United States District Court,
D. Oregon.

SMITH & NEPHEW, INC., and John O. Hayhurst, M.D,
Plaintiffs.
v.
BIOMET, INC., and Arthrotek, Inc,
Defendants.

No. 05-611-KI

Nov. 21, 2005.

Brenna K. Legaard, Chemoff, Vilhauer, McClung & Stenzel, LLP, Portland, Oregon, for Plaintiffs.

Robert C. Weaver, Jr., Laura Caldera Taylor, Garvey Schubert Barer, Portland, Oregon, Richard D. Harris, Herbert H. Finn, Greenberg Traurig, LLP, Chicago, Illinois, for Defendants.

OPINION AND ORDER

KING**, J.**

Smith & Nephew, Inc. and John O. Hayhurst, M.D. (collectively, "Smith & Nephew") charge Biomet, Inc. and Arthrotek, Inc. (collectively "Biomet") with infringing Smith & Nephew's patent for a medical device used to repair meniscal tears during arthroscopic surgery. Before the court is Smith & Nephew's Motion for Preliminary Injunction (# 6) and Smith & Nephew's Motion to Strike the Declaration of Stephen G. Kunin (# 73). For the following reasons, I grant Smith & Nephew's motion for a preliminary injunction and grant in part and deny in part its motion to strike.

FACTUAL BACKGROUND

Smith & Nephew's complaint alleges that Dr. Hayhurst is the owner of U.S. Patent No. 5,417,691 (the " '691 patent"), that Smith & Nephew (previously Acufex) is the exclusive licensee of the '691 patent, and that Biomet's Sure Fire medical device infringes on the '691 patent. Smith & Nephew asserts in its moving papers that the '691 patent covers what it calls its T-Fix and FasT-Fix products. Biomet, in turn, contends that the '691 patent covers only Smith & Nephew's T-Fix. Both parties agree that for the most part Smith & Nephew's FasT-Fix and Biomet's Sure Fire device are similar medical devices, both in appearance and in operation.

The T-Fix, sold since 1994, is the earlier version of the FasT-Fix, which was first introduced in 2001. FN1 The T-Fix, invented by plaintiff Dr. Hayhurst, is comprised of a single elongated anchor member and attached suture, which can be used to hold torn meniscus in the human knee during arthroscopic surgery, as a form of surgical clamp, or to reattach and promote healing of torn meniscus. The T-Fix requires that the

anchor member and attached suture be loaded into a hollow needle. The surgeon then inserts the needle into the tissue and pushes an expelling member, or a hollow tube located inside the needle and behind the anchor member, toward the end of the needle. The expelling member propels the anchor member from within the needle into the tissue being sutured. To secure the first suture, the surgeon must use a separate T-Fix to tighten and knot the two sutures, or use another type of securing device.

FN1. Although the structure of the T-Fix is irrelevant for purposes of deciding this motion, I have set forth a description of the product to enhance the understanding of the FasT-Fix and Sure Fire devices.

The Sure Fire and FasT-Fix, which also may be used to close torn meniscus in the human knee to promote healing, are comprised of *two* elongated anchor members attached to a length of suture. Like the T-Fix, the Sure Fire device and the FasT-Fix have anchor members loaded into a needle and the anchor members are deployed from the needle into the area of the torn meniscus. Unlike the T-Fix, however, on both devices, the first anchor protrudes slightly from the top of the needle through a slit in the needle. Thus, as the needle is removed from the tissue, the anchor *catches* on the tissue thereby releasing it from the needle. In other words, the FasT-Fix and Sure Fire devices do not use an expelling member to propel the anchors from the needle into the tissue.

With the FasT-Fix and Sure Fire, the surgeon moves the needle about 4-5 millimeters farther down the tear, and uses a slide button to deploy the second anchor to the end of the needle so that the second anchor takes the position of the first anchor within the needle. Again, the surgeon allows the anchor to catch on the tissue in the same manner as the first anchor. Once both anchors are caught, the surgeon removes the needle leaving behind the length of suture. The surgeon can then pull the suture, closing the meniscal tear. The two anchors, then, allow the surgeon to close the meniscal tear more efficiently and avoid the need for using a separate securing device to tighten and knot the sutures.

Smith & Nephew alleges that Biomet's Sure Fire device infringes at least claims 13, 15, 18, 23 and 24 of the '691 patent, directly, and/or contributorily, and/or by inducing others to infringe. Claims 13, 23 and 24 are product claims, which cover the device itself. Claims 15 and 18 are method claims, which cover the surgical procedure that is performed when the product is used.

Smith & Nephew seeks a preliminary injunction against Biomet to stop Biomet from infringing on the '691 patent with its Sure Fire device.

DISCUSSION

I. *Smith & Nephew's Motion to Strike the Declaration of Stephen G. Kunin*

Smith & Nephew has filed a motion to strike a declaration submitted by Biomet in support of its response to Smith & Nephew's motion for preliminary injunction, arguing that it contains improper expert opinions. The declaration at issue is that of patent attorney Stephen G. Kunin. Kunin, the former Deputy Commissioner of the United States Patent and Trademark Office, offers in his declaration information related to the validity of the '691 patent.

Federal Rule of Evidence 702 permits the testimony of an expert if "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." Experts "do not testify about the law." Crow Tribe of Indians v. Racicot, 87 F.3d 1039, 1045 (9th Cir.1996) (citation

omitted). Kunin's declaration contains quotations from case law, the Code of Federal Regulations, and the Manual of Patent Examination Procedure ("MPEP"). I find that those portions of his declaration that merely recite the law should be stricken from the declaration as inappropriate expert testimony. Accordingly, I strike paragraphs 16, 17, 18, 23, and 25 from Kunin's declaration.

In addition, according to Smith & Nephew, Kunin admits he is not an expert or one of ordinary skill in the field of medical devices, yet he offers his opinion regarding double patenting based on his review of the claims in the '330 patent. *See* Kunin Dec., Ex. C.

A witness qualifies as an expert by "knowledge, skill, experience, training, or education." Fed.R.Evid. 702. I recognize that Kunin is not an expert in the field of medical devices. Nevertheless, because Kunin is experienced in examining patents and because I think his review of the application of obviousness-type double patenting to the '691 patent will be peripherally helpful to me, I do not strike those portions of his affidavit in which he opines on this subject. I do note that because the obviousness-type double patenting defense requires me to construe the claims, by giving them their customary meaning to *one of ordinary skill in the art,* Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 969 (Fed.Cir.2001) (emphasis added), I give very little credence to Kunin's opinions as he admits that he is not a technical expert in this case. Kunin Dec. para. 10.

II. ***Standards for Issuance of a Preliminary Injunction in a Patent Case***

Injunctive relief in patent cases is authorized by 35 U.S.C. s. 283, which provides that an injunction may be granted "in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." The standard for the issuance of a preliminary injunction in a patent case is determined by the law of the Federal Circuit because motions for preliminary injunction involve substantive questions unique to patent law. Hybritech, Inc. v. Abbott Labs, 849 F.2d 1446, 1451 n. 12 (Fed.Cir.1988).

In determining whether to issue a preliminary injunction, courts should balance factors including whether the movant has established: (1) a reasonable likelihood of success on the merits; (2) irreparable harm absent an injunction; (3) that the balance of hardships tips in its favor; and (4) that an injunction will have a favorable impact on the public interest. Jack Guttman, Inc. v. Kopykake Enters., 302 F.3d 1352, 1356 (Fed.Cir.2002). While granting a preliminary injunction requires analysis of all four factors, a trial court may deny a motion based on a patentee's failure to show any one of the four factors-especially either of the first two-without analyzing the others. *Id.* A clear showing of likelihood of success on the merits in a patent infringement case gives rise to a presumption of irreparable harm. Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 973 (Fed.Cir.1996).

To prove that it is likely to succeed on the merits, Smith & Nephew must demonstrate that "in light of the presumptions and burdens that will inhere at trial on the merits," FN2 (1) Smith & Nephew will likely prove infringement, and (2) Smith & Nephew's "infringement claim will likely withstand [Biomet's] challenges to the validity and enforceability of the [ ] patent." Amazon.com. Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed.Cir.2001) (citation omitted). If Biomet raises a "substantial question concerning either infringement or validity, *i.e.,* asserts an infringement or invalidity defense that the patentee cannot prove lacks substantial merit, the preliminary injunction should not issue ." Id. at 1350-51 (citation omitted).

FN2. Smith & Nephew will have to prove infringement by a preponderance of the evidence at trial.

SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 889 (Fed.Cir.1988).

I must employ a two-step analysis in determining whether Smith & Nephew will likely prove infringement. " 'First, the court determines the scope and meaning of the patent claims asserted ... [Secondly,] the properly construed claims are compared to the allegedly infringing device." ' Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed.Cir.2003) (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed.Cir.1998) (*en banc*)). Since five patent claims are involved, Smith & Nephew must show that it will not only likely prove Biomet has infringed one or more claims of the '691 patent, but also that at least one of those same allegedly infringed claims will survive validity challenges. *See* Amazon.com, 239 F.3d at 1351.

The construction of disputed claim terms begins with the intrinsic evidence, which includes the claim itself, the specification, and the prosecution history. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The starting point for claim construction is the language of the claims themselves. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201-02 (Fed.Cir.2002). Words of the claims are examined in their entirety and in the context of surrounding language. Vitronics, 90 F.3d at 1582. There is a "heavy presumption" that the terms in a claim "carry their ordinary and customary meaning" to one of ordinary skill in the art. W.E. Hall Co., Inc. v. Atlanta Corrugating, LLC, 370 F.3d 1343, 1350 (Fed.Cir.2004). Extrinsic evidence, such as expert testimony, is only considered if the intrinsic evidence does not resolve the meaning of a claim term. Vitronics, 90 F.3d at 1582.

It is improper to read a limitation from the specification into the claims. Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed.Cir.2004) ("While claims must be construed in light of the specification, limitations from the specification are not to be read into the claims, for it is the claims that measure the invention") (internal citation omitted). Furthermore, claims are limited to preferred embodiments only in very narrow circumstances. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed.Cir.2004). Nevertheless, while it is improper to interpret a patent claim as limited to the patent's disclosed embodiments, it is also improper to construe a claim in a manner that is contrary to the patent's disclosed embodiments. Vitronics Corp., 90 F.3d at 1583.

III. ***Claim Construction and Infringement***

As I indicated above, claims 13, 23, and 24 of the '691 patent are the "apparatus" claims, concerning the product itself. Claims 15 and 18 of the '691 patent are the "method" claims, concerning the method of using the product. The underlined portion of each claim below describes the element requiring construction. Biomet appears to concede infringement of all portions of the claims that are not underlined. I will construe the apparatus claims first and then the method claims.FN3

FN3. This is a tentative claim construction in order to resolve Smith & Nephew's motion for a preliminary injunction. Under the Federal Circuit's guidance, the court may "revisit[ ] and alter[ ] its interpretation of the claim terms as its understanding of the technology evolves." Jack Guttman, Inc., 302 F.3d at 1361 (citation omitted).

In its opposition to Smith & Nephew's motion for a preliminary injunction, Biomet often has not provided a proposed claim construction. Instead, it leaps immediately into a discussion about whether its Sure Fire

device infringes on the claim. However, as it recognizes in other parts of its brief, claim construction must be carried out without regard for the accused infringement. Young Dental Mfg. Co., Inc. v. Q3 Special Prods. Inc., 112 F.3d 1137, 1141 (Fed.Cir.1997). At oral argument, Biomet clarified its argument. Accordingly, I have attempted to glean a proposed claim construction from both Biomet's briefing as well as its oral argument.

A. *Claim 24*

24. An apparatus for insertion into and through tissue to provide a mechanism for manipulating and anchoring tissue within a patient, characterized by:

[a] an elongated anchor member insertable into and through the tissue;

[b] a suture attached to the anchor member, the suture having an end free for manipulating the tissue; and

[c] the anchor member having opposing end faces, at least one end face being formed in a plane that is slanted relative to the longitudinal axis of the anchor member.

Appensix A to Smith & Nephew's Memorandum for Preliminary Injunction, Ex. A (hereinafter "Ex. A"), col. 14, l. 50-60.

1. *Construction*

Biomet urges a construction of "insertable into and through the tissue" to mean the anchor member steers itself into the tissue, and is not steered into and through the tissue while contained in a needle. Indeed, according to Biomet, the claim language calls for two devices that are insertable into and through tissue, pointing to the preamble, which describes an apparatus for insertion into and through tissue, and the remainder of the claim, which calls for an elongated anchor member that, it argues, must be independently insertable into and through the tissue.

In addition, during oral argument Biomet pointed to a few references of the disputed claim language in the specification as support for its argument that the claim describes an anchor member that is separately insertable into and through the tissue. Those references are: "The anchor member *is inserted through the tissue* with the suture extending therefrom to provide a mechanism for manipulating the tissue within the joint," Ex. A, col. 2, l. 5-8 (emphasis added); "The limiting mechanism is manipulated so that the tube may be pushed forward to the tip of the needle, thereby expelling the anchor member from the tip of the needle *into or behind the piece of tissue* to be anchored," *id.,* col. 2, l. 31-34 (emphasis added); and "A rigid anchor member may be lodged within cartilage or other tissue (i.e., as opposed to being inserted between cartilage and bone) by expelling the anchor member substantially straight *into the tissue* and pulling on the suture," *id.,* col. 7, l. 51-55 (emphasis added).

Smith & Nephew responds that neither the specification nor the prosecution history supports Biomet's argument that for an anchor to be "insertable into and through the tissue" it must be capable of "steering" itself or "being projected." Instead, according to Smith & Nephew, the specification explains how the needle can be used to "deposit" the anchor. Ex. A, col. 8, l. 49-54. In addition, while "tissue" was given an explicit meaning, no definition for "into and through the tissue" appears in the specification or in the prosecution history, and the phrase does not involve any terms of art. Smith & Nephew also contends that plaintiff Dr. Hayhurst wanted to avoid damaging nerves or blood vessels by controlling the position of the anchor

member, and this goal would be undermined if the anchor member were to steer itself or be projected into tissue. *Id.,* col. 8, l. 59-63; *see* CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1160 (Fed.Cir.1997) (in construing claims, the problem the inventor was attempting to solve is relevant).

Finally, at oral argument, Smith & Nephew explained that the specification citations do not indicate whether the anchor member is inserted into and through the tissue while in the needle or while outside the needle. Insertion while in the needle is still insertion. The claim is silent as to whether the needle carries the anchor or not.

According to Smith & Nephew, the phrase "anchor member insertable into and through the tissue" should be construed to mean,

[A]n anchor member that goes both into and all the way through cartilage, tendons, ligaments and similar tissue. Further, the construction should permit the anchor members to be carried into and through the tissue by the needle-to be consistent with the disclosed embodiments-but should not read the disclosed embodiments into the claim to require that a needle be used.

Smith & Nephew's Corrected Reply Brief at 7.

I do not find support for Biomet's claim construction in the language of the claim or in the specification, and Biomet does not point me to any relevant prosecution history. The specification supports a construction of the claim that permits the needle to carry the anchor member into and through the tissue. E.g. "The anchor member is inserted through the tissue with the suture extending therefrom to provide a mechanism for manipulating the tissue within the joint," Ex. A, col. 2, l. 5-8; "The preferred means of inserting the anchor member includes a hollow needle having a sharp tip and an open butt," *id.,* col. 2, l. 11-13; "The needle tip pierces the tissue to be anchored and passes substantially through the tissue," *id.,* col. 2, l. 29-30.

Furthermore, the language of the claim does not contemplate two devices that must be separately insertable into and through tissue. Instead, the preamble's description of the claimed invention as an "apparatus for insertion into and through tissue" merely states the purpose or intended use of the invention. Indeed, the words "characterized by" in the preamble are intended to be "open-ended and [do] not exclude additional, unrecited elements or method steps" such as an insertion means for inserting the anchor member into and through the tissue. *See* Mars, Inc. v. H.J. Heinz Co., L.P., 377 F.3d 1369, 1376 (Fed.Cir.2004), citing *Manual of Patent Examining Procedure,* 8th ed., rev. 1 s. 2111.03 (2003).

Accordingly, I find the claim simply requires that the elongated anchor member go into and through tissue, and that the language of the claim is silent as to the means with which the anchor member does so.

2. *Infringement*

With the Sure Fire device, the surgeon inserts the needle into and through the tissue and leaves the anchor member in the desired area upon removing the needle from the tissue.

Based on the construction of the claim above to mean that the elongated anchor member must go into and all the way through the tissue, without regard to the means with which it does so, Smith & Nephew has demonstrated a substantial likelihood of establishing infringement of the enumerated claim.

B. ***Claim 23***

Claim 23 provides:

23. An apparatus for insertion into and through tissue to provide a mechanism for manipulating and anchoring tissue within a patient, characterized by:

[a] an elongated anchor member insertable into and through the tissue;

[b] a suture having a uniform cross-sectional shape along the entire length of the suture, the suture being attached to the anchor member, the suture having an end free for manipulating the tissue;

[c] a hollow needle having a tip and a butt; and

[d] an expulsion member positionable within the hollow needle to be slidable therein, the anchor member being positionable within the needle tip and expelled therefrom by the expulsion member.

1. ***Construction***

With respect to the "insertable into and through" portion of the claim, the analysis above on the identical language in claim 24 is applicable here.

As for paragraph [d] of claim 23, there does not appear to be any dispute about what "expulsion member" means, just whether the Sure Fire device has an "expulsion member" that expels the anchor member from the hollow needle. The specification does not use the term "expulsion member" but rather describes a hollow tube within the needle that expels the anchor member out the end of the needle. Ex. A, col. 2, l. 31-34; col. 6, l. 39-43; col. 7, l. 31-34.

2. ***Infringement***

Smith & Nephew argues the Sure Fire has an elongated rod, or expulsion member, positioned within the hollow needle that is slidable within the needle. The expulsion member is operated by a slide button. Both anchor members are positioned within the tip of the needle, and the first anchor member may be expelled from the tip when the expulsion member is slid towards the tip of the needle.

Biomet responds that there is no expulsion member for expelling any anchor member in the Sure Fire device. In their briefing, Biomet points to the fact that plaintiff Dr. Hayhurst admitted that the Sure Fire product does not have a push rod that throws the anchor member out of the end of the needle and into and through tissue. In addition, Dr. Sgaglione, Smith & Nephew's expert, testified that the '691 patent calls for expelling the anchor member out of the needle with a push rod. Dr. Sgaglione also testified that the Sure Fire repositions anchor two and anchor one via a thumb piece that enables each of the two anchors to be stripped from the needle instead of expelling them, and that the manufacturer's surgical technique directing the way in which the device should be used, which is not typically ignored, suggests releasing the first anchor by pulling back out on the needle.

Smith & Nephew replies that it is irrelevant that Biomet recommends that surgeons use the thumb slider only to advance the second anchor member to the end of the needle and not to expel the anchor member. Since claim 23 is a "product" claim, what matters is whether the Sure Fire satisfies the claim, regardless of

how Biomet recommends the product be used. In support of this argument, Smith & Nephew invokes the doctrine of capability of infringement. Intel Corp. v. U.S. Int'l Trade Comm'n, 946 F.2d 821, 832 (Fed.Cir.1991). In *Intel* the court stated:

Because the language of claim 1 refers to "programm *able* selection means" and states "whereby *when* said alternate addressing mode is selected" (emphasis added), the accused device, to be infringing, need only be capable of operating in the page mode. Contrary to [defendant's] argument, actual page mode operation in the accused device is not required.

(Emphasis in original).

Here, Smith & Nephew contends that the claim requires an expulsion member be "position *able* within the hollow needle to be slidable therein," *i.e.*, an expulsion member which is *capable* of being positioned and slid within the hollow needle. The claim also requires the anchor member to be "position *able* within the needle tip and expelled therefrom by the expulsion member," *i.e.*, an anchor member which is *capable* of being positioned within the needle tip and expelled from the needle by the expulsion member. According to Smith & Nephew, Biomet designed the Sure Fire so that it is *capable* of being used in this manner. Thus, it meets the claim.

At oral argument, Biomet responded that the device would be inoperable and dangerous if used in the way suggested by Smith & Nephew.

I permitted supplemental briefing on this issue. Biomet urges that the doctrine of capability of infringement requires something more than "mere capability," and that it must be applied only where the accused device would actually be used that way in the "real world." Biomet also contends that using the Sure Fire device as suggested by Smith & Nephew would conflict with the recommended surgical technique and would not repair a meniscal tear. Finally, Biomet limits *Intel* to the language of the claim at issue in that case.

Many of the cases Biomet relies on to support its interpretation of "reasonably capable" to mean how the accused device is actually used in the "real world" do not stand for this proposition. In actuality, the courts refused to apply the doctrine to accused devices that must be modified structurally in order to be "reasonably capable" of meeting the claim language. *See* In re Certain Surveying Devices, 214 USPQ 900 (U.S. ITC 1981); High Tech Med. Instrumentation v. New Image Indus., Inc., 49 F.3d 1551, 1555 (Fed.Cir.1995); Berkley Photo, Inc. v. Klimsch-Repro, Inc., 388 F.Supp. 586, 594 (S.D.N.Y.1975). The Sure Fire device need not be modified structurally in order for the expulsion member to expel the anchor member.

Nevertheless, I agree with Biomet that the doctrine does not apply here. Smith & Nephew explains, "[s]ince 'able' simply means 'capable of,' such a claim term is generally interpreted to require that the subject product be capable of performing the act or function described by the root verb." Smith & Nephew's Response to Supp. Brief, at 4. Interpreting the relevant claim, then, following Smith & Nephew's direction, the accused product must have an expulsion member capable of being positioned within the hollow needle and capable of sliding in the hollow needle, and the anchor member must be capable of being positioned within the needle tip and expelled therefrom by the expulsion member.

There is no question that the thumb slider in the Sure Fire is positioned within the hollow needle, is capable of sliding in the hollow needle, and that the anchor member is positioned within the needle tip. The only

question is whether the anchor member is expelled by the expulsion member. Significantly, the verb used in the claim is "expelled" not "expellable." Accordingly, the claim calls for an anchor member, which must be capable of being positioned within the needle tip, to actually be expelled from the needle tip by the expulsion member. The claim does not simply require that the device have the ability to perform this function.FN4

FN4. Such a construction of the claim does not improperly read a method step into the claim, contrary to Smith & Nephew's argument. Claim 23 requires that the expulsion member perform a specified function-expelling the anchor member.

Since I find that the doctrine does not apply here, I must evaluate whether the Sure Fire device infringes the claim. The Sure Fire is not designed to deploy the anchor member by expelling it from the needle with an expulsion member. Biomet's surgical technique illustrates that the anchor member is expelled from the needle when the surrounding tissue strips the anchor member from the needle. The thumb slider is only used to advance the next anchor member to the position vacated by the first anchor member. If the thumb slider were used to push one anchor member into the other, thereby expelling it from the needle, one anchor member would remain in the needle, and would need to be stripped from the needle by the surrounding tissue in order to safely remove the entire apparatus from the surgical area. Only one person has been seen deploying the Sure Fire anchor member in this fashion, and that was by accident. The thumb slider is present in the device for an entirely different purpose than expelling the anchor member, and it must be misused in order to expel the anchor member from the needle. *See* United Sweetener USA, Inc. v. Nutrasweet Co., 760 F.Supp. 400, 417 (Fed.Cir.1991) (one reason given for no infringement was that party had not demonstrated "infringe[ment] with expected use").

Therefore, Smith & Nephew has not demonstrated a substantial likelihood of establishing infringement of the enumerated claim.

C. *Claim 13*

13. An apparatus for insertion into and through tissue to provide a mechanism for manipulating and anchoring tissue within a patient, the apparatus comprising:

[a] an elongated anchor member insertable into and through the tissue and shaped to normally assume a substantially straight configuration; and

[b] a suture attached to the anchor member between opposite ends of the anchor member the suture having an end free for manipulating the tissue,

[c] the suture being flaccid in the vicinity of the anchor member so that the suture and anchor member do not assume a predetermined relative orientation; and

[d] the anchor member having opposing end faces, at least one end face being formed in a plane that is slanted relative to the longitudinal axis of the anchor member.

1. *Construction*

I have construed "insertable into and through the tissue" above, and that construction applies to this claim as

well. However, I have not yet construed the portion of the claim calling for an anchor member "shaped to normally assume a substantially straight configuration."

Smith & Nephew asserts that "shaped to normally assume a substantially straight configuration" means that the "anchor member-which can be either rigid or deformable-is sufficiently straight to be inserted into a needle, and cannot include an angle of 135 (deg.) or less." Smith & Nephew's Reply at 14.

Biomet argues that the only references in the specification to a "normal" shape are in the context of describing the change in shape a resilient, deformable anchor makes from its bent position to its extended position. Biomet highlights the following from the specification: "The anchor member is located within the tip of the hollow needle in either a deformed U shape, or in its *normal, substantially straight* shape," Ex. A, col. 2, l. 19-21 (emphasis added); "FIG. 6 is an enlarged perspective view of the anchor member and suture, showing the *normal and deformed configuration* of the anchor member," *id.,* col. 3, l. 49-51 (emphasis added); "Once expelled between the cartilage 18 and bone 38, the anchor member *resiliently resumes its normal shape,* as shown in FIG. 5," *id.,* col. 4, l. 42-45 (emphasis added); "As the anchor member 10 is pushed from the needle tip 26, it *resumes its normal* elongated shape," *id.,* col. 6, l. 43-45 (emphasis added); "Once the anchor member 10 has generally *resumed its normal* elongate shape behind the cartilage 18, the needle 14 and the tube 16 may be withdrawn from the joint, allowing the cartilage 18 to partially collapse around the anchor member 10 and suture 12 as shown in FIG. 5," *id.,* col. 6, l. 50-55 (emphasis added).

In addition, according to Biomet, the only drawings in the '691 patent are of deformable anchors. Therefore, the claim limitation that call for an anchor member that normally assumes a straight configuration must be limited to deformable anchors, as opposed to rigid anchors.

Smith & Nephew replies that the '691 patent expressly states that the anchor member "may be formed of a substantially rigid material." Id., col. 7, l. 45-47. Furthermore, claim 14, which is dependent on claim 13, adds a limitation requiring the anchor member to be formed of resilient material. According to Smith & Nephew, since claim 14 expressly requires that the anchor be resilient, claim 13 cannot be construed to also require that the anchor member be made of resilient material. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed.Cir.2005) (en banc) ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim").

In addition, Smith & Nephew provides prosecution history of the '691 patent. The phrase "shaped to normally assume a substantially straight configuration" was added to the claim in an amendment filed on June 19, 1992. The amendment contained an explanation that "[t]he normally substantially straight configuration of the applicant's anchor member permits insertion of the member into a tubular delivery member, such as needle 54 (Fig.8)...." Appendix "A" to Smith & Nephew's Corrected Reply Brief ("Appendix A"), Ex. V at 14 of 44. The applicant also distinguished a prior art reference which was not substantially straight, but had feet arranged at a 135 (deg.) angle. Id.

Biomet contends that Smith & Nephew cannot adequately distinguish claim 14 from claim 13. Claim 14 in its entirety reads, "The apparatus of claim 13 further characterized in that the anchor member is formed of resilient material *that* is absorbable by the tissue." Ex. A, col. 13, l. 41-43 (emphasis added). Biomet argues that Smith & Nephew is attempting to replace the word "that" with the word "and." In fact, according to Biomet, claim 14 confirms that claim 13 describes a deformable, resilient anchor. According to Biomet, "resilient" means deformable because the two words are almost always used together in the specification, and convertible from one shape to another. Claim 14 simply adds the limitation that this resilient anchor be

absorbable by tissue.

I am not persuaded by Biomet's arguments. Much of the specification cited by Biomet also supports Smith & Nephew's argument, and demonstrates that the anchor member can be either rigid or deformable. *See* Ex. A, col. 2, l. 19-21 (anchor member may be in the needle either in its deformed shape *or* its straight shape) (emphasis added); Ex. A, col. 3, l. 49-51 (Figure 6 showing both an anchor member that is deformed and an anchor member that is straight). The other portions of the specification simply calls for an anchor member that, *if* deformed, will resume a straight shape.

In addition, I read claim 14 as adding *two* additional elements to claim 13-not only that the anchor member be made of resilient material, but also that the resilient material be absorbable by tissue. It is clear that the specification considers these to be separate characteristics. Ex. A, col. 11, l. 19-23 ("[T]he anchor members may be formed of non-absorbable material (e.g. stainless steel of suitable resilience) that remains in the bone indefinitely). In addition, relying on *Phillips,* which permits me to consider unasserted claim terms used consistently throughout the patent in construing a meaning for a term in dispute, I consider claim 10. *See* Phillips, 415 F.3d at 1314. Claim 10 contains the disputed phrase "shaped to normally assume a substantially straight configuration," but also calls for an anchor member that is "formed of resilient material and deformable into the deformed position within the needle tip[.]" Ex. A, col. 12, 1. 62-63. It is clear that claim 10 requires a resilient anchor member, while claim 13 makes no mention of the material from which the anchor member must be formed. Claim 10 would not need to add the limitation for a resilient and deformable anchor if that limitation were equivalent to "shaped to normally assume a substantially straight configuration."

Additionally, given that the specification expressly states that the anchor member may be formed of rigid material, and that the prosecution history supports Smith & Nephew's interpretation, I find that "shaped to normally assume a substantially straight configuration" means the anchor member must be sufficiently straight to be inserted into a needle.

2. *Infringement*

Biomet argues the Sure Fire does not have resilient or deformable anchors, and therefore cannot respond to an "elongated anchor member" that has a "normal shape" after being deformed in the needle since it is made of rigid material.

Since I have construed the claim to mean that the anchor member must be sufficiently straight to be inserted into a needle, and because Biomet's anchor members meet this claim limitation, Smith & Nephew has demonstrated a substantial likelihood of establishing infringement of the enumerated claims.

D. *Claim 15*

15. A method for manipulating tissue within a patient characterized by the steps of:

(a) positioning within a hollow member an elongated anchor member having a flaccid suture attached thereto;

(b) inserting the hollow member into the tissue;

(c) expelling the anchor member from the hollow member so that one end of the elongated anchor member

follows another end of the anchor member; and

(d) applying tension to the suture to manipulate the anchor member into a preselected position relative to the tissue.

1. *Construction*

The parties dispute the meaning of the word "expelling" in claim 15; Smith & Nephew construes the term to mean pressure that removes the anchor member from the needle, while Biomet appears to interpret the term to require the use of an expelling member to propel the anchor member from the needle.

At oral argument, Biomet expanded its analysis of claim 15. Biomet asserted that "expelling" comes from within the apparatus, not from some external means. A review of the specification, according to Biomet, supports this interpretation: "[a] tube (16, 55) [that] fits within the needle (14, 54) and is pushed toward the needle tip to expel the anchor member (10, 50) into or behind the tissue to be manipulated or anchored." Ex. A, Abstract.

Smith & Nephew replies that Biomet is trying to read the disclosed embodiments into the claims. According to Smith & Nephew, Biomet's definition of "expelling" means "by the expulsion member," as in the preferred embodiments of the '691 patent. However, there is no mention of an expulsion member in the claim. The term "expel" was not given any particular meaning in the specification or in the prosecution history, and does not involve a term of art; it must be construed using the widely accepted meaning of the term.

According to Smith & Nephew, dictionary definitions suggest that "expel" means removing the anchor member from the needle by force, or forcing the anchor member out of the needle.

I agree with Smith & Nephew that Biomet's construction of the claim improperly inserts "by the expulsion member" into the claim. The claim calls for the expelling of the anchor member, but does not specify how that is accomplished. Although throughout the written description and in all of the embodiments, the anchor member is expelled from the hollow member in only one way-by the expulsion member, "[t]his court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed.Cir.2004). Since the patent does not in any way restrict the scope of the coverage, I do not read into the claim a requirement that the anchor member must be expelled by an expulsion member.

In addition, the term "expelling" is presumed to have its ordinary and customary meaning, unless the patent has clearly set forth a definition that is different from the term's ordinary and customary meaning. The patent is silent with respect to the meaning of "expel." Dictionaries almost uniformly define "expel" to mean to force out, eject, to drive out, or dislodge. *See American Heritage Dictionary* 644 (3d ed.1996), *Merriam Webster's Collegiate Dictionary* 408 (10th ed.1996), *Webster's Third New International Dictionary* 799 (1993), *Webster's New World College Dictionary* 478 (3d ed.1996).

I find "expelling the anchor member" to mean that the anchor member is forced out, ejected, driven out or dislodged from the "hollow member."

2. *Infringement*

"A method claim is directly infringed only by one practicing the patented method." Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 775 (Fed.Cir.1993). "Although not direct infringement under 35 U.S.C. s. 271(a), a party's acts in connection with selling equipment may, however, constitute active inducement of infringement or contributory infringement of a method claim under 35 U.S.C. s. 271(b) and (c)." *Id.* at 774.

According to Smith & Nephew, the claim is met because, when the Sure Fire is used, both anchor members are expelled from the hollow needle by the pressure from the tissue as the needle is withdrawn. Furthermore, the anchor members are loaded into the hollow needle lengthwise, so when each anchor member is expelled from the needle, one end of the member follows the other end.

Since the claim does not require the anchor member to be expelled from the hollow member by any particular method, and since Biomet sells the Sure Fire which has anchor members that are forced out, ejected, driven out, or dislodged from the needle when the anchor members catch on the tissue, Smith & Nephew has demonstrated a substantial likelihood of establishing contributory or induced infringement of the enumerated claims.FN5

FN5. Biomet also asserts that the anchor member in the Sure Fire device does not follow the other end out of the needle, but Biomet never fully articulates this argument. When examining Dr. Hayhurst, Biomet appeared to suggest that as the anchor member starts to leave the needle, it begins to rotate in order to end up lengthwise against the backside of the tissue. Without further explanation, I cannot evaluate whether this portion of the claim is infringed, and accordingly I do not consider it at this time.

D. *Claim 18*

18. The method of claim 15 wherein the positioning step includes positioning within a hollow member an elongated anchor member having a flaccid, non-stiffened suture attached thereto.

Both parties agree that because claim 18 is dependent on claim 15, if claim 15 is infringed so is claim 18.

Based on the above, Smith & Nephew has demonstrated a substantial likelihood of establishing contributory or induced infringement of this claim.

IV. *Validity*

A patent is presumed valid. 35 U.S.C. s. 282. "The presumption of validity under 35 U.S.C. s. 282 carries with it a presumption that the Examiner did his duty and knew what claims he was allowing." Intervet America, Inc. v. Kee-Vet Labs, Inc., 887 F.2d 1050, 1054 (Fed.Cir.1989). At trial, invalidity must be proven by clear and convincing evidence. North American Vaccine v. American Cyanamid Co., 7 F.3d 1571, 1579 (Fed.Cir.1993). Nevertheless, the presumption of a patent's validity "does not relieve a patentee who moves for a preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." Helifix, Ltd v. Blok-Lok, Ltd., 208 F.3d 1339, 1351 (Fed.Cir.2000) (citation omitted). At this stage, the question is whether Biomet raises a "substantial question concerning ... validity, *i.e.,* asserts an ... invalidity defense that the patentee cannot prove lacks substantial merit." Amazon.com, 239 F.3d at 1350 (quotation omitted).

Biomet argues that the '691 patent is invalid for two reasons: the judicial doctrine of "obviousness-type double patenting" and inequitable conduct.

A. ***Obviousness-Type Double Patenting***

Biomet points to Dr. Hayhurst's third application, which was eventually issued on May 3, 1988 as U.S. Patent No. 4,741,330 (the " '330 patent"), and asserts that the '691 patent is invalid for obviousness-type double patenting because it is not patentably distinct from the '330 patent. The '330 patent expired May 3, 2005. Biomet argues claims 13, 15, 18, 23 and 24 of the '691 patent are obvious variations of claim 7 of the '330 patent.

Obviousness-type double patenting occurs when a second patent would "effectively extend the life of the patent that would have the earlier of the two issue dates." Gerber Garment Tech., Inc. v.. Lectra Systems, Inc., 916 F.2d 683, 686 (Fed.Cir.1990). Whether a claim is invalid based on obviousness-type double patenting is a question of law. Texas Instruments Inc. v. United States Int'l Trade Comm., 988 F.2d 1165, 1179 (Fed.Cir.1993). Biomet is required at trial to prove double patenting by clear and convincing evidence, proceeding on a claim-by-claim basis, which is a "heavy and unshifting burden." Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1580 (Fed.Cir.1991) However, keeping these principles in mind, because Smith & Nephew seeks a preliminary injunction it needs to prove that Biomet's claim of double patenting lacks substantial merit.

"Generally, an obviousness-type double patenting analysis entails two steps. First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences." Eli Lilly & Co., 251 F.3d at 968. "Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." *Id*. The second step, in other words, requires the court to determine if the claim in the later patent is obvious, relative to the claim of the earlier patent.FN6

FN6. Both parties present alternative tests. Biomet asserts the test is as follows: "If the claims of the later issued patent ... cannot be infringed without infringing at least one claim of the earlier issued patent, then obviousness type double patenting is established ." Biomet's Memo. in Response at 22. Biomet does not cite any case law in support of this test. Instead, Biomet cites Kunin's declaration, who also does not cite any case law. Furthermore, I have stricken the relevant paragraph from the declaration. Smith & Nephew argues the opposite test applies: "[I]f a hypothetical device would not infringe the later issued patent, but would infringe an earlier issued patent, the later issued patent is *not* invalid for obviousness-type double patenting. Smith & Nephew's Corrected Reply Brief at 19. Smith & Nephew's test neglects to consider whether that non-infringing hypothetical device may be an obvious variation of the earlier claimed invention.

Therefore, as required by the law, I must first construe the claims at issue and then determine the differences in subject matter between them. The relevant claim of the '330 patent provides as follows:

Claim 7: A device for *securing tissue* within a joint, comprising:

(a) a hollow needle having a tip end and a butt end;

(b) an expulsion tube positionable within the hollow needle to be slidable therein;

(c) an elongated anchor member positionable within the hollow needle, the anchor member having opposing

end faces, at least one end face being formed in a plane that is slanted relative to the longitudinal axis of the anchor member, the anchor member being expellable from the needle by the expulsion tube; and

(d) an elongated suture having one end attached to the anchor member, the suture extending from the interior of the expulsion tube butt end when the anchor member is positioned within the hollow needle and when the expulsion tube is positioned within the needle, the portion of the suture near the anchor member being normally flaccid and usable for securing tissue adjacent to the [sic] expelled anchor member.

Appendix A, Ex. Y, col. 11, l. 17 through col. 12, l. 18 (emphasis added).

Smith & Nephew points out first that claim 7 of the '330 patent is directed to "securing tissue." Id., col. 11, l. 17. In contrast, claims 24, 23, and 13 describe an apparatus for "manipulating and anchoring tissue." *See* Ex. A, col. 14, l. 51 and l. 37 and col. 13, l. 24. Claims 15 and 18 describe a method for manipulating tissue.

According to Smith & Nephew, in the '330 patent, "securing" means "holding" tissue. *See* Ex. Y, col. 1, l. 12 ("a device ... for holding and manipulating ... tissue"); col. 1, l. 20 ("Conventional medical clamps have serious disadvantages when used for securing and manipulating" tissue); col. 1, l. 66 (none of the prior art disclose "apparatus suitable for holding and manipulating cartilage during arthroscopic surgery"); col. 3, l. 7-8 (during surgery, once the anchor member is deposited, the cartilage can be "secured with the use of tension on the suture").

In contrast, according to Smith & Nephew, in the '691 patent, "anchoring" tissue means "to permanently reattach" tissue. Ex. A, col. 1, l. 47-51 ("the present invention provides a relatively compact and easy to use apparatus for manipulating cartilage and other fibrous tissue, and for anchoring the tissue to other tissue or to bone"). Therefore, according to Smith & Nephew, claim 7 in the '330 patent describes a device for holding the tissue while the surgeon cuts and removes it, while the relevant claims in the '691 patent are directed to a device for anchoring tissue to tissue so a tear can heal.

"Differences among claims can ... be a useful guide in understanding the meaning of particular claim terms." Phillips, 415 F.3d at 1314. Claim 7 is the only claim in the '330 patent directed solely to "securing" tissue, while all of the other claims in the '330 patent describe a device for use in "anchoring and manipulating" tissue. In addition, all of the claims except claim 7 limit the claimed invention to one that includes a retainer to keep the anchor member in place. The retainer is described in the specification as a means of "hold[ing] tissue permanently in place." Ex. Y, Abstract, col. 3, l. 22-34, col. 8, l. 32-38. Therefore, "anchoring and manipulating" contemplates a claimed invention that permanently holds the tissue. "Securing," on the other hand, must mean something different from "anchoring and manipulating," as those terms are used in the '330 patent. Differentiating claim 7 from the other claims in the '330 patent, and referring to the specification referenced by Smith & Nephew, I find that "securing" in claim 7 means temporarily holding.

As for the '691 patent, claims 15 and 18 describe a method for "manipulating" tissue. Absent a definition for manipulating in the specification, the term carries its ordinary and customary meaning. Manipulating is generally understood to mean handling. Accordingly, claims 15 and 18 describe a method for handling tissue, while claim 7 describes a device for holding tissue.

A device that is capable of holding tissue can also handle tissue. Indeed, the '330 specification recognizes that a device that can secure tissue can also manipulate tissue. *See* Ex. Y, col. 1, l. 12 ("a device ... for

holding and manipulating ... tissue"); col. 1, l. 20 ("Conventional medical clamps have serious disadvantages when used for securing and manipulating" tissue); col. 1, l. 66 (none of the prior art disclose "apparatus suitable for holding and manipulating cartilage during arthroscopic surgery"). Similarly, the '691 patent specification confirms that a device that secures tissue is implied in a device that manipulates tissue. *See* Ex. A, col. 1, l. 15 ("an apparatus and method for manipulating ... tissue"); col. 1, l. 20 ("Conventional medical clamps have serious disadvantages when used for manipulating" tissue); col. 1, l. 56 (none of the prior art disclose "apparatus suitable for manipulating fibrous tissue during arthroscopic surgery").

Although claim 7 of the '330 patent and claims 15 and 18 of the '691 patent use different terminology, the claims are so alike as to render the '691 claims obvious in view of the '330 claim. As a result, I find that Smith & Nephew has not demonstrated that Biomet's claim of double patenting with respect to claims 15 and 18 lacks substantial merit.

The remaining claims of the '691 patent that Biomet asserts are invalid are directed to a device for "manipulating and anchoring tissue." I have construed "manipulating" to mean handling, and I use that definition in construing claims 24, 23 and 13. Phillips, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims").

As for the meaning of "anchoring," I turn to the claims of the '691 patent not in suit that describe a device used solely for "anchoring" tissue. These claims all identify devices that provide for permanent placement of the anchor member in the tissue or bone, presumably for healing purposes. One device requires a hole to be drilled into the bone, another calls for insertion of the apparatus into the bone, while another prevents a "suture from being withdrawn" from the tissue. Ex. A, col. 11, l. 33-35, col. 14, l. 15-20, and col.13, l. 15-18. Therefore, I find that anchoring means holding permanently.

Since claims 24, 23 and 13 call for a mechanism for both manipulating and anchoring tissue, the question becomes whether a device that handles and permanently holds tissue is an obvious variation of a device that temporarily holds tissue. While a device that simply handles tissue is an obvious variation of an apparatus that holds tissue, a device that both handles and permanently holds tissue is a patentably distinct device. Indeed, claim 7 is directed to a different objective than are claims 24, 23 and 13. Claim 7 claims an invention to be used in the place of medical clamps, while claims 24, 23 and 13 describe inventions to permanently attach tissue.

In sum, Smith & Nephew has not demonstrated that Biomet's claim of double patenting with respect to claims 15 and 18 lacks substantial merit, but has shown that claims 24, 23, and 13 are not likely invalid for double patenting.

B. ***Inequitable Conduct***

At trial, Biomet must show "misrepresentation or omission of a material fact, together with an intent to deceive the PTO. Both of those distinct elements must be shown by clear and convincing evidence." Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359 (Fed.Cir.2003) (emphasis added). When seeking a preliminary injunction, however, Smith & Nephew bears the burden of showing that Biomet's claim of inequitable conduct lacks substantial merit. *See* Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed.Cir.2001).

Relying in part on Kunin's declaration, Biomet argues that the '691 patent is unenforceable due to plaintiff Dr. Hayhurst's violation of the duty of disclosure. According to Biomet, Dr. Hayhurst failed to bring the scope of the '330 patent claims to the attention of the '691 patent examiner. Merely identifying the '330 patent in the "continuity section" of the '691 patent does not satisfy Dr. Hayhurst's obligation to disclose all information material to patentability.

Smith & Nephew replies that it brought the patent to the attention of the examiner in the form of an Information Disclosure Statement filed on July 15, 1991 in U.S. Serial No. 07/192, 813 ("the '813 application"): The statement provided, "This application is a continuation-in-part of U.S. Application Serial No. 848,241, filed April 4, 1986, now U.S. Patent No. 4,741,330...." Appendix A, Ex. V at 6 of 44.

I find it difficult to believe that bringing the '330 patent to the attention of the examiner in a document entitled "Information Disclosure Statement" would not be sufficient to satisfy plaintiff Dr. Hayhurst's duty of disclosure, even if the reference appeared in the third paragraph of that document. However, even if that reference constitutes an omission of a material fact, I am unable to find evidence at this point that Dr. Hayhurst or Hughey intended to deceive the Patent Office.

At oral argument, Biomet offered the testimony of Hughey, the attorney who prosecuted both the '330 and '691 patents, as evidence of an intent to deceive the Patent Office. Hughey purportedly agreed that claim 24 of the '691 patent is broader than claim 7 of the '330 patent.

Q: Do you agree, sir, that claim 24 of the '691 patent appears to be broader than claim seven of the '330 patent?

MR. HEBERT: Objection.

Q: In view of those requirements that are missing [apparently referring to elements of claim 7 that do not appear in claim 24].

A: In view of those requirements, yes, it is broader.

Taylor Dec., Hughey Depo., Ex. R at 44. Biomet also asserts that Hughey admitted he pursued claims beyond the '330 patent with the intent to obtain broader coverage. The testimony upon which Biomet relies is as follows:

Q: Okay. All right. What was the purpose of filing nearly five years after the 330 patent the application that eventually issued as the 691 patent?

...

A: We wanted to get the claims allowed.

Q: You wanted more coverage, didn't you, sir?

A: We wanted to get claim coverage, yes.

Q: You wanted claim coverage beyond that of the 330 patent; isn't that correct, sir?

A: Beyond that?

Q: Yes.

A: I'd have to look at the-to see the claims, compare the claims to be able to characterize whether it's beyond it or not.

Taylor Dec., Hughey Depo., Ex. R at 34-35.

The deposition testimony does not support Biomet's argument that Hughey intentionally deceived the Patent Office. It is unclear whether or not Hughey admits the claims in the '691 patent are broader than those in the '330 patent. If anything, he may admit that one claim is broader-claim 24 of the '691 patent, but even this conclusion is questionable looking at the deposition testimony set forth above. Furthermore, the statements alone are not evidence of an intent to deceive the Patent Office.

I find that Smith & Nephew has met its burden of showing Biomet's claim of inequitable conduct lacks substantial merit since Biomet has failed thus far to demonstrate that Hughey or plaintiff Dr. Hayhurst intended to mislead the Patent Office.

V. ***Irreparable Harm***

Smith & Nephew has demonstrated that it will likely prove infringement with regard to claims 24, 13, 15, and 18, and it has shown it will likely withstand challenges to the validity of claims 24 and 13. (Although it has shown claim 23 is likely valid, it has been unable to show it will likely prove that claim has been infringed.) Accordingly, Smith & Nephew is entitled to a presumption of irreparable harm, and Biomet has the burden of negating the presumption. Polymer Techs., 103 F.3d at 974. The types of evidence found to rebut the presumption include: "(1) the non-movant has or will soon cease the allegedly infringing activities ... (2) movants have engaged in a pattern of granting licenses under the patent ... or (3) movants unduly delayed in bringing suit." *Id*.

First, Biomet has not ceased to manufacture or sell the infringing Sure Fire device. Secondly, Smith & Nephew has not granted a license to the '691 patent. While Smith & Nephew granted a license under the '557 patent (closely related to the '691 patent), it has never granted a license for the '691 patent.FN7 Finally, Smith & Nephew learned of the Sure Fire device in December of 2004, learned of its release in February of 2005, and brought suit in May of 2005. At most a six-month delay, Smith & Nephew did not unduly drag its feet in bringing this lawsuit. *See T.J. Smith & Nephew Ltd. v. Consolidated Medical Equip., Inc.,* 821 F.2d at 648 (Fed.Cir.1987) (15-month delay and the granting of a license overcame presumption of irreparable harm); High Tech Med., 49 F.3d at 1557 (17-month delay too long); *Polymer Techs*. (4-month delay insufficient to rebut presumption). Accordingly, I find that Biomet has failed to rebut the presumption of irreparable harm that Smith & Nephew will suffer if a preliminary injunction is not granted.

FN7. A Settlement and Sublicense Agreement between Smith & Nephew and the licensee also prohibits the licensee from infringing Smith & Nephew's T-Fix, both as to trademark and patent law.

VI. ***Balance of the Hardships and the Public Interest***

I also finds that the balance of hardships tips in favor of Smith & Nephew. Although an injunction will cause Biomet some hardship, sales of the Sure Fire are just beginning. Biomet made its eleventh commercial sale of the Sure Fire device in March of 2005, and that was to Smith & Nephew. In contrast, Smith & Nephew is in full production of its FasT-Fix product.

Finally, the public interest favors enjoining Biomet from infringing the '691 patent. The public interest favors protecting rights in a valid patent. Hybritech, Inc. v. Abbott Labs., 849 F .2d 1446, 1458 (Fed.Cir.1988). Both parties claim their product is superior to the other; I find that this factor is a wash. However, Biomet also argues that in granting a preliminary injunction, the public would be denied a choice in suture systems, and physicians would be denied the suture system they have come to rely on. At this point, Biomet's Sure Fire device is too new to harm the public interest by the grant of preliminary relief. I find that the public interest favors the grant of a preliminary injunction.

CONCLUSION

Smith & Nephew's Motion for Preliminary Injunction (# 6) is granted and Smith & Nephew's Motion to Strike the Declaration of Stephen G. Kunin (# 73) is granted in part and denied in part. Biomet, Inc. and wholly owned subsidiary Arthrotek, Inc. are preliminarily enjoined from infringing U.S. Patent No. 5,417,691 through their manufacture and sale of the product known as a "Sure Fire" medical device.

IT IS SO ORDERED.

D.Or.,2005.
Smith & Nephew, Inc. v. Biomet, Inc.

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