United States District Court,
C.D. California.

BAUSCH & LOMB, INC,
Plaintiff.
v.
OASIS MEDICAL, INC,
Defendants.

No. CV 00-11298 MRP

July 18, 2002.

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MEMORANDUM OF DECISION RE: Claim Construction

MARIANA R. PFAELZER**, District Judge.**

I. INTRODUCTION

In this case, Bausch & Lomb ("B & L") claims that Oasis infringes its patent, U.S. Patent No. 6,051,009 ("the '009 patent"). The patent is in pertinent part directed to the shape of a blade assembly to be used in a microkeratome, a device for cutting the cornea. The patented microkeratome is designed to rapidly oscillate the blade while driving it in an arcuate path, thereby cutting a circular flap in the cornea. Typically, the cutting is performed as part of a laser vision correction procedure. The blade is claimed in terms of "edges," and the patent further describes how the blade is to be coupled with a blade holder so that it can easily fit into the cutting head assembly of a microkeratome. The parties dispute a number of terms in the patent.

On July 18, 2001, the Court issued a preliminary claim construction but also invited further briefing by the parties. The briefing was submitted and a claim construction hearing was held on June 10, 2002. After considering the papers submitted, the arguments of counsel, and the record in this case, the Court rules as follows.

II. LEGAL STANDARD

Interpretation of patent claims is a matter of law reserved for the court. *See* Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent

itself, including the claims, the specification, and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). "In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such situations, it is improper to rely on extrinsic evidence." Id. at 1583.

III. DISCUSSION

A. "Edge"

The claims at issue describe a front cutting edge, a pair of side edges, and a rear trailing portion containing a rear edge. The parties disagree about what an "edge" is, within the meaning of the patent, and whether it must be distinct. Oasis contends that "edge" should mean "simply a border, boundary or side of the blade." *See* Oasis' Opening Markman Brief, at 2. It agrees with the Court's preliminary ruling that the "rear edge" may have a variety of shapes and that the "side edges" are the two surface borders on each side of the blade. However, it argues further that the '009 patent requires that the rear edge "be a distinct surface border or boundary defining the rear side of the blade that does not overlap with, wrap around or include any portion of 'the two surface borders on each side of the blade.' " Oasis' Opening Markman Brief at 2 (emphasis omitted). Oasis also requests that the Court modify its "margin of intersection" definition of "edge". Bausch and Lomb supports the Court's preliminary construction.

In its preliminary claim construction, the Court held that "edge" is used in two senses in the '009 patent. First, it could mean "the actual physical margin of intersection between two surfaces," such as a sharp edge of a blade. *See* Preliminary Claim Construction Order at 4. Second, it could "simply define the surface boundary created by that margin of intersection." Id. The Court has concluded that this definition should be revised.

Although not required by the claims, a blade covered by the '009 patent typically has a top surface and a bottom surface. As Oasis notes, these surfaces do not technically intersect, except possibly at the sharp forward cutting edge. In order to avoid uncertainty, and because the "margin of intersection" component of the preliminary construction is not necessary to the Court's construction, the Court finds it is not useful here. An "edge" is more clearly defined by its location at the boundary of the top and bottom surfaces.

This so-called "surface boundary" is that portion of the blade where the top and bottom surfaces end. At that location, there is a "lateral surface" which extends completely around the blade. This lateral surface is simply the expression of the width of the blade. Although perhaps a first inclination would be to term such a lateral surface "the side," in this case such a use would be confusing. The patentee defined a six-sided polygon as having four edges in Figure 6C of the patent, and therefore an "edge" is surely not a "side" in the geometric sense. However, the edges do occur along "the side," perimeter, or width of the blade, which the Court also terms the lateral surface of the blade. FN1 These are all simply synonyms for each other. The illustration below further demonstrates the lateral surface, or width of the blade.

FN1. As a result, it is not possible to have an edge which comprises an imaginary line through part of the blade's top and bottom surfaces, as Oasis claims B & L argues. An "edge" according to the Court's construction includes only a specific portion of the lateral surface of the object in question, and therefore may be measured only along the outer perimeter of the blade.

Tabular or graphic material set at this point is not displayable.

In this illustration of a four-sided object, two sides (representing one half of the lateral surface) are shaded. The large top and bottom surfaces, and the other half of the lateral surface, are not shaded.
Knowing generally where edges exist on the blade, however, does not necessarily allow one to distinguish between specific edges. Although it is difficult to make such distinctions in this case because of the apparently broad manner in which the "edges" were claimed, the claims do require that such distinctions be made.

The patentee in this case has chosen to be his own lexicographer with regard to the definition of "edge". The '009 patent indicates that "the cutting blade can be formed to have other shapes" beyond those described in the specification. *See* '009 patent, col. 11, l. 49-50. A wide range of such "other shapes" may challenge those seeking to identify transition points between edges. The parties have brought examples including half-circles and triangles to the Court's attention, but an infinite range of such challenging shapes can be imagined. A proper construction of "edge" or "side" must be applicable to all shapes, and not just the accused blade in this case.

In addition to describing a wide range of possible shapes, the patentee indicated that a single "edge" within the meaning of the patent may include angles or curves. *See, e.g.,* '009 patent, Figure 6C (showing a six-sided polygon yet describing it as having four edges, the "side edges" comprising two distinct lines separated by an angle); Figure 7 (depicting curved side edges). It is therefore clear that a single "edge" may contain more than one line, or may be curved. *See* id.

The patent does not expressly describe any angles or arcs in the front cutting edge or the rear edges, but it also does not exclude such shapes. Because the side edges may clearly include angles or arcs, and because the patentee expressly indicated that the blade could have different shapes, the Court sees no reason why the front and rear edges should not be construed as having the same flexibility. The patentee refers to the sides, as well as the front and rear, as "edges" without limiting the range of possible shapes. Therefore, as with the side edges, the front and rear edges may also consist of varied shapes.

In order for a specific edge to be identifiable, however, it is necessary to know precisely where it begins and ends. Such assessments may be impossible with some hypothetical blade shapes, thus leaving them outside of the patent's protection. Yet in order for a blade to fall within the patent's claims, certainty is necessary in light of the requirement that any blade covered by the patent must have four edges.

As noted before, many possible blade shapes present challenges with regard to determining where one edge ends and another begins. For example, in any given embodiment, the rear trailing portion may contain both side edges and a rear edge. One skilled in the art must make fine distinctions in order to discern edge transitions in shapes like this, as well as other shapes. The challenges inherent in making these fine distinctions are further amplified by the fact that the rear edge need not be parallel to the front cutting edge. *See* '009 patent at Col. 11, l. 26-28 (stating that, in a preferred embodiment, the rear edge need only be "generally parallel," thereby leaving open the option that the rear edge not be parallel in a less-preferred embodiment). Indeed, as discussed above, the rear edge need not even be a straight line.

Because innumerable blade shapes are possible, the very existence of a rear edge itself will be debatable in many shapes. In the absence of a distinctiveness requirement, there would be no guidance as to whether a shape has a rear edge, or whether a certain part of the lateral surface is part of a side edge rather than part of the rear edge. In order to say that a blade with so many possible shapes has a rear edge, that edge must be

distinguishable by those skilled in the art. Any less would lead to a range of shapes with an uncertain number of edges. In order for the public to have notice of what is claimed, those skilled in the art must be capable of ascertaining if a shape has the four edges expressly required by the patent.

The fact that the edge must be distinct does not necessarily mean, however, that there must be a physical feature, such as a change in angle or curvature, distinguishing it. If one skilled in the art would readily identify and distinguish a rear edge even without such a feature, then a blade will meet the rear edge requirement.

The distinctiveness requirement is inherent in the requirement that the edges be identifiable, because one cannot really know there is an edge at all unless it has an identifiable beginning and end. Because each edge must be distinct, each edge is also inherently measurable. The distinctiveness requirement, and the fact that each edge is therefore measurable, is further supported by the limitation in certain claims that the rear edge must be shorter than the front cutting edge. The inventor in these claims simply refers to "the edge" as if it is naturally subject to measurement. He does not single out only "special" edges for measurement, but rather assumes that any rear edge would be measurable in order to determine if it is shorter than the front. Because the patentee has chosen to be his own lexicographer with regard to "edge," the fact that he viewed edges as measurable provides additional support for the idea that the inventor believed that the edges could be readily identified and measured by those skilled in the art. The Court's preliminary claim construction, while recognizing the potential breadth of the "rear edge," did not explicitly require those skilled in the art to distinguish the rear edge from the rest of the blade. For the reasons discussed above, the Court now holds that although a claimed edge may be located in any location on the blade, it must also be distinct-subject to identification and measurement.

There is no particular need to construe each edge separately and the Court declines to do so. Each "edge" is simply that portion of the lateral surface which is distinct, measurable, and distinguishable as either a front cutting edge, rear edge, or side edge.

Some claims of the '009 patent require that the side edges (or at least one side edge) taper between the front and rear portions (*See* '009 patent, claims 1, 36 and 54). Although both parties initially disagreed about "tapering," they appeared to agree at oral argument that the blade may taper at any point according to Claim 54, but must taper from the front part to the rear part in claim 1. The Court sees no further need to construe where the tapering must occur. Regardless of where the tapering occurs, a blade with two sides that taper to a point may nevertheless be said to have a rear edge if such an edge is distinct and measurable. FN2

FN2. In such a case it would not be the point itself that would be considered an edge, but rather some portion of the lateral surface that those skilled in the art would recognize as a "rear edge" according to the definition expressed in the patent.

B. The Preamble

"Whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire ... patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.' Corning Glass Works v. Sumitomo Electric U.S.A., Inc., 868 F.2d 1251, 1257 (Fed.Cir.1989)." Catalina Marketing Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed.Cir., May 8, 2002).

A preamble may limit claim scope if the patentee depends on a particular phrase therein to provide an antecedent basis for subsequent references. Such reliance on the preamble indicates that both the preamble and the claim body must be used to define the claimed invention. *See* Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620(Fed.Cir.1995); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1306 (Fed.Cir.1999).

A preamble may also limit claim scope if it recites additional structure or steps which were underscored as important by the specification. *See, e.g.,* General Electric Co. v. Nintendo Co., 179 F.3d 1350, 1361-62 (Fed.Cir.1999) (limiting claim scope to a "raster scanned display device" rather than display systems generally, where specification had focused on prior art problem of displaying binary data on a raster scan display device).

On the other hand, a preamble is generally not limiting when the claims describe a structurally complete invention which would be unaffected by deleting the preamble phrase. *See* IMS Tech., Inc. v. Haas Automation, Inc., 206 F.3d 1422, 1434 (Fed.Cir.2000) (stating that the preamble phrase "control apparatus" merely gives a name to a structurally complete invention).

A preamble is generally also not limiting where it simply describes the purpose or intended use of an invention, because the patentability of an apparatus depends on the claimed structure, as opposed to its purpose. An inventor is entitled to all the uses to which an invention may be put, not only those uses conceived by the inventor. *See* Catalina Marketing, 289 F.3d at 809-810 (citing cases).

Oasis argues that the preambles of the claims in '009 patent are not limiting, but are rather mere statements of "the intended use of the blade assemblies in particular environments." Oasis Medical's Opening Markman Brief at 21. B & L argues that the claims' dependence on preamble phrases requires the preamble to be read as a limitation.

The preamble of claim 34 is generally representative of the preambles of the claims in suit. It describes a cutting blade assembly to be used with a surgical device that cuts at least partially across a cornea, the surgical device containing a positioning ring, a cutting head assembly (described in some detail), and a drive means operably connected to the cutting head assembly for moving the assembly across the positioning ring and for oscillating the cutting blade assembly. The claimed cutting blade assembly comprises (i) a cutting blade having the claimed "edges" discussed above, (ii) a blade holder having a top side "including means for lockingly engaging the drive means and for being operably driven by the drive means of the surgical device," and (iii) an integral blade unit being sized and configured to be introduced through the access opening formed in the cutting head assembly and into an operative position. This claim and other similar claims depend on their preambles, relying on them not only for antecedent bases, but also because they recite structure that the specification underscores as important to the invention.

Claim 34 requires that the blade holder engage with and be operably driven by the "drive means of the surgical device." The "surgical device" is a structure which only has meaning in light of the preamble and the specification. The "drive means" is also detailed in the preamble, which in turn refers the reader to the structure disclosed in the specification by virtue of its means plus function format. Because the "drive means" and "surgical device" have essential antecedent bases in the preamble, the preamble must be considered a limitation on the claim. It is impossible to understand how the blade holder is claimed to engage with and be driven by the drive means without examining the drive means and surgical device of the preamble.

The description of the integral blade unit provides further support for the conclusion that the preamble must be construed as a limitation. It requires that the integral blade unit be sized and configured to be introduced through the access opening in the cutting head assembly. Although the claims discuss a cutting *blade* assembly, the preamble describes the cutting *head* assembly. Because the size and configuration of the cutting blade assembly is described in terms of the cutting head assembly, which appears only in the preamble, the preamble provides a necessary antecedent basis for the description of the integral blade unit. It also elucidates important additional structure, the cutting head assembly, that the specification considers critical to the invention, by describing it and the structures it interfaces with in great detail.

In saying that the preamble is limiting, the Court is not saying that structures disclosed only in the preamble should be imported into the claims. Rather, the preamble serves to further describe the structure of the blade assembly by reference to the structures disclosed in the preamble. These additional structures from the preamble need not themselves exist. Rather, their characteristics as described in the preamble are used only indirectly in determining whether a blade infringes the claim. Although one of the preamble's requirements is that the surgical device be capable of partially cutting across a cornea, the surgical device need not actually be used to cut a cornea. Similarly, the blade need not actually be used with the surgical device or any other disclosed structures. The claims require only that the blade could be used with such a device, and that the device could be used to cut partially across the cornea of an eye.

In determining whether a particular cutting blade assembly infringes, it is therefore necessary to imagine the range of configurations that could be created according to the structures disclosed in the preamble and the claims, and to apply those structures to the allegedly infringing blade assembly. The claims are broadly drafted, but this breadth also applies when evaluating any prior art that may exist.

C. Aperture and Lock Segment

A number of claims, including claims 1, 34, 66 and 67, require an "aperture" in the blade. Others, including claims 11 and 38, also require a "lock segment" which engages with the aperture. B & L argues that the aperture need not completely pass through the blade, but rather may be only a recess or opening in the blade sufficient to allow the lock segment to engage it. In support of its argument, B & L argues that the purpose of these structures is to mate the blade with the blade holder, and that the terms should be construed broadly to effect this purpose. It also argues that not all claims expressly require the lock segment to extend "through" the aperture and that the doctrine of claim differentiation therefore requires the Court to construe the term as not including this limitation. Finally, B & L argues that a dictionary definition providing that an aperture is "an opening, as a hole, gap or slit: orifice," supports its construction.

The dictionary definition does not provide a great deal of assistance to B & L, because opening, hole, gap, slit and orifice can all carry a connotation of passing completely through an object. For example, Oasis presents a dictionary definition for "opening" which describes an open space affording passage or view, and which specifically states that "aperture" is a synonym for "opening". The intrinsic evidence is even less favorable to B & L's position.

The doctrine of claim differentiation is not appropriately applied in this instance because claims 11, 12, 38 and 39 do not further define or limit the "aperture". Rather, they simply impose additional limitations on the structure disclosed in the respective independent claims. Claims 11 and 2 8 require a lock segment structured to extend through "said aperture." This is the same aperture referred to in the independent claims.

The lock segment must extend "through" this aperture, meaning that in all cases the aperture is capable of receiving a lock segment that extends through it. The aperture in the independent claims need not contain a lock segment extending completely through it, but because it is the same aperture discussed in the dependent claims, it must in all cases be capable of accepting such a lock segment. Similarly, claims 12 and 39 are directed to a lock segment which includes a flanged portion to engage an edge of "said aperture." This simply describes the same aperture with a lock segment extending through it and engaging the other side with a flanged portion. This further reinforces the need for the aperture to be capable of accepting a lock segment that extends completely through it.

"Aperture" is twice used in the specification to describe a hole passing entirely through something and is not used in any other sense. First, the specification depicts the apertures on the cutting blade in Figure 6C, as two holes passing completely through the blade. The specification also refers to the lock segment "structured and disposed to extend through the aperture formed in the cutting blade so as to become secured thereto." See '009 patent, Col. 12, l. 15-17. Nowhere is there any indication that the aperture in the cutting blade extends less than all the way through the blade. Although not dispositive on the issue, in combination with all the other intrinsic evidence it also tends to show that the aperture was intended by the patentee to go all the way through the blade. The second aperture referred to in the patent is the positioning ring, "aperture 33" in Figure 3, as "sized to permit the cornea C, of the eye to pass therethrough and be exposed ..." '009 patent, col. 6, l. 63-67.

Based on all the intrinsic evidence, it is therefore clear that an "aperture" must be "an opening which passes completely through the cutting blade."

The parties do not appear to seriously disagree about the meaning of "lock segment", except in the context of its impact on the construction of "aperture". B & L argues that the lock segment is "a structure that protrudes from the blade holder and which is shaped to be received within the aperture of the blade." Bausch & Lomb's Memorandum of Points and Authorities in Support of Claim Construction, at 15. Oasis argues that the lock segment must extend through the aperture.

Although it appears that each claim requiring a lock segment also requires that the lock segment extend through the aperture, the parties did not argue this point specifically. The Court believes that generally "through" is properly taken to mean "entirely through". However, because they examined this language in light of its impact on the term "aperture", the parties have not thoroughly addressed construction of the term "through" in light of the lock segment. It does not appear that they ever intended to address the term in that context. "Through" in the context of the lock segment therefore does not require construction at this time.

D. "Coupling element" and "coupling member"

Claim 53 describes "a blade having ... at least one coupling element; and a blade holder having at least one coupling member," which cooperate to secure the blade and blade holder together.

Oasis argues first that these terms do not recite sufficient structure, and that they therefore must be interpreted under 35 U.S.C. s. 112 para. 6. As such, it argues that the "coupling element" should be construed as an aperture formed in the blade, and that the "coupling member" is a lock segment structured and disposed to extend through the aperture. *See* Oasis' Opening Markman Brief at 23-24. Even if not construed as a means plus function claim, Oasis argues that "coupling member" must be construed as an extension or beam-like structure.

The Court finds that these terms should not be construed under s. 112 para. 6. If the word "means" is not used, there is a presumption against such construction. *See* Personalized Media Comm., LLC v. Int'l Trade Comm'n, 161 F.3d 696, 703-04 (Fed.Cir.1998). ("the failure to use the word "means" creates a presumption that 112 para. 6 does not apply."); *Al-* Site Corp. v. VSI Intern., Inc. 174 F.3d 1308, 1318 (Fed.Cir.1999) ("when an element of a claim does not use the terms 'means,' treatment as a means-plus-function claim element is generally not appropriate."). The word "means" is not used to describe the coupling structures in the asserted claims, and Oasis has not provided enough evidence to overcome the resulting presumption. Indeed, there is ample support for the proposition that "coupling element" and "coupling member" recite sufficient structure even in the absence of such a presumption.

From the descriptions of a coupling element and member, respectively, it is clear that the blade and the blade holder must each contain a structure for coupling-a structure designed to interconnect with the reciprocal structure on the other part. "Coupling element" and "coupling member", although broader than the "aperture" and "lock segment" disclosed in other claims, refer to specific structures which together are capable of coupling the blade to the blade holder.

With regard to the further question of whether the "coupling member" must be shaped in the form of an extension or beam-like structure, the Court finds no such requirement. Although "member" is sometimes used in this sense, there is by no means a fixed definition that requires such an interpretation and nowhere does the specification support such a construction of the term here.

The American Heritage Dictionary of the English Language, Fourth Edition (2000) defines a "member" as "[a] structural unit, such as a beam or wall." It does not specify that the member must be an extension, but rather merely "a structural unit." Similarly, The Oxford English Dictionary, Second Edition (1989) defines "member" as "[e]ach of the constituent portions of a complex structure."

Yet dictionary definitions are not even required to construe the term "member," because it is clear that the inventor used "member" to generally describe structural features throughout the patent. The patentee refers to a groove, element 42 in Figure 3, as a "channel member." *See* '009 patent, col. 7, l. 28-29. He states that the positioning ring includes a "connection member 37, which as illustrated in FIG. 2 and 3, is in fluid communication with an undersurface of positioning ring 32." *See* '009 patent, col. 7, l. 5-7. He also describes "rigid upstanding member 44 compris[ing] a post member 45." *See* '009 patent, col. 7, l. 65-66. He describes a "door member" which may be open or closed, *see, e.g.,* '009 patent, col. 9, l. 53-66, and a "plate member," *see, e.g.,* '009 patent, col. 13, l. 22-31.

The inventor used "member" to describe a diverse range of structural elements including a rigid upstanding member, plate member, door member, channel member, and coupling member. This broad use suggests the inventor was using the term "member" generically to describe a structural feature-a use which is also consistent with the two dictionary definitions above. "Element" and "member" simply provide a convenient set of terms to distinguish the two structures for the reader's benefit.

The Court therefore adopts B & L's proposed construction, that " 'coupling element' and 'coupling member' are structures that interlock with each other to securely join the blade and the blade holder together."

E. "Integral blade unit"

In the claims at issue, the blade is secured to the blade holder to provide an "integral blade unit." B & L suggests, based largely on statements in the specification, that this integral blade unit must also be disposable. The patent, at col. 10, l. 6-27 discusses the integral blade unit as capable of being slidably inserted into the cutting head assembly, and being capable of rapid removal. The specification also states that "an object of the present invention is to provide an improved cutting blade and blade holder which is integrally formed and consequently, which is easy to remove from a microkeratome device, and ideally, which is disposable." '009 patent at col. 4, l. 66-col. 5, l. 3.

B & L also argues that the prosecution history supports a requirement that the integral blade unit must be disposable. In an office action issued on August 28, 1998, claim 34 (then claim 37) was rejected over U.S. Patent No. 4,884,570 to Krumeich et al. Krumeich apparently discloses a reusable blade. In response to that office action, the patentee added "said integral blade unit being sized and configured to be unitarily introduced through the access opening formed in the cutting head and into an operative position." *See* Response to Office Action, March 1, 1999. In explaining this change, the applicant noted a number of advantages which would not have been obvious to those familiar with Krumeich.

Specifically, the applicant noted that the integral blade unit eliminated the need to open the cutting head assembly for positioning or removal of the blade. He noted that the structure of the blade, "as amended, facilitates the proper aligned positioning of the cutting blade, as well as the removal of the cutting blade subsequent to a procedure and/or whenever a blade must be changed." Response to Office Action, filed March 1, 1999. The applicant therefore noted a number of distinct advantages to the integral blade unit which Krumeich did not possess-advantages which did not include the disposability of the unit. Moreover, the applicant stated that the blade design facilitated removal "whenever" a blade must be changed. This statement implies that the blade need not be disposed of after each use, because "whenever" implies that there are options besides immediate disposal.

As with the prosecution history, the specification does not support a disposability requirement for the integral blade unit. The patent states that the blade is "ideally" disposable-a strong indication that a non-ideal blade could be made which is not disposable. Nowhere is such a blade foreclosed in the patent. In fact, the features of the integral blade unit which appear most crucial to the patentee are the ease of inserting and removing it from the cutting head assembly, not its disposability. The ability to dispose of the integral blade unit is one advantage of a preferred embodiment, but it is surely not a limitation of any claims at issue.

The "integral blade unit" is plainly described in the claims and no further construction is needed. As discussed above, there is no requirement that it be disposable.

F. The person of ordinary skill in the art

B & L argues that a person of ordinary skill in the art when the '009 patent was filed was "an educated mechanical design engineer or physician, either of who have a number of years experience in the design of precision mechanical devices for cutting the eye." It argues that instruments designed to cut the eye are typically designed by those with experience in the field of eye surgery. In this regard, it notes that although Mr. Hellenkamp had no experience in designing instruments for cutting the eye when he designed the ACS microkeratome, he worked with Dr. Ruiz on that project, who did have such experience. It also notes that Mr. Barraquer, a pioneer in the microkeratome field, had extensive experience with microkeratomes. B & L also argues that the '009 patent explicitly states that it is directed to a "cutting blade assembly to be used in conjunction with an automatic surgical device for cutting the cornea of a patient's eye."

Oasis argues that one skilled in the art must have experience designing precision cutting devices, but that such experience need not be limited to the design of cutting devices specifically for cutting the eye. In support of its argument, Oasis points out that before he collaborated on the ACS blade, Mr. Hellenkamp was simply a precision machinist. It also argues that a keratome is simply a modified dermatome, a device for cutting skin. An Oasis expert, Dr. Salz, testified that other precision cutting devices are also relevant, such as a mucotome, a similar device for removing tissue from the mouth.

As a preliminary matter, the Court must identify the relevant art before it can determine the level of skill possessed by a person of ordinary skill in that art. The '009 patent is directed to a precision surgical device for cutting the eye. The positioning ring of the surgical device is specially designed to contain and provide suction to the eye, and the inventor directed his attention to solving the problem of cutting at least partially across a cornea. The Court therefore finds that the corresponding art is limited to the design of precision mechanical devices for cutting the eye. Similar precision surgical blades may exist that do not cut the eye, and they may in fact be analogous art for the purposes of an obviousness inquiry. However, the relevant art for the purpose of determining level of skill is narrower in view of the invention before the Court.

In determining the level of skill in the art, the Court must look to factors such as "the educational level of the inventor; the type of problems encountered in the art; the prior art solutions to those problems; the rapidity with which innovations are made; the sophistication of the technology; and the educational level of workers in the field." *See* Helifix Ltd. v. Blok-Lok Ltd., 208 F.3d 1339, 1347 (Fed.Cir.2000).

Here, although Mr. Hellenkamp had no experience designing blades for eye surgery prior to his work on the ACS blade, he worked with Dr. Ruiz, an opthamologist, on that project. There is also evidence that Mr. Barraquer, a pioneer in the field, had experience with microkeratomes. As B & L also points out, the '009 patent is explicitly directed to blades for eye surgery, *see* '009 patent, Col. 1, l. 16-19, and the patent office has its own classification for patents directed to corneal cutters.

This is sufficient to demonstrate that some skill in designing blades for cutting the eye was required of one skilled in the art at the time the application was filed. The fact that Mr. Hellenkamp did not have experience in this area when he designed the ACS blade is not particularly persuasive given his collaboration with Dr. Ruiz. Similarly, the fact that dermatomes and mucotomes are similar to keratomes does not compel a conclusion that knowledge of the former is all that is required for one to be skilled in the art of designing the latter.

B & L urges that one skilled in the art must be "an educated mechanical design engineer or physician, either of who have a number of years experience in the design of precision mechanical devices for cutting the eye." *See* B & l's Memorandum of Points and Authorities in Support Of Claim Construction, at 7. However, it has not presented sufficient evidence that a person skilled in the art must be a mechanical design engineer or physician-members of other professions may also be skilled, or gain skill, in the keratome art. It also has not provided evidence of how many years of experience are required. Given this lack of evidence, the Court is unable to rule with any more specificity regarding the person of ordinary skill in the art at this time. As a preliminary matter, the Court finds that one skilled in the art is simply "a person with experience in the design of precision mechanical devices for cutting the eye."

IV. CONCLUSION

A. "Edge"

Each "edge" is that portion of the lateral surface of the blade that is distinct, measurable, and distinguishable as either a front cutting edge, rear edge, or side edge.

B. The Preambles

The preambles at issue form antecedent bases for certain claim terms, recite structures deemed important by the specification, and are essential to understanding the claims. The preambles therefore must be viewed as limiting the claimed blade assembly.

C. Aperture and Lock Segment

An "aperture" is "an opening which passes completely through the cutting blade." The "lock segment" does not require construction.

D. "Coupling element" and "coupling member"

'Coupling element' and 'coupling member' are structures that interlock with each other to securely join the blade and the blade holder together.

E. "Integral blade unit"

There is no need to construe this term. There is also no requirement that the integral blade unit be disposable.

F. The person of ordinary skill in the art

The relevant art is limited to the design of precision mechanical devices for cutting the eye. As a preliminary matter, the Court finds that one skilled in the art is "a person with experience in the design of precision mechanical devices for cutting the eye."

C.D.Cal.,2002.
Bausch & Lomb, Inc. v. Oasis Medical, Inc.

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