalents of the above structure. NOMOS Opening Brief at 11. **ZMED's Proposed Construction:**

The means for indicating the position of the means for generating must be a conventional position sensing system comprising either a camera/LED emitter system or a microphone/ultrasonic emitter system. The LED or ultrasonic emitter must be attached to the ultrasound probe and the camera or microphone must be attached to the room. ZMED Opening Brief at 20. *Construction:*

[7] "The means for indicating the position of the means for generating the at least one ultrasound image when the ultrasound image is generated must be a conventional position sensing system comprising either a camera/LED emitter system or a microphone/ultrasonic emitter system (or their equivalents)."

Commentary:

This element is yet another means plus function claim. Here, the function, by its plain language, is indicating the position of the means for generating an ultrasound probe relative to the radiation treatment device.

Turning then to the disclosed structures in the specification, the '026 patent describes both a camera/LED emitter system and a microphone/ultrasonic emitter system. Although the language of the specification indicates at column 8, lines 5-8, that "[a]ny number of conventional positionsensing systems can be used to determine the position of the ultrasound probe with respect to the linear accelerator," 35 U.S.C. s. 112, para. 6 does not allow such broad language to have operative effect. Only the disclosed structures and their equivalents may be covered. *See, e.g.,* Fonar Corp., 107 F.3d at 1551; Faroudja Labs., 76 F.Supp.2d at 1010-1013. The additional language ZMED proposes, "[t]he LED or ultrasonic emitter must be attached to the ultrasound probe and the camera or microphone must be attached to the room," creates unnecessary limitations on the means for indicating the position of the means for generating the at least one ultrasound image. *See* Acromed Corp., 253 F.3d at 1382. Most likely, the LED or ultrasonic emitter must be attached to the ultrasound probe to be useful, but it is entirely unclear why the camera or microphone must be attached to the room rather than any other fixed point within the room (for example). Accordingly, ZMED's proposed language is not adopted.

4. Claim 1; Element (b): Part (II)

Text:

... whereby the position of the lesion in the ultrasound image can be compared with a position of the lesion in the radiation therapy plan. '026 Patent, col. 12, ll. 16-19. *NOMOS's Proposed Construction:*

[T]he whereby clause of element (b) of claim 1 should be construed to mean that the system must be structured to compare the position of the lesion in the two dimensional image generated by the ultrasound probe with the position of the lesion identified in the radiation therapy plan. NOMOS Opening Brief at 12 (quotation marks and citation omitted). *ZMED's Proposed Construction:*

The claimed system must be structured to compare (undefined) the position of the lesion in the 2D image which is the direct output of the ultrasound probe with the position of the lesion identified in the radiation therapy plan. ZMED Opening Brief at 21.

Construction:

The whereby clause of element (b) of claim 1 means "the system must be structured to compare the position of the lesion in the two-dimensional image generated by the ultrasound probe with the position of the lesion identified in the radiation therapy plan."

5. Claim 6: Preamble

Text:

6. A method for verifying the position of a lesion, having an outer surface, within a body of a patient for use in a radiation treatment plan which includes a plurality of diagnostic images, which each depict an outline of the outer surface of the lesion, comprising the steps of:

'026 Patent, col. 12, 11. 37-42.

NOMOS's Proposed Construction:

NOMOS indicates that the preamble should be given the effect of a claim limitation "[f]or the same reasons given above with respect to the preamble to claim 1." NOMOS Opening Brief at 9. Returning to NOMOS's position for the preamble to claim 1 reveals the following proposal:

Thus, the lesion position verification system of claim 1 [here, claim 10] should be construed as a system that functions with a radiation therapy device and a radiation therapy plan.

NOMOS Opening Brief at 9.

ZMED's Proposed Construction:

The preamble specifies a "method" which would be one or more steps to verify the position of a lesion. This method must be useable in a radiation therapy plan. The radiation therapy plan includes a plurality of diagnostic images, which each depict an outline of the outer surface of the lesion. ZMED Opening Brief at 24. *Construction:*

[8] The preamble to claim 6 is a claim limitation, limiting the claim to a system that functions with a radiation therapy device and a radiation therapy plan.

Commentary:

Many of the steps of claim 10 refer back to the preamble, using the phrases " *the* lesion," " *the* radiation therapy plan," " *the* radiation therapy device," " *the* outer surface," " *the* diagnostic images," and " *the* outlines." Accordingly, when looking at the patent as a whole, the preamble is essential for understanding claim 6. *See* Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999).

6. Claim 6: Step (a)

Text:

(a) disposing the patient on a treatment table of a radiation therapy device;
'026 Patent, col. 12, ll. 43-44. *NOMOS's Proposed Construction:*

[A]rranging the position of the patient in relation to or near the treatment table ... (i.e. positioned in relation to the treatment table, and in fact in contact with it). NOMOS Opening Brief at 14-15. ZMED's Proposed Construction: This step requires placing the patient on a treatment table of a radiation therapy device. ZMED Opening Brief at 25. *Construction:*

[9] Step (a) means "placing the patient on (in contact with and supported by) a treatment table of a radiation therapy device."

Commentary:

[10] This dispute centers on the construction of the words "disposing" and "on." A term should be given its ordinary meaning unless the patent owner chooses to be his or her own lexicographer. Monroe Eng'g Prods., Inc. v. J.W. Winco, Inc., 915 F.Supp. 901, 905 (E.D.Mich.1996), *aff'd in part, rev'd in part*, Monroe Eng'g Prods., Inc. v. J.W. Winco, Inc., 121 F.3d 728 (Fed.Cir.1997). Here, the term "disposing" is not defined in the patent, but is used repeatedly. *See, e.g.*, '026 Patent, col. 5, In 32; col. 6, 1. 16; col. 7, Il. 8, 14, and 56; and col. 8, Il. 32, 34. By comparing the various places in which the term is used, I conclude that, in context, "dispose" means "to place." Meaning is least strained by this definition across Steps (a)-(c) of claim 6.

The word "on," of course, has a range of meanings. Here, the most reasonable construction of the word, and the one which reflects its ordinary and common use, Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984), is "in contact with and supported by."

7. Claim 6: Step (b)

Text:

(b) disposing on the treatment table a means for generating an ultrasound image; '026 Patent, col. 12, ll. 45-46. *NOMOS's Proposed Construction:*

[A]rranging the position of the ultrasound probe in relation to or near the treatment table ... (positioned in relation to or) near the treatment table. NOMOS Opening Brief at 14-15. ZMED's Proposed Construction:

This step requires attaching a conventional, commercially available 2D ultrasoundprobe to the treatment table. The probe must be mounted to the treatment table by means of a bracket. The probe is mounted so it can be moved upwardly and downwardly with respect to the bracket. ZMED Opening Brief at 26. *Construction:*

Step (b) means "placing on (in contact with and supported by) the treatment table a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image (and its equivalent)."

Commentary:

The plain language compels this reading of Step (b), once the meaning of "disposing" and "on" are established. In consonance with the analysis of claim 1, step (a), the means for generating at least one ultrasound image of the lesion in the patient's body must be a conventional, commercially available

ultrasound probe that generates a two-dimensional ultrasound image (and its equivalent).

8. Claim 6: Step (c)

Text:

(c) generating at least one two-dimensional ultrasound image of the lesion in the patient's body, with the ultrasound image generating means being disposed in a known geometric orientation for each ultrasound image generated;

'026 Patent, col. 12, ll. 47-51. NOMOS's Proposed Construction:

[T]he ultrasound probe is disposed (i.e. arranged) in a known geometric position under circumstances where the position of the ultrasound probe with respect to the radiation therapy device is indicated. NOMOS Opening Brief at 15. *ZMED's Proposed Construction:*

This step requires using the ultrasound probe to generate a two dimensional ultrasound image (which is the direct 2D output of the ultrasound probe) for use in identifying the position of the lesion and knowing the orientation and position of the probe at the time the image is made. ZMED Opening Brief at 27. *Construction:*

This step means "placing a conventional, commercially available ultrasound probe that generates a twodimensional ultrasound image in a known geometric orientation when each ultrasound image is generated of the lesion in the patient's body."

Commentary:

The plain language of step (c) compels this reading, once the meaning of "disposing" is established.

9. Claim 6: Step (d)

Text:

(d) outlining the outer surface of the lesion in at least one of said ultrasound images; and '026 Patent, col. 12, ll. 52-53. *NOMOS's Proposed Construction:*

Step (d) should be interpreted as identifying the surface of the lesion in the ultrasound image and creating an outline of the surface of the lesion. This outlining may, for example, be accomplished using a conventional software program. Several methods were available at the time of the '026 patent to accomplish this. One embodiment of "outlining" would require a physician to trace a line on an image of the lesion, which was projected on a workstation display. Another embodiment would require the physician to adjust the contrast of the image so that the surface of the lesion was well defined. Another embodiment would use image processing algorithms that automatically identify the surface of the lesion. NOMOS Opening Brief at 15 (citations omitted). *ZMED's Proposed Construction:*

This step requires taking the two dimensional ultrasound image created by the probe and using the computer to draw a line along the surface of the lesion in that image. ZMED Opening Brief at 27. *Construction:*

[11] Step (d) means "using computer software either to draw a line around the image of the surface of the lesion manually or through image processing algorithms that automatically identify the surface of the lesion, in at least one of said ultrasound images."

Commentary:

The term "outlining" is clarified by reference to intrinsic evidence (the specification and prosecution history). The specification states:

the outer surface of the lesion in each ultrasound image is outlined, such outlining being performed by a conventional software program, such as in the radiation treatment planning system previously described, which permits a physician to outline the outer surfaces of each ultrasound image, in a similar manner in which the outer surface of lesion was outlined on the diagnostic images, or slices

'026 Patent, col. 7., ll. 32-40 (figure numbers omitted). The "radiation treatment planning system previously described," is of no help.

I conclude that a person skilled in the art would interpret the word "outline" to mean using computer software either to draw a line around the image of the surface of the lesion manually or through image processing algorithms that automatically identify the surface of the lesion, in at least one of said ultrasound images. *See* Electro Med. Sys., S.A., v. Cooper Life Scis., Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994) ("Claims speak to those skilled in the art."). It does not include adjusting the contrast to see the surface of the lesion better.

10. Claim 6: Step (e)

Text:

(e) comparing the outlines of the outer surface of the lesion of the said at least one ultrasound image with the outline of the outer surface of the lesion of at least one of the diagnostic images, whereby the position of the lesion with respect to the radiation therapy device may be verified to conform to a desired position of the lesion in the radiation treatment plan.

'026 Patent, col. 12, ll. 54-61.

NOMOS's Proposed Construction:

NOMOS submits that step (e) of claim 6 is clear on its face, and may be construed in accordance with the plain meaning which is not altered by the specification of the '026 patent. NOMOS Opening Brief at 16 (citations omitted).

ZMED's Proposed Construction:

This step requires comparing the computer generated line drawn along the surface of the lesion in the twodimensional ultrasound image to the computer generated line drawn along the surface of the lesion in a two dimensional image from the treatment plan. ZMED Opening Brief at 28. *Construction:*

[12] Step (e) means "comparing the two-dimensional outlines of the outer surface of the lesion generated from the at least one ultrasound image (which has positional data regarding the third dimension), with the three-dimensional rendering outline of the outer surface of the lesion generated from the at least one of diagnostic images, whereby the position of the lesion with respect to the radiation therapy device may be verified to conform to a desired position of the lesion in the radiation treatment plan."

Commentary:

Since step (e) is not a means plus function claim, the analysis starts and ends, if possible, with the claim language. Looking at the claim language, I interpret the outlines in question to be two-dimensional outlines compared to a three-dimensional rendering outline from the "at least one of the diagnostic images."

The second outline must be three-dimensional because of a slight difference in language:

comparing the *outlines* of the outer surface of the lesion of the said at least one ultrasound image with the *outline* of the outer surface of the lesion of at least one of the diagnostic images

'026 Patent, col. 12, ll. 54-57 (emphasis added). A *single* " *outline* of the outer surface of the lesion" can only be a three-dimensional outline (the actual surface of a lesion cannot be two-dimensional). Therefore, the second "outline" must be, from the claim language, a three-dimensional rendering generated from the initial imaging device. The specification supports this interpretation. *See, e.g.*, '026 Patent, col. 8, ll. 60-62.

The claim language in step (e) alone does not allow for a determination of whether the first "outlines" are two-dimensional or three-dimensional because the word is plural. However, I determine that the "outlines" being discussed in step (e) are in fact two-dimensional, drawn on specific two-dimensional ultrasound images which contain positional information regarding the third dimension, despite the fact that they could be combined to create a three-dimensional rendering.

As described above in claim 6, the ultrasound probe must be a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image. It therefore makes sense that the first "outlines" must be on two-dimensional ultrasound images. Additionally, while it is conceivable that several three-dimensional rendering "outlines" would be compared to the single three-dimensional rendering "outline" of the outer surface of the lesion generated from the diagnostic images, comparing several two-dimensional "outlines" better explains the use of the plural "outlines." Finally, I make this determination in light of claim 16 of the '026 patent, which explicitly discusses comparing a three-dimensional rendering to a three-dimensional rendering. Under the doctrine of claim different language. Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed.Cir.1991) (explaining that different claims should be construed, when possible, to cover different inventions). FN1

FN1. It is true that this construction is not in complete harmony with the specification, which describes converting the outlines into three-dimensional renderings. *See, e.g.*, '026 Patent, col. 7, ll. 44-47, 52-54; col. 8, ll. 56-62. However, the claim language should control when there is an apparent conflict between the claim language and the specification.

II. Construction of ZMED's '154 Patent

1. Claim 1: Preamble

Text:

1. A method for determining the position of a patient's organ with respect to at least two imaging devices, including the following steps: '154 Patent, col. 11, 11. 9-11.

ZMED's Proposed Construction:

The claim method is for determining the location of a patient's organ using two imaging devices.... The plain and ordinary reading of the preamble indicates the preamble merely sets forth the purpose of the method and should not be construed as a limitation.

ZMED Opening Brief at 7. NOMOS's Proposed Construction:

NOMOS agrees that the preamble is not a claim limitation. Oral Argument at 66. *Construction:*

The preamble is not a claim limitation.

2. Claim 1: Step (a) FN2

FN2. The '154 patent does not use letters such as "(a)" to mark each subpart in its claims. The parties, however, have referred to each subpart as a "step" and designated them with letters. In the interest of clarity, I adopt this nomenclature for both claim 1 and claim 10 of the '154 patent.

Text:

making at least one 3D first image of an organ of a patient having a first coordinate system and of a surface of the organ or skin region with a first imaging device while the patient is in a pre-operation site without fixing any mark to the patient;

'154 Patent, col. 11, 11. 12-16. ZMED's Proposed Construction:

Making a 3D image or rendering of the organ of interest. This could be done by use of a CT scan or an MRI. The image is taken with respect to a first coordinate system, for example, the coordinate system of the first imaging device, a point in the room containing the first imaging device or the radiation therapy plan. ZMED, Inc.'s Br. in Opp. To NOMOS Corp.'s Proposed Construction of the Claims of U.S. Patent No. 5,411,026 and U.S. Patent No. 5,447,154 ("ZMED Opposition Brief") at 4. *NOMOS's Proposed Construction:*

[T]he specification of the '154 patent describes the step of making a first image as "making at least one 3D

image of the organ and of its surface or of the surface of the skin region with the first imaging device." Particularly, the specification of the '154 patent describes the first image as a 3D image generated by X-ray scanner or MRI device.

NOMOS Opening Brief at 20 (citations omitted).

NOMOS agreed at oral argument with ZMED's construction up to the point at which ZMED suggests that the image would be taken with respect to a first coordinate system, "of the first imaging device, a point in the room containing the first imaging device or the radiation therapy plan." Oral Argument at 66.

Construction:

Step (a) means "making a three-dimensional rendering of the organ of interest. This may be done by use of a CT or a MRI device. The image is taken with respect to a first coordinate system while the patient is in a pre-operation site and without fixing any mark to the patient."

Commentary:

The additional detail that ZMED seeks, "for example, the coordinate system of the first imaging device, a point in the room containing the first imaging device or the radiation therapy plan," is unnecessary and not within the claim language, and therefore is omitted.

3. Claim 1: Step (b)

Text:

placing the patient in an operation site having a second coordinate system; '154 Patent, col. 11, 11. 17-18. *ZMED's Proposed Construction:*

Putting the patient in a location relative to a second coordinate system, for example, the coordinate system of the treatment room or the second imaging device.

ZMED Opening Brief at 8. NOMOS's Proposed Construction:

NOMOS agreed at oral argument with ZMED's construction up to the point at which ZMED suggests that the patient would be placed relative to a second coordinate system, "for example, the coordinate system of the treatment room or the second imaging device." Oral Argument at 66-67.

Construction:

Step (b) means "placing the patient in a location at the operation site relative to a second coordinate system."

Commentary:

The additional detail that ZMED proposes, "for example, the coordinate system of the treatment room or the second imaging device," is unnecessary and not within the claim language, and therefore is omitted.

4. Claim 1: Step (c)

Text:

determining a first position of a second imaging device with respect to the second coordinate system of the operation site;

'154 Patent, col. 11, 11. 19-21. ZMED's Proposed Construction:

Determining the position of the second imaging device (e.g., the ultrasound probe) relative to the second coordinate system (the treatment device coordinate system, the second device coordinate system, etc.). ZMED Opening Brief at 8.

NOMOS's Proposed Construction:

NOMOS agreed at oral argument with ZMED's construction up to the point at which ZMED suggests that the second imaging device would be placed relative to a second coordinate system, "(the treatment device coordinate system, the second device coordinate system, etc.)." Oral Argument at 67.

Construction:

Step (c) means "determining the position of the second imaging device (e.g., the ultrasound probe) relative to the second coordinate system."

Commentary:

The additional detail that ZMED wants, "(the treatment device coordinate system, the second device coordinate system, etc.)," is unnecessary and not within the claim language, and therefore is omitted.

5. Claim 1: Step (d)

Text:

making a second image with said second imaging device, the second image corresponding to a cloud of points of the surface of the organ or skin region; '154 Patent, col. 11, 11. 22-24.

ZMED's Proposed Construction:

Using the second imaging device (e.g., the ultrasound probe) to make an image showing the organ. ZMED Opening Brief at 9. *NOMOS's Proposed Construction:*

While the vague and ambiguous term "cloud of points" is not defined at all in the '154 patent, the "second image corresponding to a cloud of points" of step (d) must be construed to be a "3D image." Moreover the specification of the '154 patent supports the interpretation of the "second image corresponding to a cloud of points" as being a "3D image." Particularly, the specification describes the second image as a 3D image generated by either (1) an echography probe where the 3D image sought is that of a cloud of surface points of an organ, or (2) a non-contact 3D surface imaging device where the image sought is of a skin region. Therefore, when construed in light of the specification, the second image that is specified in step (d) of claim 1 is a 3D image. NOMOS Opening Brief at 20-21 (citations omitted).

Construction:

[13] Step (d) means "using the second imaging device (e.g., the ultrasound probe that takes two-dimensional images) to make a three-dimensional rendering showing the organ."

Commentary:

Analysis begins with the claim language. As the parties acknowledge, "the second image corresponding to a cloud of points of the surface of the organ or skin region," is ambiguous. Therefore, reference to the specification must be made.

The specification, unfortunately, is jumbled. On the one hand, it indicates that the ultrasound probe takes images in a "plane" and "a viewing plane." '154 Patent, col. 3, 1. 60; col. 5, 11. 22-23. By definition, images of planes or viewing planes are two-dimensional. But on the other hand, the specification repeatedly refers to the second image as a "3D morphologic image." '154 Patent, col. 3, 11. 21, 24, and 35.

However, some clarification may be derived from the specification:

One of the originalities of the invention lies in the use of a device that does not provide functional information but only images of surface points to serve as an intermediate device operable for matching different coordinate systems. In particular, the idea of using an echography [ultrasound] probe to carry out this coordinate alignment is one of the aspects of the invention since, a priori, an echography image provides less valuable information than a MRI or scanner-type apparatus. Indeed, echography usually provides a series of plane and independent cross-sectional images of an organ instead of a volume image structured in series of parallel image slices.

'154 Patent, col. 3, 11. 51-62. The paragraph explains that an ultrasound device *usually* makes twodimensional images, but impliedly is not used to do so in the '154 patent. Instead, the ultrasound probe here is used not to create its usual two-dimensional images, but rather to create "images of surface points." I find that the "surface points" are the same as "a cloud of points of the surface" in the claim itself (although neither party so argues). This meaning of "a cloud of points" is buttressed by the statement in the specification that "[i]n an embodiment, the present invention aims at providing a method in which the onsite image results from a cloud of points obtained by echography examination of the region of interest, which permits visualizing objects that have been previously segmented." '154 Patent, col. 7, 11. 10-14.

Consequently, "the second image corresponding to a cloud of points of the surface of the organ or skin region" must be a three-dimensional rendering, as the surface of an organ or skin region, even if mostly flat, is still a three-dimensional surface. The direct output of the ultrasound probe, a two-dimensional image, is not the "second image" being discussed in the claim.

This conclusion is reinforced by a discussion in the specification of the drawbacks in matching threedimensional and two-dimensional images. '154 Patent, col. 2., 1. 34-col. 3., 1. 5. The discussion implies that this invention is a remedy to those problems.

6. Claim 1: Step (e)

Text:

matching the at least one 3D first image and the second image where the at least one 3D first image is located with respect to the first coordinate system of the patient.

'154 Patent, col. 11, 11. 25-28. **ZMED's Proposed Construction:**

Matching the image of the organ taken in the pre-operation site (by the CT scan or MRI device) with the appropriate ultrasound image taken in the operation site by localizing the first and second coordinate systems to allow a comparison of the position of the organ in the two images.

ZMED Opening Brief at 9 (citation omitted).

NOMOS's Proposed Construction:

[S]tep (e) of claim 1 can only properly be construed as providing the step of merging or combining the 3D first image and the 3D second image, or, more particularly, as providing the step of aligning the coordinate system of the 3D first image generated by the MRI device with the coordinate system of the 3D second image generated by the echography probe.

NOMOS Opening Brief at 21 (citation omitted). Construction:

[14] Step (e) means "aligning the at least one three-dimensional first rendering, which is located with respect to the first coordinate system, with the three-dimensional second rendering."

Commentary:

Step (d) determined that the second image should be construed to be a three-dimensional rendering. The remaining dispute in step (e) centers around the term "matching."

If the meaning of "matching" were not clear, then it would be appropriate to turn to the specification to find meaning for the term. In the specification, the word "matching" is defined by inference twice, once to mean "combin[ing]" and once to mean "merg[ing]." '154 Patent, col. 3., 11. 17-18; col. 9, 1.23. It is also referred to as "localiz[ing]." '154 Patent, col. 5., 1.62.

However, the common-sense understanding of "matching" in this context is "aligning," and therefore I adopt that definition based on the plain language of the claim. As a note, it is the three-dimensional renderings that are aligned, not necessarily their coordinate systems.

7. Claim 1: Step (f)

Text:

providing a third device having a third coordinate system in the operation site and determining a first position of the third device with respect to the second image of the second imaging device, whereby the third coordinate system of the third device is positioned with respect to the second image of the second imaging device and thereby with respect to the at least one 3D first image from the first imaging device. '154 Patent, col. 11, 11. 29-37.

ZMED's Proposed Construction:

Providing a third device (e.g., a linear accelerator) having its own coordinate system (e.g., relative to the isocenter) and determining the position of the third device relative to the position of the second image (and thus the organ) and moving the machine and patient relative to each other to place the third device in the desired position relative to the organ.

ZMED Opening Brief at 11.

NOMOS's Proposed Construction:

The "third device having a third coordinate system" of step (f) of claim 1 is defined in the specification of the '154 patent as being an imaging device such as a gamma-scintigraphy camera, a positron emission tomography (PET) apparatus, a magnetoencephalography (MEG) apparatus, or a synchrotron radiation apparatus. Accordingly, step (f) of claim 1 should be construed as the step of "providing a third imaging device having a third coordinate system."

NOMOS Opening Brief at 20-21 (citation omitted).

Construction:

[15] Step (f) means "providing a third device (e.g., a radiation transmission apparatus or an imaging device) having its own coordinate system and determining the position of the third device relative to the position of the second rendering and therefore the first rendering (and thus the organ or lesion)."

Commentary:

The "third device" may be a "third imaging device" or may be another device, such as a linear accelerator. This construction is based on the text of the claim, which uses the terms "first imaging device" and "second imaging device," but not "third imaging device." Logically, this difference suggests that "third device" is meant to be broader than simply a "third imaging device." Given the primacy of claim language in the patent construction process, that closes the inquiry. However, the specification provides additional support for this construction by listing several embodiments of the "third device," including a radiation transmission apparatus and an imaging device. *See* '154 Patent, col. 1, 11. 14-21.

8. Claim 10: Preamble

Text:

10. A method for determining the position of an organ of a patient using at least two imaging devices, comprising the steps of:
'154 Patent, col. 12, 11. 62-64.
ZMED's Proposed Construction:

The claimed method is for purposes of determining the location of a patient's organ using two imaging devices.

ZMED Opening Brief at 11. NOMOS's Proposed Construction:

NOMOS agrees that the preamble is not a claim limitation. Oral Argument at 86.

Construction:

The preamble of claim 10 of the '154 patent is not a claim limitation.

9. Claim 10: Step (a)

Text:

making a first image of the organ with respect to a first coordinate system using a first imaging device;

'154 Patent, col. 12, 11. 65-66. ZMED's Proposed Construction:

Making an image or rendering of the organ of interest. This could be done by use of a CT scan or an MRI. The image is taken with respect to a first coordinate system, for example, the coordinate system of the first imaging device, a point in the room contain the first imaging device or the radiation therapy plan. ZMED Opening Brief at 12.

NOMOS's Proposed Construction:

The specification describes the step of making a first image as "making at least one 3D image of the organ and of its surface or of the surface of the skin region with the first imaging device." The "first imaging device" should be construed to mean a CT or MRI device that makes three-dimensional images of an organ in a patient's body.

NOMOS Opening Brief at 22 (citations omitted).

NOMOS agreed at oral argument with the ZMED construction up to the point at which ZMED describes the second coordinate system, "for example, the coordinate system of the first imaging device, a point in the room contain the first imaging device or the radiation therapy plan." Oral Argument at 86-87.

Construction:

[16] Step (a) of claim 10 means "making a three-dimensional rendering of the organ of interest. This may be done by use of a CT or a MRI device. The rendering is taken with respect to a first coordinate system."

Commentary:

As with claim 1 of the '154 patent, the additional detail that ZMED seeks, "for example, the coordinate system of the first imaging device, a point in the room contain the first imaging device or the radiation therapy plan," is unnecessary and not within the claim language, and therefore is omitted.

As to whether the "first image" is two-dimensional or three-dimensional, the parties have not focused their arguments on this issue in claim 10 in step (a). I find that the "first image" should be a three-dimensional rendering, as explained in detail in claim 10, step (e), of the '154 patent below.

10. Claim 10: Step (b)

Text:

placing the patient with respect to a second coordinate system; '154 Patent, col. 12, 11. 67-68. *ZMED's Proposed Construction:*

Placing the patient in a location relative to a second coordinate system, for example, the coordinate system of the treatment room or the second imaging device. ZMED Opening Brief at 13. *NOMOS's Proposed Construction:*

NOMOS agreed at oral argument with the ZMED construction up to the point at which ZMED describes the second coordinate system, "for example, the coordinate system of the treatment room or the second imaging device." Oral Argument at 86-87.

Construction:

Step (b) means "placing the patient in a location relative to a second coordinate system."

Commentary:

The additional detail that ZMED proposes, "for example, the coordinate system of the treatment room or the second imaging device," is unnecessary and not within the claim language, and therefore is omitted.

11. Claim 10: Step (c)

Text:

determining a first position of a second imaging device with respect to the second coordinate system; '154 Patent, col. 13, 11. 1-2. **ZMED's Proposed Construction:**

Determining the position of the second imaging device (e.g., the ultrasound probe) relative to the second coordinate system (the treatment device coordinate system, the second device coordinate system, etc.). ZMED Opening Brief at 13. *NOMOS's Proposed Construction:*

NOMOS agreed at oral argument with the ZMED construction up to the point at which ZMED describes the second coordinate system, "(the treatment device coordinate system, the second device coordinate system, etc.)." Oral Argument at 86-87.

Construction:

Step (c) means "determining the position of the second imaging device (e.g., the ultrasound probe) relative to the second coordinate system."

Commentary:

The additional detail that ZMED suggests, "(the treatment device coordinate system, the second device coordinate system, etc.)," is unnecessary and not within the claim language, and accordingly is omitted.

12. Claim 10: Step (d)

Text:

making a second image with said second imaging device; '154 Patent, col. 13, 11. 3-4. ZMED's Proposed Construction:

Using the second imaging device (e.g., the ultrasound probe) to make an image showing the organ. ZMED Opening Brief at 14. *NOMOS's Proposed Construction:*

The specification describes the step of "making a second image" as making a 3D image with (1) an

echography probe (i.e., ultrasound) where the 3D image sought is obtained by imaging a cloud of surface points of an organ, or (2) a non-contact 3D surface imaging device where the image sought is of a skin region. Furthermore ... the narrower disclosed meaning (3D second image) must be adopted for the second image.

NOMOS Opening Brief at 23. *Construction:*

[17] Step (d) of claim 10 means "using the second imaging device (a two-dimensional ultrasound probe) to make a three-dimensional rendering showing the organ."

Commentary:

The language of claim 10, step (d), differs from claim 1, step (d), in that it omits reference to a "cloud of points," which was a basis for concluding that the "second image" should be a three-dimensional rendering in claim 1. The "second image," freed from having to correspond to a "cloud of points," could be two-dimensional or three-dimensional. Since ZMED admits that there were no true three-dimensional ultrasound probes when this patent was filed and under consideration, Oral Argument at 18, then the ultrasound probe must produce, as a direct output, two-dimensional images only. It follows that because the plain language of the step is "making a second image with said second imaging device," the "second image" might simply be the output of the "second imaging device," which is a two-dimensional image. Accordingly, claim 10 could be read to be broader than claim 1.

However, claim 10 recounts making only one "second image," which, to be accurate, must be threedimensional, not two-dimensional (a single two-dimensional image could not locate an organ or lesion precisely in the body). Moreover, the specification, while conflicted, leads to the conclusion that it should be only a three-dimensional rendering that is being created.*See* claim 1, step (d), of the '154 patent above.

13. Claim 10: Step (e)

Text:

matching the first image and the second image; and '154 Patent, col. 13, 1. 5. **ZMED's Proposed Construction:**

Matching the image of the organ taken in the pre-operation site (by the CT device or MRI device) with the appropriate ultrasound image taken in the operation site by localizing the first and second coordinate systems to allow a comparison of the position of the organ in the two images. ZMED Opening Brief at 14. *NOMOS's Proposed Construction:*

[S]tep (e) of Claim 10 can only properly be construed as providing the step of merging or combining the 3D first image and the 3D second image, or, more particularly, as providing the step of aligning the coordinate system of the 3D first image generated by the MRI device with the coordinate system of the 3D second image generated by the echography probe.

NOMOS Opening Brief at 23 (citation omitted). *Construction:*

[18] Step (e) means "aligning the three-dimensional first rendering with the three-dimensional second

rendering by reference to their separate coordinate systems."

Commentary:

There was little argument in step (a) of claim 10 of the '154 patent about whether the "first image" would be two-dimensional or three-dimensional. Instead, that debate is focused in step (e). Because the claim language in steps (a), (e), and (f) of claim 1 specifies that the "first image" should be three-dimensional, and claim 10 does not so specify, it follows that the first image under claim 10 could be either two-dimensional or three-dimensional. However, claim 10 only refers to a single first image, whereas steps (a), (e), and (f) of claim 1 contemplate "at least one 3D image." Accordingly, the claim language works both ways: it implies by omission that it could be two-dimensional or three-dimensional, but also, by using the singular "first image," implies that it must be three-dimensional, as a single two-dimensional image would not accurately determine the position of an organ or lesion.

I find that the "first image" must be a three-dimensional rendering, relying on the principles of claim construction that emphasize construing claims to be valid and to embrace the narrower possible meaning when two possibilities arise. *See* 35 U.S.C. s. 101 (requiring invention to be "useful" to obtain a patent); Talbert Fuel Sys. Patents Co. v. Unocal Corp., 275 F.3d 1371, 1376 (Fed.Cir.2002) ("a construction that renders the claimed invention inoperable should be viewed with extreme skepticism"); Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed.Cir.1996) ("Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning."). Given the choice between a broader reading, "either two-dimensional or three-dimensional," and a narrower reading, "three-dimensional only," the law requires the selection of the narrower.

The "second image" must be a three-dimensional rendering as determined in step (d) of claim 10 of the '154 patent.

14. Claim 10: Step (f)

Text:

providing a third device having a third coordinate system and determining a first position of the third device with respect to the second image of the second imaging device, the third coordinate system of the third device positioned with respect to the second image of the second imaging device and with respect to the first image from the first imaging device.

'154 Patent, col. 13, 1. 6-col. 14, 1. 6. *ZMED's Proposed Construction:*

Providing a third device (e.g., a linear accelerator) having its own coordinate system (e.g., relative to the isocenter) and determining the position of the third device relative to the position of the second image (and thus the organ) and moving the machine and patient relative to each other to place the third device in the desired position relative to the organ.

ZMED Opening Brief at 15. NOMOS's Proposed Construction:

[S]tep (f) of claim 10 should ... be construed as the step of "providing a third imaging device having a third

coordinate system." NOMOS Opening Brief at 24 (citation omitted). *Construction:*

[19] Step (f) means "providing a third device (e.g., a radiation transmission apparatus or an imaging device) having its own coordinate system and determining the position of the third device relative to the position of the second rendering and therefore the first rendering (and thus the organ or lesion)."

Commentary:

This language is the nearly same as in claim 1, step (f), of the '154 patent. The "third device" may be a "third imaging device" or may be another device, such as a linear accelerator. This construction is appropriate based on the plain language of the claim. The claim language uses the terms "first imaging device" and "second imaging device," but not "third imaging device," which logically implies that "third device" is meant to be broader than simply a "third imaging device." Given the primacy of claim language in the patent construction process, that closes the inquiry. However, the specification provides further support for this construction by listing several embodiments of the "third device," including a radiation transmission apparatus and an imaging device. *See* '154 Patent, col. 1, 11. 14-21.

III.

The terms of the '026 patent and '154 patent are construed as described above.

It is so ordered.

MEMORANDUM AND ORDER

This patent case concerns competing devices designed to increase the accuracy with which organs and lesions inside the human body can be located and, in turn, improve the effectiveness of radiation treatment. On June 26, 2002, the Court issued a Memorandum and Order construing the claims of the '026 and '154 patents known as a *Markman* decision. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed.Cir.1995), aff'd, 517 U.S. 370, 388-390, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

By letter of July 15, 2002, NOMOS asked the Court to correct what it considers to be a typographical error in the Markman decision. The matter in question relates to element (a) of claim 1 of NOMOS' '026 patent. I construed that element as:

The means for generating at least one ultrasound image of the lesion in the patient's body must be a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image (and its equivalent), mounted to the treatment table by means of a bracket or fixation device.

NOMOS suggests that the phrase "(and its equivalent)" should be moved to the end of the entire sentence, and switched to the phrase "(and equivalents thereof)."

ZMED responds that NOMOS' letter amounts to a request for reconsideration of the decision, under the guise of correcting a typographical error. It asserts that the Marksman decision ruled that a bracket fixation device is "require [d]," and therefore no change is necessary.

Under 35 U.S.C. s. 112, a means plus function claim such as NOMOS claim 1 is construed to cover the means disclosed in the specification *and* any equivalent structures. Since I held that the means disclosed was "a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image, mounted to the treatment table by means of a bracket or fixation device," the phrase indicating the coverage of equivalent structures should go at the end of the phrase, not the middle.

Accordingly, the construction of element (a) in claim 1 of NOMOS' patent is corrected to read:

The means for generating at least one ultrasound image of the lesion in the patient's body must be a conventional, commercially available ultrasound probe that generates a two-dimensional ultrasound image mounted to the treatment table by means of a bracket or fixation device (and equivalents thereof).

It is so ordered.

D.Mass.,2002. NOMOS Corp. v. ZMED, Inc.

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