United States District Court,
D. Massachusetts.

NOVA BIOMEDICAL CORPORATION,
v.
CORPORATION.

No. CIV.A. 95-11396-RGS

Oct. 7, 1997.

Patentee brought action for infringement of patent for method of analyzing hematocrit. Alleged infringer moved for construction of disputed claim. The District Court, Stearns, J., held that patent was limited to devices incorporating standardizing solution keyed to real blood reference.

Patent construed.

4,686,479. Cited.

John J. Regan, Donald R. Steinberg, Wayne M. Kennard, Hale & Dorr, Boston, MA, for Nova Biomedical Corp.

Peter B. Ellis, Donald R. Ware, Foley, Hoag & Eliot, Boston, MA, Samuel D. Rosen, Paul, Hastings, Janofsky & Walker, New York, NY, for Defendants.

MEMORANDUM AND ORDER ON I-STAT'S MOTION FOR CLAIM CONSTRUCTION

STEARNS**, District Judge.**

i-STAT manufactures a portable, point-of-care analyzer used to measure the hematocrit level of blood. FN1 Nova makes a similar nonportable device that is protected by U.S. Patent No. 4,686,479 (the '479 patent). The ' 479 patent teaches a method for analyzing hematocrit.

FN1. Hematocrit is the percentage of the volume of a blood sample composed of cells of red blood.

The i-STAT and Nova devices are based on a common principle. Red cells in the blood conduct electricity poorly while electrolytes in the blood (principally sodium and chloride) are highly efficient conductors. FN2 The i-STAT and Nova devices measure the hematocrit value of a blood sample by comparing the conductivity of the sample to that of a known standardizing solution. The i-STAT and Nova devices also adjust the reading to account for differing concentrations of electrolytes in the two exemplars. Finally, both devices use an aqueous calibrating solution to overcome the physical limitations involved in using real

blood as a reference.

FN2. The conductivity of blood, in other words, is inversely influenced by the concentration of red blood cells. '479 patent, col. 1, lines 10-23.

The dispute in this case centers on the meaning of the '479 patent term equating the conductivity of the '479 standardizing solution to a "known equivalent hematocrit value." See November 14, 1996 Hearing Tr., at 7. The ' 479 patent, at col. 1, lines 56-60, defines "known equivalent hematocrit value" to mean "the hematocrit level of a blood sample having a conductivity corresponding to that of the standardizing solution." i-STAT asks for the court's construction of this specific language.

On March 7, 1997, the court issued a tentative construction of the disputed patent language and invited the parties' comments on its understanding of the underlying scientific and technical issues, and on the relevance, if any of the Supreme Court's post-briefing decision in Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., --- U.S. ----, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

DISCUSSION

[1] [2] [3] [4] "A literal patent infringement analysis involves two steps: the proper construction of the asserted claim and a determination as to whether the accused method or product infringes the asserted claim as properly construed." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576,1581-1582 (Fed.Cir.1996), citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, ----, 116 S.Ct. 1384, 1393, 134 L.Ed.2d 577 (1996). "[C]onstruction of a patent claim is a matter of law exclusively for the court." 52 F.3d at 977 (citations omitted). In construing claims, a court should first "look to the words of the claims themselves, both asserted and non-asserted, to define the scope of the patented invention." Vitronics, 90 F.3d at 1582, *citing* Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620 (Fed.Cir.1995). The court should also look to the patent specification. "The specification contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make it and use it. Thus, the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582.

[5] [6] [7] The claims, specifications and file history constitute the patent's "public record ... on which the public is entitled to rely." Vitronics, 90 F.3d at 1583. Thus, it is inappropriate for a court to consider extrinsic evidence, such as expert testimony, unless the testimony is necessary to understand the meaning or scope of a technical term in the claims. *Id., citing* Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed.Cir.1995); Markman, 52 F.3d at 980-981 (same). "[W]here the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." Vitronics, 90 F.3d at 1583.

Interpretation of the Term "Known Equivalent Hematocrit Value"

[8] The meaning of the term "known equivalent hematocrit value" is, as previously noted, at the heart of the dispute over the construction of the claims of the '479 patent. The court held a *Markman* hearing focused largely on this issue on November 14, 1996, and entertained a number of post-hearing submissions. Nova's argument, as it has been refined over the course of the litigation, seeks to delink the patent term "equivalent hematocrit value" from the hematocrit value of an actual blood sample.

The actual hematocrit of a standardizing solution is never negative or positive; because the standardizing solution contains no red blood cells, its actual hematocrit is, by definition zero ... [T]he conductivity of the standardizing solution is, as stated in the claims 'indicative' or 'representative' of an 'equivalent hematocrit value,' whether positive or negative. [Thus] conductivity and 'equivalent hematocrit value' simply are the starting points from which one can measure an actual hematocrit of real blood by performing a mathematical calculation using the relative conductivities of the blood and the standardizing solution. One of ordinary skill in the art, after reading the equations in the patent (Col. 10, lines 47-68), would immediately recognize this mathematical fact.

Nova Memorandum of April 14, 1994, at 5.

i-STAT argues that this is the way Nova now wishes the patent had been written, for had it been, it would clearly encompass i-STAT's calibrating solution. i-STAT, however, points to the following limiting definition in the ' 479 patent.

The standardizing solution has a known ion species concentration and a conductivity indicative of a known equivalent hematocrit value; 'equivalent' hematocrit value is used in this application to mean the hematocrit level of a blood sample having a conductivity corresponding to that of the standardizing solution, even though the standardizing solution contains no whole blood cells and has an actual hematocrit value of 0.

'479 patent, col.1, lines 54-62.

The crux of contention, as both parties acknowledge, are the four words "of a blood sample." In the physical world, the hematocrit value of real blood is measured on a closed percentage scale of zero to 100. Zero represents pure blood plasma FN3 containing no red blood cells; 100 represents a (probably theoretical) sample consisting entirely of red blood cells.FN4 The scale of resistance values, while it can be plotted against the hematocrit scale, is not bounded by its minimum and maximum values. This means that it is possible to construct a standardizing solution with a negative hematocrit value, that is, a solution with a resistance lower (and a conductivity higher) than any value encountered in real blood.FN5 i-STAT argues that, by definition, the hematocrit value of the '479 standardizing solution must be expressed as a positive number, because no other result is possible with a real blood reference,FN6 that is, no hematocrit value found in an actual blood sample can be less than zero.FN7 This reading of the patent is, I believe, correct.

FN3. Plasma is the liquid component of blood.

FN4. In living patients actual hematocrit ranges from 10 to approximately 75. i-STAT claims that it is possible to construct a sample of physical blood with an hematocrit of 100. Whether this is true or not is not material to the construction of the '479 patent's claims.

FN5. Pure plasma with a hematocrit level of zero has a resistance value of 1.8k ohms. Real blood within the range of normal hematocrit levels (35-50) has an approximate resistance value of 4.1k ohms. i-STAT assets that its standardizing solution has a resistance value of 1.6k ohms, a value below that of plasma. As i-STAT views the method of the '479 patent, it teaches the substitution of a standardizing solution correlated to a hematocrit value derived from real blood, thus avoiding the "clotting, cleaning and resultant down time that

the repeated use of reference blood would produce in the apparatus." Zelin Aff. para. 15. If the i-STAT calibrant could be assigned an "equivalent hematocrit value," the number would necessarily be negative, that is, indicating a conductivity greater than pure plasma. Id., at para. 18. A negative hematocrit value, i-STAT argues, is a wholly artificial construct, not unlike assigning a negative value to a scale measuring velocity. The negative number that can be assigned to the i-STAT calibrant is thus merely "the result of the equation that the [i-STAT] device uses which relates the hematocrit levels of real blood samples to their resistivities." Id., at para. 19. In sum, "[t]he i-STAT system's calibrant solution cannot correspond to a blood sample as required by the asserted claims [of the '479 patent]." Id., at para. 20.

FN6. Michael Zelin, a vice-president of i-STAT, attests that the conductivity of i-STAT's calibrant solution corresponds to no blood or plasma sample which exists either physiologically or that can be construed by manipulation. "As such, i-STAT's calibrant solution has no 'equivalent hematocrit value' as per the explicit definition in the '479 patent." Zelin Reply Aff. para. 6. "The 'equivalent hematocrit value' of i-STAT's calibrant solution is unknowable." Id., at para. 19. Zelin contends that the '479 device does not work with a standardizing solution like i-STAT's which has a conductivity greater than that corresponding to an "equivalent hematocrit value" of zero. Id., at para.para. 51-67.

FN7. While it is true that the preferred embodiment of Nova's invention utilizes a standardizing solution that provides an equivalent hematocrit value of less than 5%, that value is clearly keyed to a real blood reference, even if not to an actual sample that could be drawn from a living human being.

[9] Nova argues that the '479 patent, read holistically, with its various graphs and equations, defines "equivalent hematocrit values" to encompass conductivities not only below the range of the actual hematocrit values found in real blood, but negative hematocrit values as well. This argument effectively reads out of the '479 patent the express limitation equating "known equivalent hematocrit value" with the hematocrit level of "a blood sample." FN8 Expanding on the claims of a patent by collapsing its limitations is something that patent law does not permit. See Maxwell v. J. Baker, Inc., 86 F.3d 1098, 1105 (Fed.Cir.1996) (a court cannot construe claims to read out an express limitation), *citing* Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed.Cir.1993); Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1563 (Fed.Cir.1991) (same). FN9

FN8. I am somewhat puzzled by Nova's insistence that the court confuses equivalent and actual hematocrit values. The issue is not whether the standardizing solution described in the '479 patent has an actual hematocrit value; no one is under the illusion that it does (or could have). A thermometer measures temperatures against a physical scale of relative degrees of hot and cold without necessarily reaching or exceeding the theoretical extremes of that scale (for example, absolute zero) or actually radiating the temperature it records. The issue rather is whether the '479 patent describes equivalent hematocrit value in such a fashion as to limit its claims to solutions calibrated against a real blood reference.

FN9. I simply cannot accept Nova's argument that Figure 12A in the ' 479 patent expands the express definition of equivalent hematocrit value to include negative values for two reasons. First, the patent itself describes Figure 12A as illustrating the relationship of resistance to actual hematocrit values. See col. 10, lines 48-54. Second, the figure as presented was mistakenly drawn, as Nova itself admitted in proceedings

before the European Patent Office. I agree with i-STAT that Heidelberger Druckmaschinen AG v. Hantscho Commercial Products, Inc., 21 F.3d 1068 (Fed.Cir.1994), is of no particular relevance as i-STAT is not seeking to rely on a decision of a foreign patent examiner, but only upon Nova's admissions in the foreign proceeding. See Caterpillar Tractor Co. v. Berco, S.P.A., 714 F.2d 1110, 1116 (Fed.Cir.1983).

INFRINGEMENT UNDER DOCTRINE OF EQUIVALENTS

[10] [11] [12] Under the doctrine of equivalents, an accused product is infringing if it performs "substantially the same overall function or work, in substantially the same way, to obtain substantially the same overall result as the claimed invention." Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 934-935 (Fed.Cir.1987), citing Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 901-902 (Fed.Cir.1984); Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 70 S.Ct. 854, 856, 94 L.Ed. 1097 (1950). However, simply because two processes are capable of performing the same task does not establish infringement. Pennwalt Corp., 833 F.2d at 937.

Though the doctrine of equivalents is designed to do equity, and to relieve an inventor from a semantic straight jacket when equity requires, it is not designed to permit wholesale redrafting of a claim to cover non-equivalent devices, i.e., to permit a claim expansion that would encompass more than an insubstantial change.... "It is ... well settled that each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device." Lemelson v. United States, 752 F.2d 1538, 1551 (Fed.Cir.1985) (footnote omitted). To be a "substantial equivalent," the element substituted in the accused device for the element set forth in the claim must not be such as would substantially change the way in which the function of the claimed invention is performed.

Perkin-Elmer Corp., 822 F.2d at 1532-1533.

An important restatement of the doctrine of equivalents is found in *Hilton Davis,* supra,which, while affirming the validity of the doctrine, gives it a stringent construction. The Supreme Court acknowledged the concern expressed by the dissenting judges in the Federal Circuit "that the doctrine of equivalents, as it has come to be applied since *Graver Tank,* has taken on a life of its own, unbounded by the patent claims," thereby contradicting "the definitional and public-notice functions of the statutory claiming requirement." Hilton Davis, 520 U.S. at ---- - ----, 117 S.Ct. at 1048-1049. The Court adopted the suggestion of one of the dissenting judges that the doctrine be refocused on the elements of the disputed claims rather than the overall result of the invention.

"[T]hat the accused device or process must be more than 'equivalent' *overall* reconciles the Supreme Court's position on infringement by equivalents with its concurrent statements that 'the courts have no right to enlarge a patent beyond the scope of its claims as allowed by the Patent Office.' [Citations omitted.] The 'scope' is not enlarged if courts do not go beyond the substitution of equivalent elements." 62 F.3d at 1537-1574 (Nies, J., dissenting) (emphasis in original).

We concur with this apt reconciliation of our two lines of precedent. Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus, the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such

broad play as to effectively eliminate that element in its entirety.

Id., 520 U.S. at ----, 117 S.Ct. at 1049.

There is no doubt but that *Hilton Davis,* as Nova contends, endorses the view that infringement under the doctrine of equivalents is ordinarily an issue for the jury. But if the term "known equivalent hemocratic value," is correctly construed as limiting the claims of the '479 patent to devices incorporating a standardizing solution keyed to a real blood reference, it is difficult to perceive what it is that a jury would be expected to decide.

This brings me to Nova's complaint that it "has not been allowed to conduct technical discovery concerning infringement, and that the [court's] request for briefing concerning the doctrine of equivalents is inconsistent with the court's prior statements of record that the defendant's summary judgment motion on infringement would be deferred until Nova has been provided with the usual discovery in a patent case." Nova's Memorandum of April 14, 1997, at 1. The only "technical" information relevant to the issue of literal infringement that comes to mind relates to the composition of i-STAT's calibrant solution. i-STAT represents that it has provided Nova with samples and the chemical formula of its solution. Nova is perhaps right to complain that my tentative opinion strayed beyond the bounds of a *Markman* construction by considering extrinsic evidence that i-STAT's calibrating solution does not literally infringe on the claims of the '479 patent, although it had been my impression that Nova did not dispute the fact that i-STAT's solution reports a negative hematocrit value. However, to avoid any unfairness, I will give Nova twenty-one days to specify the nature and relevance of the discovery it wishes to conduct before the issues of literal infringement and infringement under the doctrine of equivalents are joined.

CONSTRUCTION

For the foregoing reasons, the court construes the claims of the '479 patent to be limited to devices that measure hematocrit by utilizing a standardizing solution with a conductivity indicative of the hematocrit values found in real blood.

SO ORDERED.

D.Mass.,1997.
Nova Biomedical Corp. v. i-Stat Corp.