

United States District Court,
N.D. Illinois.

DEPUY ORTHOPAEDICS, INC,
Plaintiff.

v.

Gary ANDROPHY,
Defendant.
Gary ANDROPHY, M.D,
Plaintiff.

v.

JOHNSON & JOHNSON PROFESSIONAL, INC,
Defendant.

Jan. 19, 2000.

MEMORANDUM OPINION AND ORDER

GETTLEMAN, District J.

On January 7, 1999, plaintiff Gary Androphy, an orthopaedic surgeon, filed a patent infringement suit (99 C 68) alleging that defendant Johnson & Johnson Professional Inc. infringed U.S. Patents 4,487,203 (the '203 patent) and 4,567,885 (the '885 patent). On July 2, 1999, the executive committee of this Court ordered that two other suits involving these same two patents be reassigned to Judge Gettleman for the purpose of a coordinated claim construction proceeding. The parties from the two other suits involving plaintiff's patents are Smith & Nephew (Case No. 98 C 1078) and Depuy Orthopaedics Inc. (Case No. 97 C 8017). In September 1999, defendants in the Smith & Nephew et al case settled with plaintiff. In the Depuy case, Depuy filed a declaratory judgment action and plaintiff, Androphy, counterclaimed for patent infringement. Hereafter, this opinion refers to both Depuy and Johnson & Johnson as "defendants."

On May 12, 1999, the court entered a stipulated order pursuant to which the parties agreed to stay all discovery other than that related to resolution of the interpretation of claim elements the two patents at issue. On November 5, 1999, the court conducted a claim construction proceeding pursuant to the principles of *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir.) (*in banc*), *aff'd*, 517 U.S. 370 (1996).

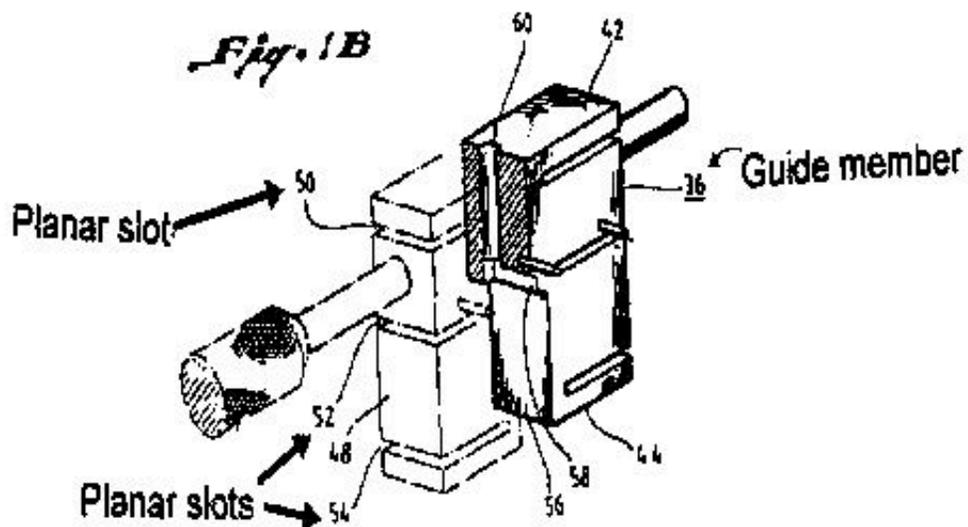
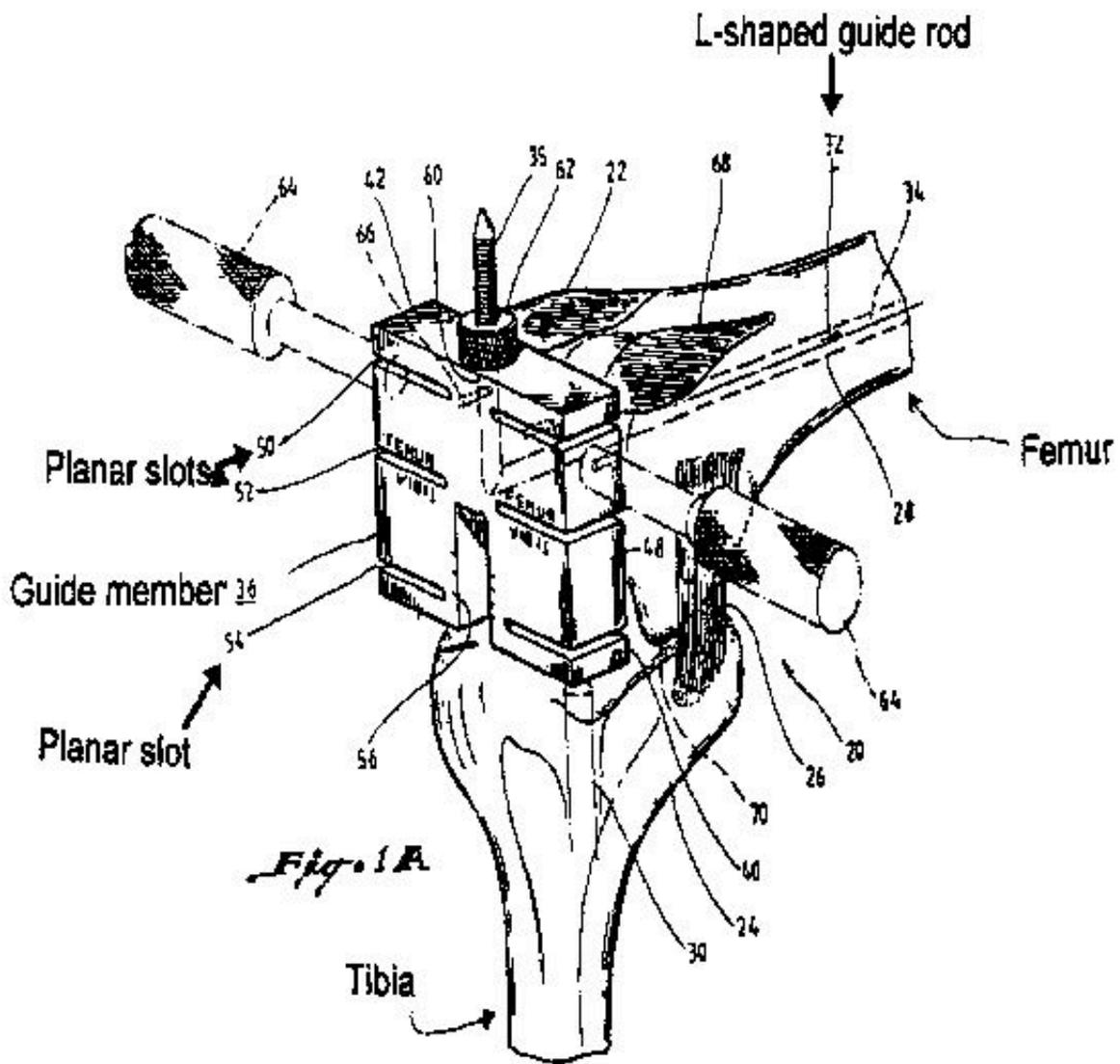
The '885 patent is entitled "triplanar knee resection system." The claims of the '885 patent generally relate to a set of instruments that guide a surgeon in removing portions of the bones around a patient's knee to make room for the installation of an artificial knee. Please refer to Figures 1A, 1B, and 2A-E of the '885 patent located below, as necessary. One piece of this set of instruments is a guide member (36). The guide member (36) is essentially a cutting template. The guide member (36) secures to the patient's femur in one portion of the surgery and the patient's tibia in another portion of the surgery by affixing to an L-shaped guide rod (32). The rest of the instruments that aid in securing the guide member (36) at the proper position and angle are referred to as a femur bar, a tibia bar (80), and a tibia adapter (72). The guide member's characteristics,

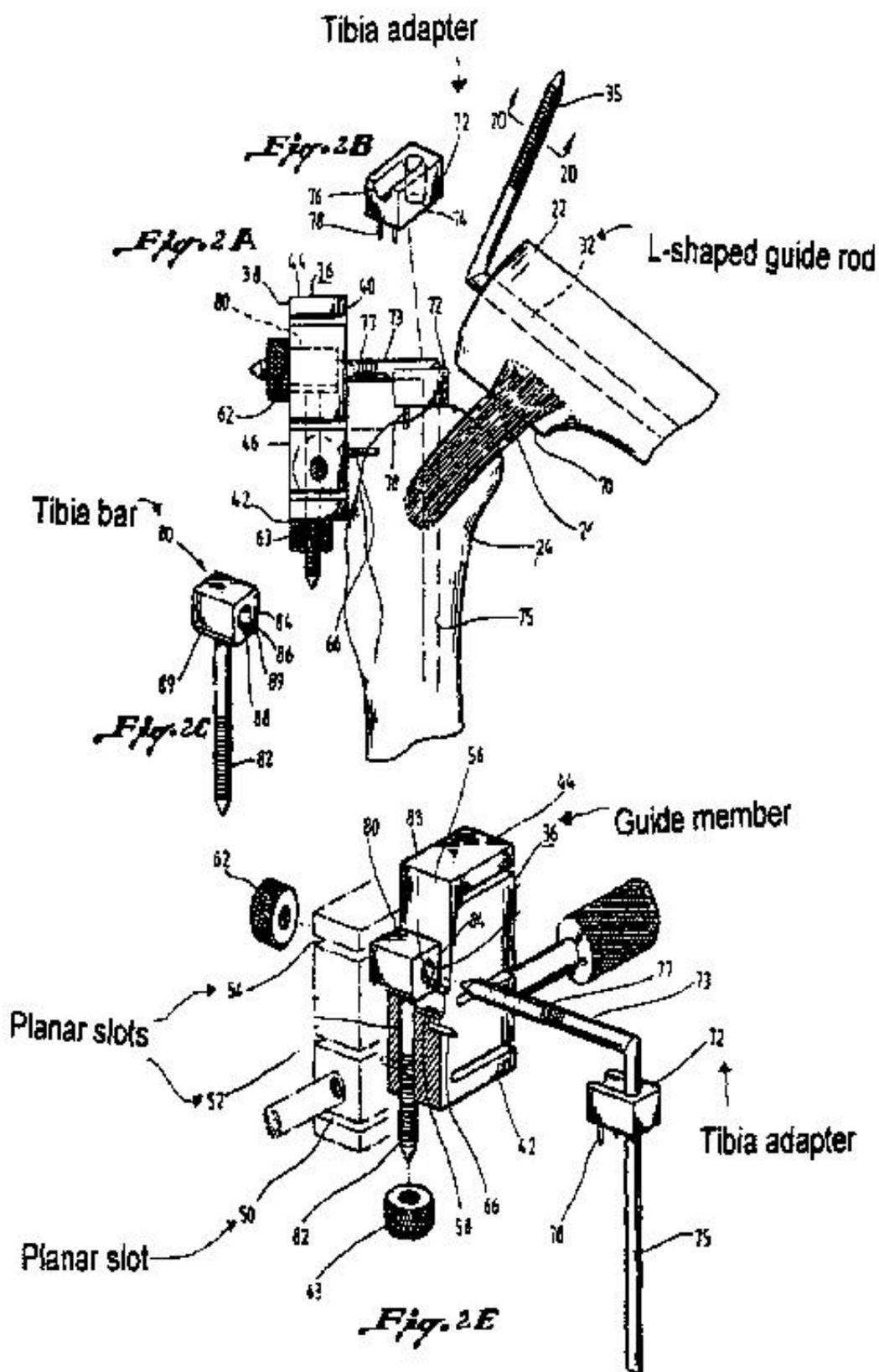
such as overall shape, planar slots (50, 52, 54), and indicia, guide a surgeon in using a saw to remove sections of the bones that form a patient's knee. As illustrated in Figure 4, a prosthesis may be installed on the bones that have been shaped by the resections to receive the prosthesis. Essentially, in wood shop one would refer to this set of instruments as a cutting jig.

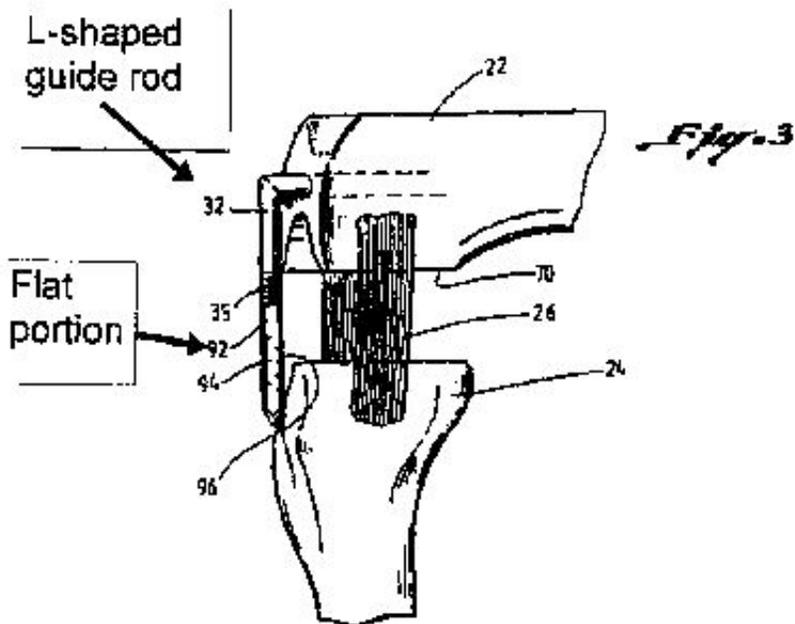
The '203 patent is entitled, "Triplanar knee resection method." The claims of the '203 patent generally relate to a method for cutting the bones that form the knee in a triplanar fashion in order to shape the patient's tibia and femur for a prosthesis. The specification of the '203 is substantially identical to the '885 patent.

Plaintiff originally filed the '203 patent and the '885 patent as a single application containing ten claims. Five claims were directed at the set of instruments and became part of the eventual apparatus patent. Five claims were directed at the method of making the triplanar knee resections by using those instruments and became part of the eventual method patent. The examiner placed a restriction requirement on the application, indicating that the ten claims recited two related but separate inventions. The examiner stated, "In this case, the apparatus can be used to practice another and materially different process, e.g. making accurate cuts in pieces of wood." The apparatus claims that examiner referenced became the claims of the '885 apparatus patent.

Plaintiff elected to prosecute the parent application containing the eventual '203 method claims before submitting the divisional application containing the claims of the '885 patent. On August 8, 1983, the examiner rejected the method claims of the '203 application as obvious in view of the Richards reference, entitled R .M.C. Total Knee System. In an Amendment, plaintiff patentably distinguished his invention over the Richards reference. On May 29, 1984, plaintiff received a notice of allowance for the '203 patent. Approximately four months later, September 18, 1984, plaintiff filed a divisional application for the apparatus claims. In 1984, the parent application issued as the '203 patent. In 1986, the divisional application issued as the '885 patent.







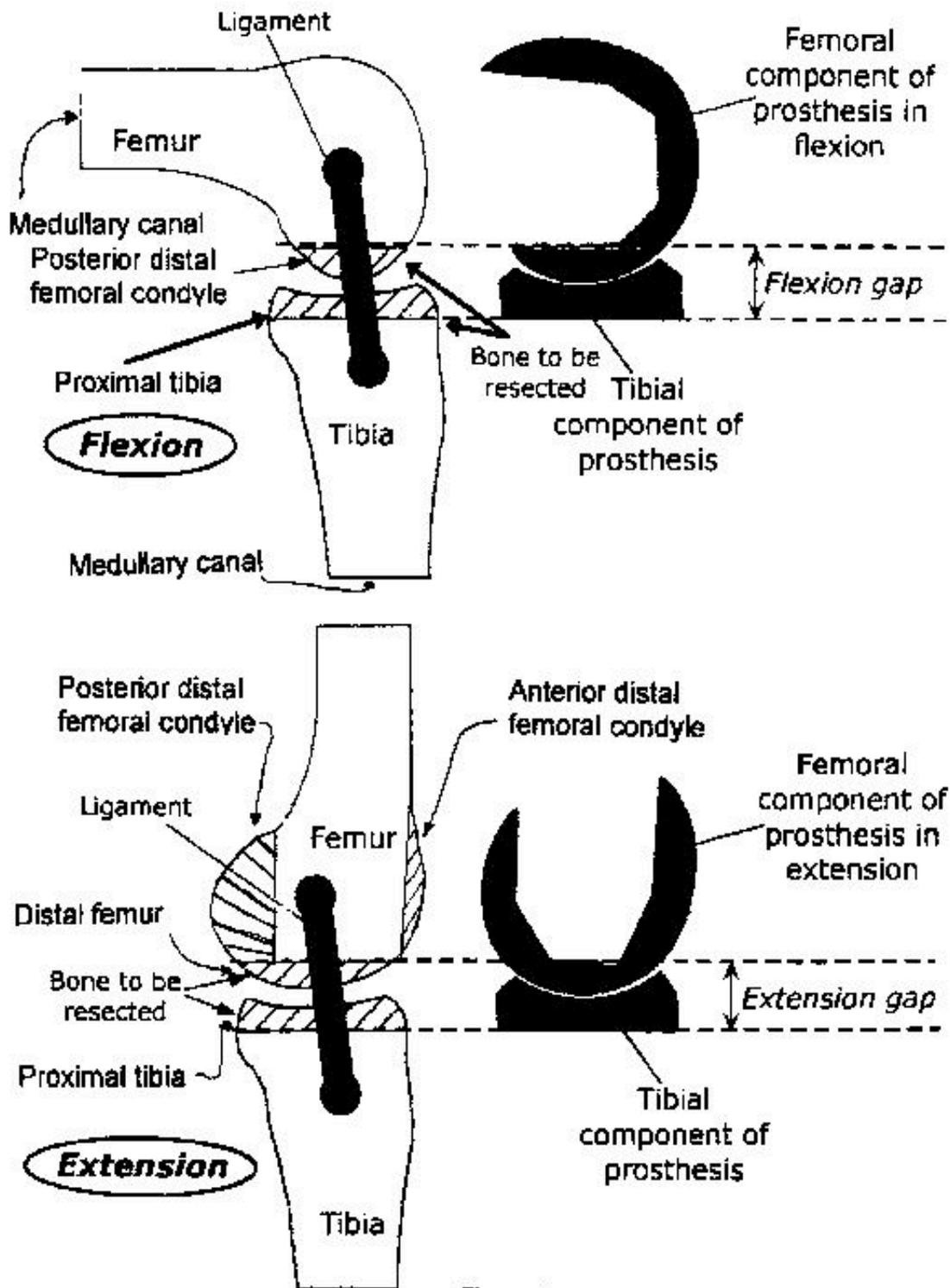


Figure 4

Glossary of Medical Terminology

The court adopts plaintiff's proposed glossary of medical terminology and Figure 4 to help explain or illustrate the patents at issue. Please refer to this glossary, the '885 figures, and Figure 4 as necessary. Figure 1A of the '885 patent illustrates the guide member (36) affixed to an L-shaped guide rod (32) and in

position to make the anterior distal femoral condyle resection while the knee is in flexion. Figure 2A of the '885 patent illustrates the guide member (36) affixed to an L-shaped tibia guide rod (73) and in position to make the proximal tibia resection. Figure 3 of the '885 patent illustrates the engraved measurement markings on the flat portion (92) of the L-shaped guide rod (32). Figure 4 illustrates the areas of the bones to be resected in order to shape the bones to receive the prosthesis. Figure 4 also illustrates the flexion gap when the knee is in the flexion position and the extension gap when the knee is in the extension position. Plaintiff's glossary of medical terms:

Source: *Taber's Cyclopedic Medical Dictionary* (15th Ed.1985); except where otherwise stated.

Anterior: Before or in front of.

Condyles: A rounded protuberance at the end of a bone forming an articulation.

Distal: Farthest from the center, from a medial line, or from the trunk. Opposed to proximal.

Extension gap: The distance between the resected surface of the proximal tibia femur and the resected surface of the distal femur when the knee is in extension. ('885 Patent, Col. 7, lines 23-26).

Femur: The thigh bone. It extends from the hip to the knee and is the longest and strongest bone in the skeleton.

Flexion gap: The perpendicular distance between the resected surface of the proximal tibia and the resected surface of the posterior distal femur condyles when the knee is in flexion. ('885 Patent, Col. 7, lines 19-23).

Intramedullary canal: Within the marrow cavity of a bone.

Posterior: 1. Toward the rear or caudal end; opposed to anterior. 2. In man, toward the back; dorsal. 3. Situated behind; coming after.

Prosthesis: Replacement of a missing part by an artificial substitute, such as an artificial extremity.

Proximal: Nearest the point of attachment, center of the body, or point of reference. Opposite of distal.

Resecting: To cut off, or to cut out, a portion of a structure or organ, as to cut off the end of a bone or to remove a segment of the intestine.

Sagittal Plane: A vertical plane through the longitudinal axis of the trunk dividing the body into two sections.

Tibia: The inner and larger bone of the leg between the knee and ankle articulating with the femur above and with the talus below.

Valgus angle: A term denoting position, meaning bent outward or twisted, applied esp. to deformities in which a part is bent outward and away from the midline of the body, as talipes valgus, q.v., or hallux valgus, q.v.

The '203 and '805 patent claims.

The '203 patent method patent contains the following claims:

1. A method for making triplanar bone resections for total knee replacement, including the steps of:

resecting the proximal tibia such that it is perpendicular to an imaginary axis extending through the ankle joint, knee joint, and hip joint;

resecting the anterior and posterior distal femoral condyles such that they are parallel to each other and perpendicular to said axis when the knee is in flexion;

determining the flexion gap;

inserting an L-shaped femur guide rod into the medullary canal of the femur, the femur guide rod having a first portion and a second portion disposed at a right angle with respect to said first portion, the first portion being inserted in said canal;

placing the knee in extension;

partially extending said guide rod relative to said femur such that the outer surface of the second portion abuts the resected proximal tibia;

affixing a guide member having a first planar slot therein onto the second portion of said guide rod such that said slot is disposed perpendicular to the femoral medullary canal and relative to said canal to compensate for the valgus angle and such that said slot is spaced from the outer surface of the second portion a distance equal to the flexion gap;

placing the knee in flexion, while maintaining said guide rod relative to the distal femur;

and

resecting the distal femur in reference to said slot while the knee is in flexion.

2. The method of claim 1, wherein said step of resecting the proximal tibia comprises:

inserting an L-shaped tibia guide rod into the medullary canal of the tibia with the knee in flexion, the tibia guide rod having a first portion and a second portion disposed at a right angle therewith, the first portion being inserted in said canal;

stabilizing the tibia guide rod such that said rod is substantially coplanar with the tibial medullary canal;

affixing said guide member onto the second portion of the tibia guide rod such that said planar slot is disposed perpendicular to the tibial medullary canal; and

resecting the proximal tibia in reference to said slot while the knee is in flexion.

3. The method of claims 1 or 2, wherein said guide member includes second and third planar slots therein and wherein said step of resecting the anterior and posterior distal femoral condyles comprises:

affixing said guide member onto the second portion of the femur guide rod such that said second and third slots are disposed parallel to the femoral medullary canal and perpendicular to the tibial medullary canal, said second and third slots being parallel to said first slot; and

resecting the anterior and posterior distal femoral condyles in reference to said second and third slots, respectively.

4. The method of claim 3, wherein said step of resecting the anterior and posterior distal femoral condyles is accomplished prior to said step of resecting the proximal tibia.

5. The method of claim 3, wherein said step of resecting the proximal tibia is accomplished prior to said step of resecting the anterior and posterior distal femoral condyles.

6. The method of claim 1, wherein said step of resecting the distal femur in reference to said slot is accomplished by resecting said distal femur through said slot while the knee is in flexion.

7. The method of claim 1, wherein said L-shaped femur guide rod includes markings on its second portion for determining the flexion gap, and wherein said guide member includes markings corresponding to said markings on said guide rod, and wherein said method further comprises the steps of:

orienting said L-shaped femur guide rod such that said second portion of said guide rod is generally perpendicular to the resected surface of the proximal tibia;

determining the flexion gap in response to said marks on said second portion of said guide rod;

and

positioning said guide member relative to said guide rod in response to said marks on said guide member and said determined flexion gap.

8. The method of claim 1,

wherein said guide member includes an indicator which lies perpendicular to said first planar slot

and

wherein said step of affixing a guide member having a first planar slot therein on a second portion of said guide rod such that said slot is disposed perpendicular to the femoral medullary canal and relative to said canal to compensate for the valgus angle comprises the step of aligning with the axis extending from the guide member through the hip joint.

The '885 apparatus patent contains the following claims:

1. In a system for making triplanar bone resections for total knee replacement, the system including a set of

instruments for resecting the anterior and posterior femoral condyles, the proximal tibia, and the distal femur, the resections being made to provide equal flexion and extension gaps, the improvement comprising a simplified set of instruments, including:

an L-shaped guide rod having a first elongated portion adapted to be inserted into the medullary canal of the femur and a second portion disposed at a right angle to the first portion; and

a guide member having a planar slot therein, said member being adapted to be mounted on the second portion of said guide rod with said slot being parallel to the second portion and disposed relative to the first portion at a minor angle equal to 90 degree(s) minus the valgus angle.

2. The system of claim 1, further including:

a femur bar having a key lock and being adapted to be inserted into the guide member and being adapted to be mounted on the second portion of said guide rod, and wherein the second portion of said guide rod has a key seat, the key seat being adapted to cooperate with the key lock of the femur bar to compensate for the valgus angle, such that said planar slot in the guide member is disposed relative to the first portion of said guide rod at said minor angle.

3. The system of claims 1 or 2, wherein the guide member is adapted to be mounted on the second portion of the guide rod and is adapted to cooperate with said guide rod such that said planar slot is perpendicular to said second portion and perpendicular to the sagittal plane extending through the femoral medullary canal.

4. The system of claims 1 or 2, wherein the first portion of said guide rod is adapted to be inserted into the medullary canal of the tibia, and further including:

a tibia adapter adapted to be mounted on the first portion and adapted to stabilize said guide rod such that the second portion thereof is coplanar with the sagittal plane extending through the tibial medullary canal; and

a tibia bar adapted to be inserted into the guide member and adapted to be mounted on the second portion of said guide rod such that the planar slot of the guide member is disposed perpendicular to the first portion of said guide rod.

5. The system of claim 4, wherein the tibia bar has a key lock adapted to cooperate with the key seat of the second portion of said guide rod to position the tibia bar and the guide member inserted thereon such that said planar slot is disposed perpendicular to the first portion of said guide rod.

Discussion

A. Basic Principles of Claim Construction.

To construe the claims, the court first examines intrinsic evidence. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). The intrinsic evidence consists of the patent claims, the specification, and, if in evidence, the prosecution history. *Id.* Claims are construed from the vantage point of a person of ordinary skill in the art at the time the application is filed. *Id.* at 986. Where the specification does not use a term in a special or unique way, the ordinary meaning of the term to one skilled in the art controls. *Ekchian v. Home Depot, Inc.* 104 F.3d 1299, 1303 (Fed.Cir.1997). If an apparatus claim recites a general structure

(e.g., a noun) without limiting that structure to a specific subset of structures (e.g., with an adjective), the court generally construes the claim to cover all known types of that structure that are supported by the patent disclosure. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249-50 (Fed.Cir.1998).

Claim construction begins with the language of the claim itself. *North American Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1575 (Fed.Cir.1993). Terms used in the claims are read in light of the specification, which may act as a sort of dictionary providing clues to how specific terms are used. *Markman*, 52 F.3d at 979-980. The prosecution history similarly may present the patentee's understanding of specific claims as well as limit the meaning of the claims' terms to exclude any interpretation that was disavowed by the inventor in his or her effort to obtain the patent. *Id.* at 980. Claims are to be interpreted in light of the specification and with a view to ascertaining the invention, but it does not follow that limitations from the specification may be read into the claims. *Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir.1998). In construing a claim, a court does not impart additional limitations into a claim from reviewing the specification. *Ethicon Endo-Surgery Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1578. (Fed.Cir.1996). Rather, the court looks to the specification to aid the court in interpreting the meaning of a term already in a claim. *Id.*

A construing court does not accord the specification, prosecution history, and other relevant evidence the same weight as the claims themselves, but consults these sources to give the necessary context to the claim language. *Eastman Kodak Co.,v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1552 (Fed.Cir.1997). When two or more equally plausible definitions exist for a disputed term in a patent claim, then the court should adopt the narrower interpretation because the claim provides objective and reasonable notice to the public of the exclusionary rights granted to patentee. *Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*, 73 F.3d 1573, 1579 (Fed.Cir.1999). The court consults extrinsic evidence to ensure that the claim construction being considered by the court "is not inconsistent with clearly expressed, plainly apposite, and widely held understandings in the pertinent technical field." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed.Cir.1999). Extrinsic evidence is external to the patent and file history, such as expert testimony, inventor testimony, dictionaries, technical treatises, articles, and prior art not cited. *Vitronics*, 90 F.3d at 1584. Therefore, if the intrinsic evidence alone resolves any ambiguity, then it is improper to rely on extrinsic evidence. *Id.* at 1583.

B. Claim Construction of the '885 patent and '203 patent claims.

The parties agreed at the *Markman* hearing that a dispute exists about the limitations attached to five terms/phrases used in the claims. Nevertheless, plaintiff's and defendants' briefs raise a total of seven issues which the court addresses:

- 1) The extent the court delineates structure associated with a disputed term in a claim;
- 2) the extent this court imparts limitations from the file history of the '203 method patent into the '885 apparatus claims;
- the proper construction of the following disputed terms/phrases: 3) "L-shaped guide rod," 4) "planar slot,"
- 5) "simplified set of instruments," 6) "equal flexion and extension gaps," and
- 7) the required order of performance for the steps recited in the '203 method claims.

1. When Construing a Claim Not Written in a Means Plus Function Manner, the Court Must Delineate the Structure Associated With a Term Used in the Claim.

Plaintiff asserts that as a matter of law defendants improperly request the court to construe the claims and decree the structures associated with each element because the claims at issue are not written as means plus function claims.

The court agrees with plaintiff's assertion that the '203 and '885 claims at issue are not written in a means plus function manner. Therefore, the scope of a term in the '203 and '885 claims will not be limited solely to the structure(s) FN1 described in the specification associated with that term. See, *Al-site Corp. v. VSI International Inc.*, 174 F.3d 1308, 1318-19 (Fed.Cir.1999). However, in construing an apparatus claim the court must delineate the meaning and structure associated with the term in the claim being construed. *Markman*, 52 F.3d at 979. A distinction exists between the scope of the structures construed from a means plus function claim term and the scope of structures construed from a literal term used in the claim. The distinction lies in the scope of reasonable structures that an ordinary person skilled in the art would place upon the term used in the claim rather than limiting the scope of the structures solely to those structures and their equivalents disclosed in the specification. See *Markman*, 52 F.3d at 986. (The focus in construing a disputed term in the claim language * * * focus[es] on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.) Therefore, the court construes the disputed claim terms and delineates the structures within the scope of those terms as defendants request.

FN1. Under 35 U.S.C. s. 112 paragraph 6, the scope of the structures would be the literal structures described in the specification and the equivalents of those described structures.

2. On a Divisional Application, the Court May Consider the Statements Made in Prosecution the History of the '203 Patent in Construing the Meaning of the Terms used in Claims of Both the '203 and '885 Patents.

Plaintiff asserts two arguments.

1) Plaintiff states that the Manual of Patent Examining Procedure section 802.01 dictates that the '203 method patent and the '885 apparatus patent are separate and distinct inventions. Plaintiff concludes that the statements made to the examiner in the prosecution of the '203 method patent to overcome the prior art may not be used to limit the type of structures that may fall within the scope of the claims in the '885 apparatus patent.

2) Alternatively, plaintiff argues if the court considers the '203 prosecution history in construing the '885 claims, then plaintiff's remarks made in the amendment associated with the '203 patent discussed only the techniques used or method differences but not the structural differences between his invention and the reference art.

First, plaintiff relies on *Al-site Corp. v. VSI International Inc.*, 174 F.3d 1308 (Fed.Cir.1999), to argue that the prosecution history of a related patent does not limit the claims of another related patent. However, *Al-Site* is not applicable to the present case. In *Al-Site*, during an amendment specific limitations, i.e. actual additional words, were written into a claim of the earlier patent to make that invention patentable over the prior art. *Id.* at 1322. The related patents had different limitations-- different words-- written in their claims that made these related inventions patentable over the prior art. *Id.* The court concluded that the specific

limitations (terms) added to gain allowance of the earlier patent did not expressly appear in the claims of the related patent. *Id.* Therefore, the court did not read the limitations from the prosecution history of the earlier patent into the claims of the later issued patents, when those terms did not expressly appear in the claims of those later issued patents. *Id.*

What controls the issue in the instant case is: 1) the fact that the '885 patent claims the benefit of the earlier file date of the '203 patent; and 2) that the '203 method patent and the '885 apparatus patent use the same common terms in the claims.

In accordance with 35 U.S.C. 121, plaintiff obtained the earlier filing date of the '203 patent for the '885 patent by filing the apparatus claims of the '885 patent as a divisional application. "This is a division of my co-pending application Ser. No. 317,875 filed Nov. 3, 1981, now U.S. Pat. No. 4,487,203." ('885 patent, Col. 1, Lines 3-6.) The requirement for a divisional application is:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. (35 U.S.C. s. 121 Divisional Applications).

Accordingly, section 201.04 of the Manual of Patent Examining Procedure clearly mandates that all patents from a divisional application spring from a parent application if the later application claims the benefit of the parent application's earlier filing date.

The term "parent" is applied to an earlier application of an inventor disclosing a given invention. Such invention may or may not be claimed in the first application. Benefit of the filing date of the co-pending parent application may be claimed under 35 U.S.C. 120. (Manual of Patent Examining Procedure section 201.04.)

The Federal Circuit holds that the prosecution history of a parent application may limit the scope of a later application using the same claim term. *Augustine Medical Inc. v. Gaymar Industries, Inc.*, 181 F.3d 1291, 1300 (Fed.Cir.1999). This court agrees with plaintiff's assertion that the '885 divisional patent is a distinct and independent patent. However, plaintiff chose to receive the benefit of the earlier filing date of the '203 application. Thus, when plaintiff uses a claimed element to distinguish over the prior art and that claim term is common to the claims of both patents, the prosecution history may disavow structures in the scope of the claims in both patents. See, *Jonsson v. The Stanley Works*, 903 F.2d 812, 818 (Fed.Cir.1990).

A purpose of the patent and its prosecution history is to give the public objective and reasonable notice of the exclusion rights granted to the patentee. The '885 patent as a divisional patent of the '203 patent contains a virtually identical disclosure, numerous identical claim terms, and directs the public specifically to the '203 patent as the parent application of the '885 patent. Yet, plaintiff asserts that the comments made regarding those terms common between both patents during the prosecution of the '203 patent should have no bearing on the public's interpretation of those identical terms used in the '885 patent. This court disagrees.

Loral Fairchild Corp. v. Sony Corp., 50 U.S.P.Q.2d 1865 (Fed.Cir.1999), is analogous to the instant case. In *Loral*, the district court found support for construing plaintiff's terms used in the claims of plaintiff's method patent by examining the prosecution history of plaintiff's contemporaneous prosecution of a divisional

application directed to the apparatus. See *Id.* at 1873. In the instant case, this court similarly finds that the common terms used in plaintiff's prosecution of the '203 patent are relevant to interpreting those same terms used in the '885 claims.

2) Second, plaintiff asserts that if the court considers the '203 prosecution history in construing the '885 claims, then plaintiff's amendment made during the '203 prosecution discussed only the techniques used or method differences, but not the structural differences between his invention and the reference art.

The court accepts plaintiff's argument to the following extent. In rejecting the '203 patent application, the examiner considered as limitations "inserting the L-shaped guide rod," "affixing the guide member having a slot," "resecting the distal femur," and "the sequential procedure of placing the knee in the flexion and extension position." Thus, on each common term the court evaluates whether plaintiff, when using that term, patentably distinguished over the prior art by purely the intangible method of employing the term or the tangible structural differences in the prior art and his invention. In other words, the court reviews the prosecution history to determine the extent, if any, that plaintiff disavowed structures in patentably distinguishing over the prior art by using an express term found in the '885 patent claims.

3. The Proper Construction of the Term of an "L-Shaped Guide Rod" as Used in the Claims of Both the '203 and '885 Patent.

The Parties' Proposed Claim Construction of an L-Shaped Rod.FN2

FN2. Neither party argues that a substantial difference exists between the term an "L-shaped guide rod" used in the '885 patent and the terms an "L-shaped *femur* guide rod" and an "L-shaped *tibia* guide rod" used in the '203 patent. In addition, the specification states that the L-shaped *tibia* guide rod and the L-shaped *femur* guide rod are identical. ('203 patent, Col. 2, Lines 17-19). Thus, the discussions and arguments concerning the L-shaped rod applies to all three structures.

Defendants assert that a proper construction of the term an "L-shaped guide rod" would be "a slender, integral, round bar with two straight portions joined at 90 degrees to each other in the shape of an 'L'." Defendants emphasize that the rod is made entirely out of one piece.

Plaintiff argues that the term "an L-shaped rod" should be construed to mean the following. "A two portion structure. The first portion is generally the longer portion of the guide rod and is adapted to be inserted into the medullary canal. The second portion is generally the shorter portion of the guide rod and is at approximately right angles to the first portion." Thus, plaintiff emphasizes that one leg of the "L" could be formed by attaching a separate part to the straight rod. Additionally, plaintiff argues that defining the "L-shaped rod" by using the term a "bar" contradicts the patent's claims and specification because a "rod" defines one type of structure found in plaintiff's claims and a "bar" describes another type of structure found in plaintiff's claims. Furthermore, plaintiff argues that limitations not expressly appearing in a claim should not be read into plaintiff's claims.

In support of defendants' construction of an L-shaped rod, defendants submit that the ordinary meaning of the term "rod" is "A slender, straight, round stick or metal bar." Oxford American Dictionary, 786 (1980). However, extrinsic evidence such as a dictionary may not contradict the meaning of a term used in a claim. *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed.Cir.1998). In the '885 patent claims, an L-shaped rod, a tibia bar, and a femur bar are three distinct structures found within the claims. (See

claims 1, 2, and 4). Moreover, the court finds that the term "rod" is common word possessing a customary meaning. "Words in a claim are generally given their ordinary and customary meaning." Vitronics, 90 F.3d at 1582. Therefore, the court finds that defining the L-shaped rod by using the term "bar" would be inappropriate.

Next, plaintiff argues that limitations not appearing in a claim should not be read into a claim. See, Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998). (Claims are to be interpreted in light of the specification and with a view to ascertaining the invention; however, it does not follow that limitations from the specification may be read into the claims). Plaintiff submits that the limitation of "one integral piece" modifying the term of "an L-shaped rod" does not expressly appear in the prosecution history, the written disclosure, or in the claim language. Thus, plaintiff asserts that the intrinsic evidence imposes no limit on the number of pieces that can be fastened or joined together to make up the claim element of "an L-shaped guide rod." Similarly, plaintiff asserts that the express words of "straight, slender, or round" do not appear anywhere in the claims or in the written disclosure.

Defendants counter by submitting that figures 1a, 2a, 2e, 3, 6, and 7b of the patents do illustrate an L-shaped guide rod bearing all four of those characteristics. The drawings along with the written disclosure and original claims constitute the specification. Vitronics, 90 F.3d at 1584. Therefore, the structures described in the specification including the drawings guides a court in construing the literal scope of the terms used in the claims, but do not restrict the scope to solely those structures. "In construing a claim, a court does not impart additional limitations into a claim from reviewing the specification; rather, the court looks to the specification to aid the court in interpreting the meaning of a term already in a claim." Ethicon Endo Surgery Inc. v. U.S. Surgical Corp., 93 F.3d 1572, 1578 (Fed.Cir.1996). Thus, this Court must examine the claim language in light of the specification to determine the literal scope of the disputed term.

The Language of the Patents' Claims Concerning an L-shaped Guide Rod.

The term, an L-shaped guide rod, appears in claims 1 through 5 of the '885 patent and claims 1, 2, 3, 7, and 8 of the '203 patent. Claim 1 of the '203 patent typifies the term's use in the claims. Claim 1 recites: "Inserting an *L-shaped femur guide rod* into the medullary canal of the femur, the *femur guide rod having a first portion and second portion disposed at right angles with respect to the first portion.*" (Emphasis added.). Claim 1 of the '885 patent uses the term, an L-shaped guide rod, in a similar manner. Claim 1 recites: " *An L-shaped guide rod having a first elongated portion adapted to be inserted into the medullary canal of the femur and a second portion disposed at a right angle to the first portion.*" (Emphasis added.) Literally, claim 1 recites "An L-shaped * * * rod * * * to be inserted," which implies that the rod is a single piece with two portions when inserted rather than a multiple piece rod that forms the 'L' shape when the guide member attaches. When two equally plausible interpretations exist of disputed term in a claim, then the court should adopt the narrower interpretation. Athletic Alternatives, 73 F.3d at 1579.

Claim 2 of the '885 patent uses the term an "L-shaped guide rod" in this context. "A femur *bar* * * * being adapted to being *mounted on* the second portion of the *guide rod*. Claim 2 supports plaintiff's argument that the patent considers a "bar" a distinct structure from a "rod."

The Specification's Use of an L-shaped Guide Rod.

The specification discloses that "the guide rod has a 90 degree angle bend and is adapted to be inserted into the femur for use in aligning the guide member." ('203 patent, Col. 2, Lines 5-11.) A second identical guide rod is provided along with a tibia adapter and a tibia bar for use with a guide member." ('203 patent, Col. 2,

17-19.) As noted above, the Figures 1a, 2a, 2e, 3, 6, and 7b in the '203 and '885 patents illustrate an integral, straight, slender, and mostly round L-shaped guide rod. The term, "L-shaped guide rod," is pervasively used throughout the specification; yet, the specification neither expressly nor implicitly indicates that the L-shaped guide rod may be formed from two distinct parts fastened together. Similarly, the specification does not expressly or implicitly indicate that the portions of the rod that form the "L" shape may be anything but straight.

The Prosecution History Concerning an L-shaped Guide Rod.

In the prosecution history of the '203 patent, plaintiff did not disclaim any interpretation of the term of "an L-shaped guide rod." Plaintiff told the examiner in his Amendment that "the guide rod includes two portions, a first portion which inserts into the femur and a second portion at a right angle to the first portion. A guide member is affixed to the second portion of the guide rod." Thus, plaintiff merely restated to the examiner the claimed elements that make up the term an "L-shaped guide rod."

Defendants' proposed construction of a "round" L-shaped guide rod is not entirely accurate. The specification describes the L-shaped guide rod as having a threaded portion possessing a flat portion along one side thereof. "The flat portion of the L-shaped rod having sets of measurement marks to indicate the thickness of the tibia components." ('885 patent Col. 5, Lines 37-40.) The described embodiment in plaintiff's patent depicts a rod that is substantially round but also possesses a flat segment on the second portion of the guide rod. (See also Figure 3.) Therefore, defendants' proposed claim interpretation of "a round bar" would not include the specification's described embodiment within the literal scope of the claim. A claim interpretation that would exclude the patentee's device is rarely the correct interpretation. *Modine Manufacturing Co. v. U.S. Intern. Trade, Com'n.*, 75 F.3d 1545, 1550 (Fed.Cir.1996).

Conclusion of the Meaning of an L-shaped Guide Rod.

The court finds that the specification does not use the term "L-shaped guide rod" in a special or unique way. The court finds that plaintiff did not disavow any interpretation of the L-shaped guide rod in his effort to obtain the patent. Therefore, the ordinary meaning of the L-shaped guide rod term to one skilled in the art controls as long as the described embodiment in the patent specification falls within the literal scope of the claim language. The court finds that no express evidence exists in the claims or specification to sustain plaintiff's assertion that the rod may be formed from multiple pieces. Similarly, the court finds that the use of the term "L-shaped guide rod" in the claims does not dictate reading the non-express limitations of "slender" or "round" into the construction of the term. Thus, the court construes the term, "L-shaped guide rod" to possess the following meaning: "an integral rod having two straight portions joined at approximately 90 degrees with respect to each other. One portion of the rod is elongated and used for insertion into the femur or the tibia and the other portion is used for receipt of a guide member."

4. The Proper Construction of the Term of a "Planar Slot" as Used in the Claims of Both the '203 and '885 Patent.

The Parties' Proposed Claim Construction of a Planar Slot.

Plaintiff submits the following for the proper construction of the term "planar slot": 1) a slot in the guide member; or 2) an outer edge of the guide member; or 3) a surface of the guide member that can be used to position the saw used for resecting the knee.

Defendants submit the following for the proper construction of the term "planar slot": a narrow opening or groove in the guide member, but simply not an outer edge or surface of the guide member. Essentially, the parties dispute whether the planar slot's location must be "in" the guide member or "either in or on" the guide member.

Plaintiff asserts a function-way-results analysis to support plaintiff's construction of the term "planar slot." A doctrine of equivalents analysis uses the function-way-results test. The scope of structures included by the doctrine of equivalents is a question of fact for the trier of fact to determine, and thus is inappropriate at this stage of the litigation in which the court construes the literal scope of the claims as a matter of law.

Defendants submit a dictionary definition to support their interpretation of the ordinary meaning of the term "slot". "A narrow opening through which something is to be put. A groove or channel or slit into which something fits." Oxford American Dictionary, 788 (1980). However, plaintiff asserts that defining "planar slot" by using the term an "opening" would contradict the patent's specification because an opening describes a structure already found in the patent's specification. The court agrees, and finds that the term "slot" is a commonly used word possessing its own ordinary meaning.

The Language of the Patents' Claims Concerning a Planar Slot.

The term "planar slot" appears in the claims 1 through 5 of the '885 patent and claims 1, 2, 3, 6, and 8 of the '203 patent. These claims do not explicitly define whether the slot is located either "in" the guide member or "in or on" the guide member. However, claim 1 of the '885 patent recites: "A guide member having a first planar slot *therein*." The term "therein" modifying the term "planar slot" implies that the slot is located "in" rather than "either in or on" the guide member.

The Specification's Use of a Planar Slot.

The specification discloses that "A vertical guide *slot* is centrally *located in* the guide member relative to the sides." ('203 patent, Col. 3, Lines 59-60.) That statement from the specification directly conflicts with the plaintiff's concept of a side of the guide member being a planar slot. Further, the specification discloses that, "An oscillating saw is *inserted* through the center slot 52 of the guide member, and the proximal tibia is then resected." ('203, Col. 5 Lines 18-20.) Similarly, "An oscillating saw is *inserted into* center slot 52 of the guide member, and the distal femur is then resected." ('203, Col. 6 Lines 46-48.) The words "inserted" suggest a slot "in" the guide member rather than a surface or edge of the guide member. When the specification refers to the drawings for a visual indication of the planar slot's location, the drawings illustrate a slot "in" the guide member rather than "in or on" the guide member. Nowhere in the specification do the patents indicate that the guide member's surface or edge may be use as a planar slot to guide the cutting of the saw. The court finds that the specification strongly indicates that the planar slot is located "in" the guide member.

The Prosecution History Concerning a Planar Slot.

The prosecution history sheds some light on the term "planar slot." Plaintiff told the examiner in his Amendment that "a slot *in* the guide member is spaced from the outer surface of the second portion of the guide rod for a distance which is equal to the determined flexion gap. (Emphasis added.)

Conclusion of the Meaning of a Planar Slot.

The court finds that the specification does not use the term, "planar slot," in a special or unique way. The court finds that plaintiff's own understanding of the location of the slot in his effort to obtain the patent was that the slot was located *in* the guide member. The court does not find support in the claims or the specification for plaintiff's assertion that the term "planar slot" may refer to an edge or surface of the guide member. Thus, the court construes the term "planar slot" to mean "a slot located within the guide member that can be used to position a saw used for resecting the bones that form the knee."

5. The Proper Claim Construction of the Phrase "The Improvement Comprising a Simplified Set of Instruments, Including:" as Used in Claim 1 of the '885 Patent.FN3

FN3. A claim contains three parts: the preamble, the transition phrase, and the body. *E.I. Du Pont De Nemours & Co. v. Monsanto Co.*, 903 F.Supp. 680, 693 (D.Del.1995). The preamble is the introductory phrase shown before the transition phrase. *R2 Medical Systems, Inc. v. Katecho, Inc.*, 931 F.Supp. 1397, 1434 (N.D.Ill.1996). The transition phrase connects the preamble to the body of the claim. *E.I. DuPont*, 903 F.Supp. at 693. The body of the claim lists the limitations that define the invention. *Id.*

The claiming format of Claim 1 of the '203 patent is not in dispute and illustrates the typical three parts of a claim.

1. A method for making triplanar bone resections for total knee replacement, including the steps of: resecting the proximal tibia such that it is perpendicular to an imaginary axis extending through the ankle joint, knee joint, and hip joint;

* * *; and

resecting the distal femur in reference to said slot while the knee is in flexion.

In Claim 1 of the '203 patent, from the beginning of the claim to the comma, "A method for making triplanar bone resections for total knee replacement, " is the preamble. In claim 1, after the comma to the colon," including the steps of:" is the transition phrase. In claim 1, everything after the colon to the period, "resecting the proximal tibia * * * in flexion" is the body of the claim.

Plaintiff submits the following for the proper construction of the phrase "the improvement comprising a simplified set of instruments, including:." The guide member and L-shaped guide rod are the two limitations which appear in the body of claim 1. The phrase is in the transition part of the claim and is merely a short-hand collective reference to two limitations that follow in the body of the claim. Therefore, the phrase places no limitation on scope of the '885 patent. Plaintiff makes the alternative argument that the phrase "the improvement comprising a simplified set of instruments," is in the Jepson format and is located in the preamble.FN4 Similarly, plaintiff asserts that the phrase places no limitation on scope of the '885 patent.

FN4. See the equal flexion and extension gaps analysis for a discussion on the preamble and Jepson claims.

Defendants submit that the phrase "simplified set of instruments" is located in the body of the claim and acts as a limitation on the invention. Defendants also argue that this phrase requires that a single guide member must be used for all of the triplanar bone resections.

The parties' briefs pose two questions in analyzing this issue: 1) is the phrase, "simplified set of instruments" part of the transition phrase or part of the body of the claim; and 2) during the prosecution of the '203 method patent did plaintiff use the guide member's structure to distinguish his invention over the prior art?

However, even if the court accepted either one of plaintiff's arguments, what controls in the present case is whether plaintiff used that phrase in the prosecution history to patentably distinguish his invention over the prior art. If any interpretation was disclaimed during a patent's prosecution, that prosecution history excludes that interpretation from the claim construction. *Vitronics*, 90 F.3d at 1583.

The Prosecution History Concerning the Phrase a "Simplified Set of Instruments."

Defendants argue that in plaintiff's Amendment to overcome the examiner's 35 U.S.C. s. 103 rejection, plaintiff unequivocally stated that the set of instruments referred to a single guide member which establishes the appropriate points of resection in the tibia and femur. Defendants further assert that the phrase "a simplified set of instruments," was a principle feature of the invention in distinguishing plaintiff's patent over the prior art. Defendants support their argument by quoting the plaintiff's Amendment:

In contrast to this [the prior art of the Richards reference] * * * [T]he technique of Richards requires the use of two wholly independent cutting guides. One [a guide member] for use on the distal femur and the proximal tibia and another for use on the distal femoral condyles. As reflected in claim 3 FN5, *all resections* made in accordance with the method of Applicant's invention *may be* made in reference to a *single guide member* which is appropriately positioned for each cut by one of two guide rods. (Emphasis added).

FN5. Claim 3 of the '203 patent that the plaintiff refers to adds two additional slots to the guide member to make the distal femoral condyles resections.

In the Amendment, plaintiff describes the intangible method of inserting the L-shaped guide rod into the medullary canal. However, plaintiff gave notice to the examiner and the public that a principle distinction between his invention and the prior art was his invention's ability to employ a single guide member to make all the necessary resections. Plaintiff distinguished the method of performing his invention by disavowing techniques, such as Richards, which require the use of two wholly independent cutting guides. The examiner accepted this limitation from the phrase "simplified set of instruments" to distinguish plaintiff's invention from the cited art.

The Specification's Use of "Simplified Set of Instruments."

In the specification, the patent contrasts the prior art knee replacement systems, which required numerous components, and the present invention which includes a single guide member for use in making the proper

bone resections. ('885 patent, Col. 1 Line 65 to Col. 2 Line 7.) The specification goes on to state that, "The guide member eliminates the necessity for a different type of guide component for each triplanar resection." ('885, Col. 8, Lines 30-35 .)

Additional Arguments Made by Plaintiff.

Plaintiff argues an infringement principle: if a written claim uses the transition phrase of "including:" or "comprising:" then the named elements are an essential component but other elements may be added and still form a construct within the literal scope of the claim." *Genentech Inc. v. Chiron Corp.*, 112 F.3d 495, 500 (Fed.Cir.1997). Plaintiff concludes that even if a single guide member is construed as a limitation on the scope of the '885 claims, the law requires that the claims can not be limited solely to a single guide member because of this infringement principle. Plaintiff is incorrect. First, because this litigation is at the stage of claim construction FN6 and is not at an infringement analysis, that principle does not apply. Second, the application of that principle to the instant case would be incorrect under the doctrine of file wrapper estoppel.

FN6. The court at this time is determining the literal scope of the disputed terms at issue.

What controls how many guide members may be used in employing plaintiff's invention is the prosecution history doctrine. During the prosecution of the '203 patent, plaintiff disavowed any interpretation that more than one guide member *must* be used to make all the cuts. Plaintiff distinguished his invention by stating, "As reflected in claim 3, all resections made in accordance with the method of Applicant's invention may be made in reference to a single guide member." The plaintiff's modifying language of "may be" is precatory language. Accordingly, the court finds that at least one of the guide members used in performing this surgery must be capable of making all the resections.FN7

FN7. Additionally, plaintiff asserts that defendants' argument in defendants' brief improperly relies on a photograph of the reference art. The court construed the claims based on only the intrinsic evidence. Therefore, the court did not rely at all on this photograph in construing the claims.

CONCLUSION ON THE MEANING OF "THE IMPROVEMENT COMPRISING A SIMPLIFIED SET OF INSTRUMENTS, INCLUDING:."

The court finds that plaintiff disavowed structures in which a single guide member may not make all the resections in the knee replacement. The court construes the phrase of "the improvement comprising a simplified set of instruments, including" to possess the following meaning: "A set of instruments used in resecting the bones that form a patient's knee. The set of instruments comprises: at least one guide member capable of making all the necessary tibia and femur bone resections; and at least one L-shaped guide rod that cooperates with the guide member."

6. The proper construction of the phrase "equal flexion and extension gaps" as used in claim 1 of the '885 patent.

Plaintiff asserts that the proper construction of the phrase "equal flexion and extension gaps" in the preamble merely describes a purpose of the invention and does not act as a structural limitation. Defendants assert that because claim 1 is written in the Jepson FN8 format that the phrase "equal flexion and extension

gaps" recites a limitation on the scope of the claim. Defendants argue that the phrase "equal flexion and extension gaps" means "the flexion and extension gaps must be measured and formed equal to each other, as the instruments are used to make each resection."

FN8. A "Jepson" claim is so named after *Exparte Jepson*, 1917 C .D. 62, 243 O.G.526. Such a claim is traditionally indicated when the transition phrase begins with the phrase, "wherein the improvement comprises:." Generally, a Jepson claim contains in the following order: "(1) a preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known; (2) a phrase such as "wherein the improvement comprises"; and (3) those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion." *See*, 37 C.F.R. s. 1.75(e) (1996).

Claim preambles may be interpreted as claim limitations when they are necessary to give life, meaning, and vitality to the claim. *Pitney Bowes*, 182 F.3d at 1306. "If the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations, and the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states, for example, the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." *Id.* The preamble is not considered a limitation where the preamble merely states a purpose or intended use of the claimed subject matter. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620-621 (Fed.Cir.1995).

The Language of the Patents' Claims Concerning "Equal Flexion and Extension Gaps."

The preamble of Claim 1 of the '885 patent recites:

1. In a system for making triplanar bone resections for total knee replacement, the system including a set of instruments for resecting the anterior and posterior femoral condyles, the proximal tibia, and the distal femur, *the resections being made to provide equal flexion and extension gaps*, (Claim 1 of the '885 apparatus patent, emphasis added).

Claim 1 of the '885 is an apparatus claim. Accordingly, the subject matter of claim 1 must be some tangible structure rather than a process. The act of creating equal flexion and extension gaps is a result of using some device. Thus, to provide equal flexion and extension gaps suggests a purpose of a device rather than a structure in a device. Further, the structural limitations in the body of the claim, the L-shaped guide rod and guide member, do not refer back FN9 to the phrase equal flexion and extension gaps in the preamble. Therefore, the limitations in the body of the claim are intrinsically set apart from the phrase "equal flexion and extension gaps" in the preamble.

FN9. The L-shaped guide rod and the guide member do not rely on the phrase for antecedent basis or to provide a proper context for those two limitations. Thus, the two limitations of the L-shaped guide rod and the guide member are intrinsically set apart from the phrase equal flexion and extension gaps located in the preamble. *See Pitney Bowes*, 182 F.3d at 1305.

The Specification's Use of "Equal Flexion and Extension Gaps."

The specification's use of phrase "equal flexion and extension gaps" implies that the gaps are a result or

purpose of the invention. "[T]he triplanar knee resection system of the present invention *ensures* equal flexion and extension gaps while providing for proper valgus alignment." ('885 patent, Col. 8, Lines 37-40.)

The Prosecution History Concerning "Equal Flexion and Extension Gaps."

In the Amendment, plaintiff explained to the examiner that for the prosthesis to be stable in the flexion and extension positions, the gap between the femur and the tibia should be equal with the knee in both positions. However, plaintiff did not rely on this phrase in his arguments to overcome the cited art. Most notably, the examiner in making his rejection did not consider the phrase equal flexion and extension gaps as a limitation of the claim. In rejecting the '203 patent application, the examiner considered as limitations "inserting the L-shaped guide rod," "affixing the guide member having a slot," "resecting the distal femur," and "the sequential procedure of placing the knee in the flexion and extension position."

Plaintiff and Defendant both assert that the preamble of claim 1 of the '885 patent is written in Jepson form FN10. Plaintiff asserts that the Jepson form preamble describes only the environment or purpose in which the claim limitations will function. Therefore, claim 1 is not limited by the phrase equal flexion and extension gaps. Plaintiff further asserts that he did not rely on phrase of equal flexion and equal gaps in distinguishing his invention over the reference art. Defendants rely on *Rowe v. Dror*, 112 F.3d 473 (Fed.Cir.1997), to argue that the preamble of the Jepson form claim is considered to positively and clearly include all of the elements or steps recited therein as limitations on the claimed combination. *Rowe*, 112 F.3d at 479. However, the Federal Circuit's reasoning in *Rowe* belies a blanket application of that rule to the instant case. In *Rowe*, the recited *structure* in the preamble was a balloon angioplasty catheter. *Id.* At issue was whether the term "angioplasty" as an adjective acted as a limitation on the balloon catheter. *Id.* at 477. The court reasoned that "the so-called 'Jepson' form [itself], *suggests* the structural importance of the recitations found in the preamble." *Id.* at 479. However in the instant case, the phrase "equal flexion and extension gaps" does not suggest a particular type of general structure; rather, the phrase describes a result achieved by use of the apparatus defined in the claim.

FN10. The transition phrase, "the improvement comprising:" signifies a traditional Jepson claim.

Conclusion on the meaning of the phrase "equal flexion and extension gaps" located in the preamble of claim I in the '885 patent.

The court finds the phrase of "equal flexion and extension gaps" merely describes a purpose of the invention claimed in the '885 patent and does not act as structural limitation on the claimed invention.

7. The Required Order of Performance for the Steps Recited in Claim I of the '203 Patent.

Defendants request the court to determine the required sequence, if any exists, for three method steps recited in claim 1 of the '203 patent:

1. whether a requirement exists for performing the method step of "determining the flexion gap" before the step of "resecting the distal femur" in claim 1 of the '203 patent; and
2. whether a requirement exists for performing the method steps of 1) "resecting the proximal tibia," and 2) "resecting the anterior and posterior distal femoral condyles" before the step of "resecting the distal femur."

The specification explicitly defines the flexion gap as the distance between the posterior femoral condylar resection and the proximal tibial resection with the knee in flexion. ('203 patent, Col. 7, Lines 15-19.) The court finds the term "flexion gap" to possess a special definition as defined within the four corners of the patent. *Accord*, Markman, 52 F.3d at 979-980 (Patentee is free to be his or her own lexicographer; however, any special definition given to a word must be clearly defined in the patent specification). Essentially, "determining the flexion gap" is simply measuring the perpendicular distance between the top of the surgically cut tibia to the bottom edge of the resected femur when the knee is flexed. (See Figure 4.)

The Parties' Proposed Claim Construction of the Sequential Order of the '203 Method Steps.

Plaintiff asserts that the chronological order of the steps set forth in the claims does not limit the order in which the steps of the knee resection process may be performed. The general rule is that unless the literal language or physical constraints of the process claim dictate otherwise, the steps of the claim have no required order of performance. *Bio-Rad Laboratories, Inc. v. Nicolet Instrument Corp.*, 739 F.2d 604, 614 (Fed.Cir.1984).

Defendants assert two arguments that either, 1) by predominant language norms, or 2) by the physical constraints of the claim language, the steps contained within claim 1 possess a required ordered of performance. First, defendants assert that by the use of "predominant language norms" a presumption exists that the steps of a patent claim must be performed in the chronological order listed. Defendants cite *Loral Fairchild Corp. v. Victor Co. of Japan, Ltd.*, 906 F.Supp. 798 (E.D.N.Y.1995), for this proposition. In *Loral*, the court explained: "Predominant language norms suggest recounting process steps in a chronological sequence. A process description flows most naturally from one step in the sequence to the next in chronological order." *Id.* at 805. However, this presumption has not been widely accepted. In *Promega Corp. v. Novagen, Inc.*, 6 F.Supp.2d 1004, 1021 (W.D.Wis.1997), the court limited *Loral*: "Although in *Loral* the court relied on "predominant language norms" to a certain extent, it found other evidence in the patent itself that the patentee intended to specify an exact procedural sequence." This Court follows the general rule that unless the literal language or physical constraints of the process claim dictate otherwise, the steps of the claim have no required order of performance. See, *Mantech Environmental Corp. V. Hudson Environmental Services, Inc.*, 152 F.3d 1368, 1375-76 (Fed.Cir.1998).

The Steps Contained in Claim 1 of the '203 Patent Posses No Literal Language Requiring a Specific Order of Performance.

No literal language is present in claim 1 of the '203 patent that requires a sequential performance of any step contained therein. Plaintiff submits that claim 1 does not use any express terms in the language of the claim, such as "prior to," "subsequently," or "then," grammatically requiring the performance of the listed steps in any specific order. In contrast, claims 4 and 5 do contain the literal language of "prior to said step" expressly requiring the performance of those steps in particular sequence.

The court agrees that claim 1 lacks any express terms that grammatically require the flexion gap to be determined before the resection of the distal femur.

The physical constraints of Claim 1 require that the step of "determing the flexion gap" must occur before the step of "resecting the distal femur."

Nonetheless, the step of "determining the flexion gap" must be performed prior to the step of "resecting the distal femur" due to the physical constraints of claim 1 and the '203 prosecution history. If a step in a

method claim as written relies on a device already physically in existence or the result of another step, then the existence of those physical constraints act as a condition precedent on that method step. *Accord*, Mantech, 152 F.3d at 1375-76. The claim language of the distal femur resection step recites: "resecting the distal femur in reference to said *slot* while the knee is in flexion." (Claim 1, '203 patent; emphasis added.) The express language suggests that a slot already exists and the slot position establishes a reference point for the resection. In fact, plaintiff in the Amendment represented to the examiner that the plain language of claim 1 requires that: 1) the flexion gap must be determined in order for the slot to be spaced correctly; and 2) the slot must be spaced correctly in order to resect the distal femur. Plaintiff links portions of three of the method steps in claim 1 to prove this physical constraint to the examiner and, thereby, contrast his invention from the cited prior art.

The plaintiff links the physical constraints between these three steps:

determining the flexion gap;

affixing a guide member having a first planar slot therein * * * said slot is spaced * * * a distance equal to the flexion gap;

resecting the distal femur in reference to said slot * * *.

(Claim 1, '203 patent).

In the Amendment, plaintiff concludes his representations to the examiner by stating, "The distal femur is *then* resected in reference to *this slot* and, thus, in reference to the *determined* flexion gap." (Emphasis added.) Therefore, the court finds that the step of determining the flexion gap must occur before the step of resecting the distal femur.

The specification further supports the finding that the step of determining the flexion gap must occur before the step of resecting the distal femur. The only method for making triplanar bone resections described in the specification of the '203 patent resects the proximal tibia and posterior femoral condyles prior to resecting the distal femur. ('203 patent, Col. 5 Line 51-Col. 6 Line 53.)

Nonetheless, plaintiff asserts that the step of determining the flexion gap is not a single act but rather a dynamic process of making measurements and adjustment cuts to make the flexion and extension gap equal in order to achieve a goal of a tightly fitting prosthetic implant. Accordingly, no express limitations appear in the claims stating that the determining of the flexion gap step may be performed only once during the entire process. Thus, the court will not read such limitations into this claim. Essentially, determining the flexion gap is measuring the perpendicular distance between the top of the surgically cut tibia to the bottom edge of the resected femur when the knee is flexed. However, at least one determination of the flexion gap must occur before the initial resection to the distal femur occurs.

The physical constraints of Claim 1 require that the method steps of 1) "resecting the proximal tibia" and 2) "resecting the anterior and posterior distal femoral condyles" must occur before the step of "resecting the distal femur."

The specification explicitly defines the flexion gap as the distance between the posterior femoral condylar resection and the proximal tibial resection with the knee in flexion. ('203, Col. 7, Lines 15-19). Thus, both

of those bones must be cut surgically before a flexion gap can be determined. Accordingly, if the flexion gap is determined prior to the first resection of the distal femur, then the resections of the proximal tibia and posterior distal femoral condylar occur before the resection of the distal femur.

In view of the arguments above, this court finds that the flexion gap is determined prior to the resection of the distal femur. Therefore, by definition and as a result of a condition precedent method step, a physical constraint requirement exists for performing the method step of resecting the proximal tibia before the step of resecting the distal femur. Similarly, a physical constraint requirement exists for performing the method step of resecting the anterior and posterior distal femoral condyles before the step of resecting the distal femur. Therefore, the method steps of resecting the proximal tibia and resecting the anterior and posterior distal femoral condyles must occur before the step of resecting the distal femur.

Conclusion on the Required Sequential Order of the '203 Method Steps.

The court finds that the '203 patent uses the term "flexion gap" in a special way. The '203 patent explicitly defines the term within the four corners of the document. By definition in order to determine the flexion gap, the posterior femoral condylar and the proximal tibia must be resected. Thus, an initial resection of the posterior femoral condylar and the proximal tibia must occur before the distal femur is resected. A determination of the flexion gap may occur at any time after the initial resections occur to the posterior femoral condylar and the proximal tibial. However, a final determination of the flexion gap must occur before the final resection to the distal femur occurs. FN11

FN11. Plaintiff raised an additional argument. Plaintiff cites non-claim construction cases for the proposition that a presumption in the law can be rebutted by actual evidence. Because the court is not basing its decision on a presumption, the court will not address plaintiff's proposition.

Conclusion

The court construes the claims of the '203 and '885 patent's as set forth above. This matter is set for a report on status, January 27, 2000, at 9:30 a.m.

N.D.Ill.,2000.

Depuy Orthopaedics Inc. v. Androphy

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