United States District Court,
S.D. New York.

NOVO NORDISK A/S, Novo Nordisk of North America, Inc. and Novo Nordisk Pharmaceuticals Inc,
Plaintiffs.
v.
BECTON DICKINSON AND COMPANY,
Defendant.

No. 96 Civ. 9506 BSJ

March 21, 2000.

OPINION and ORDER

JONES**, J.**

At the request of the parties, this Court held a *Markman* hearing to construe the terms of United States patents owned by the plaintiff Novo Nordisk ("Novo"). Familiarity with this Court's opinions in Novo Nordisk A/S v. Becton Dickinson, 997 F.Supp. 470 (S.D.N.Y.1998), and Novo Nordisk A/S v. Becton Dickinson, 997 F.Supp. 459 (S.D.N.Y.1998), is assumed.

I. Markman Hearing

Under patent law, an inventor sets forth the invention to which he claims exclusive rights in a series of claims. In litigation, interpretation of the terms used in patent claims has been declared to be a matter of law to be decided by the Court. *See* Markman v. Westview Instruments, Inc., 52 F.3d 967, 978-81, 987 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370 (1996). In cases where a party's view that a patent has been infringed or is invalid turns on how the claims are construed, the *Markman* decisions suggest a procedure for claim construction in the case-a *Markman* hearing-to facilitate resolution of patent cases as a matter of law. *See* MediaCom Corp. v. Rates Technology, Inc., 4 F.Supp.2d 17, 21-22 (D.Mass.1998) ("These hearings run the gamut from mid-trial sidebar conferences that undergird relevance rulings ... to virtual mini-trials extending over several days and generating extensive evidentiary records.") (citations omitted).

II. Claim Construction

A. Legal Standards Governing Claim Construction

Claim construction requires a degree of imagination from the Court. First, the Court must obtain sufficient currency with the technical terms employed to read the patent because the objective of claim construction is to ascertain the meaning that a person of ordinary skill in the art would give to the terms in dispute. *See* Wiener v. NEC Electronics, Inc., 102 F.3d 534, 539 (Fed.Cir.1996); Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1578 n. 4 (Fed.Cir.1993). Second, the Court must travel in time, for the operative time for interpreting the claim terms is the date of the application for the patent. *See* Wiener, 102 F.3d at 539.

When interpreting the claims, the Court may resort to certain sources, which are arranged in hierarchical order. The Court looks first to those sources on which the general public may rely to ascertain the scope of a patent, i.e., the patent itself, which includes the claims and the specification, and, if relevant, the prosecution history before the Patent and Trademark Office. *See* Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). These sources comprise the "intrinsic evidence" of the patent's meaning, and, together they are "the most significant source of the legally operative meaning of disputed claim language." Vitronics, 90 F.3d at 1582.

Construction begins with the wording of the claims, asserted and non-asserted, which are to be examined in their entirety. *See* Bell Communications Research, Inc. v. Vitalink Communications Corp ., 55 F.3d 615, 620 (Fed.Cir.1995). The claim's words and phrases should be given their ordinary and customary meaning. However, a patentee may choose to be her own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition is clearly stated in the patent specification or file history. Vitronics, 90 F.3d at 1582.

Perhaps the most difficult rule of claim construction to apply is that the claims "must be read in view of the specification, of which they are a part." Markman, 52 F.3d at 979. 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 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. *See* Vitronics, 90 F.3d at 1582. However, the limitations of the specification may not be read into the claims. *See* Comark, 156 F.3d at 1186. The Federal Circuit acknowledges that "there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Id*.

Prosecution history should also be considered as intrinsic evidence, including the record of proceedings before the Patent and Trademark Office. *See* Vitronics, 90 F.3d at 1582 (prosecution history is "often of critical significance in determining the meaning of the claims"). Those proceedings may incorporate the patentee's representations as to claim scope, together with a review of the prior art. *See* id. at 1583.

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Id*. However, if ambiguity remains, the Court may consult extrinsic evidence such as expert testimony, dictionaries or learned treatises. *See Thomson,* 3 F.Supp.2d at 52. Nevertheless, such extrinsic evidence may not contradict the manifest meaning of the claims as set forth, even by implication, in the specification and prosecution history. *See* Vitronics, 90 F.3d at 1584-85.

To the extent there exists any ambiguity as to the proper claim construction, the Federal Circuit has ruled, consistent with traditional canons of construction, that claims should be construed narrowly against the patent owner since it is the "party responsible for drafting and prosecuting the patent." Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 951 (Fed.Cir.1993). Further, there is an axiom that when interpreting a claim, a court should construe the claim if possible, so as to sustain its validity. *See* Rhine v. Casion, Inc., 183 F.3d 1342, 1345 (Fed Cir.1999). But the Federal Circuit has also admonished against judicial rewriting of claims to preserve validity. *See* Becton Dickinson & Co. v. C.R. Bard, Inc., 922 F.2d 792, 799 & n. 6, 17 U.S.P.Q.2d 1097, 1102 & n. 6 (Fed.Cir.1990). Therefore, if the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid. *See* Rhine, 183 F.3d at 1345.

B. Claims of the Patent in Suit

The parties have agreed in their briefs and at the *Markman* hearing that only the following are in dispute: (1) whether the claims containing the term "standard" cannot be construed; (2) whether Novo Nordisk's needle assembly claims are limited to needles used on pens using replaceable cartridges; and (3) whether the claim "thinner than G-29" means thinner than 29 gauge, but not thinner than 30 gauge.

1. Standard Insulin Needle Fitting/Standard Mounting

Novo argues that the terms standard insulin needle fitting and standard mounting in the claim language "[a] standard insulin needle fitting for removably mounting said needle assembly on a pen-type syringe having a standard mounting" FN1 are unambiguous.

FN1. *See* (Claims 1-4 of the '323 patent & Claims 11-14 of the '906 patent.) The '906 patent "is an insulin injection system comprising a pen shaped syringe having a cartridge with insulin and an injection needle, the system being characterized in that the needle is a G30 needle and the cartridge contains an insulin type which may flow freely through a G30 needle." ('906 Patent at 2.)

Novo argues that the term "standard" is defined as "regularly and widely used, available, or supplied." *Merriam-Webster's College Dictionary,* 1145 (10th ed.1998). According to Novo "[s]tandard insulin needle fitting" plainly refers to needle fittings which are commonly used on pen-type insulin delivery devices.

Further, it argues that the significance of the term "standard" is evident when the claim is construed as a whole. Novo contends that in claim 1 of the '323 patent, the structure of the needle hub is defined with reference to an unclaimed object, namely, a pen syringe. In its view, without the term "standard," a person skilled in the art would be unable to ascertain the structure of the needle hub, and thus the claim would be vague, because a pen syringe could potentially be designed to accommodate any needle hub. The word "standard" allows persons skilled in the art to understand the scope of the claim with reasonable clarity, because a person skilled in the art would know what needle hubs are standard at any given time.

Becton submits that the limitations "standard insulin needle fitting" and "standard mounting" had no discernible meaning for one of ordinary skill in the art when Novo's Danish application was filed in 1991. At that time, it contends, there was neither a *de facto* standard needle nor an industry-accepted standard for pen needles. To support its contention, Becton cites statements of Frits Bonnichsen, Novo's co-inventor in charge of the development of the 30 gauge pen needle. *See* (Sharrott Decl., Exh. 13, at 125-126.) In addition, Becton argues that there is no basis whatsoever for construing the terms "standard" fitting and "standard" mounting. In its view, there is no description of a standard fitting or mounting that at the time of the alleged invention would convey with reasonable clarity to one skilled in the art that the inventors were in possession of the claimed needle assembly inventions.

At the Court's *Markman* hearing, Novo argued the following: (1) that the "standard" limitations first appeared in July 1996 when Claims 1-4 were added to Novo's '323 patent application by amendment; (2) that "standard". does not reflect an industry or government standard; FN2 (3) that there could be more than one "standard"; and (4) that while the drawings submitted in support of Novo's patent application are examples of a "standard," the standard can change over time. *See* March 6, 2000 Tr. at 5-11.

FN2. Becton does concede that by 1996 there was a standard "insulin needle fitting" and "mounting" for

insulin pen syringes in the U.S. market.

It is quite clear that after examining the intrinsic evidence-the claim language and the prosecution history-and the extrinsic evidence,FN3 this Court cannot determine what "[a] standard insulin needle fitting for removably mounting said needle assembly on a pen-type syringe having a standard mounting," was at the time of the patent. The Court can and does construe the word standard in accordance with the dictionary definition of standard to mean: "regularly and widely used, available, or supplied." Again, as to what needle fittings and mountings were "regularly and widely used, available, or supplied," at the time of the patent, this Court assumes that the parties will adduce proof on this point at trial on the issue of infringement.

FN3. This Court notes that Novo has not submitted any extrinsic evidence relevant to the question of what was "standard" either in 1991, 1994 or 1996-the key time periods for purposes of the patents.

2. Durable Syringes/Disposable Prefilled Syringes

At issue here is whether the language "Pen-type insulin syringe ... which accepts cartridges" FN4 applies only to pens which accept replaceable prefilled insulin cartridges or also applies to disposable pen syringes that include a pre-filled insulin cartridge. Throughout the prosecution history of the patents, it is abundantly clear that the claim language applies to both durable pen syringes and prefilled pen syringes.

FN4. "Pen-type insulin syringe ... which accepts cartridges containing...." (Claims 1-4 of the '323 patent & Claims 11-14 of the '906 patent.)

Claims 3 and 9 of the '535 patent recite that the pen syringe, which parent claim 1 recites as including a cartridge containing insulin, "is a disposable device prefilled with insulin." Thus, the disposable pen syringe claimed in claims 3 and 9 must accept the insulin cartridge at some stage of the manufacture. Both disposable syringes (claims 3 and 9) and durable syringes (claims 4 and 10 of the '535 patent) accept cartridges containing insulin. The difference is that disposable syringes are manufactured so that, once the cartridge is inserted, it cannot be removed and replaced by the user.

Becton argues that the language applies only to pen syringes that accept replaceable, refilled insulin cartridges, and not to disposable pen syringes that are prefilled with insulin. It relies statements by an attorney for Novo, (*see* Sharrott Decl., Exh. 8), which are confusing and could be read to limit the scope of Claims 1-4 to only those pen syringes that accept replaceable insulin syringes, to the exclusion of any pen syringes that are prefilled with insulin which do not accept replaceable cartridges.

However, this Court finds that this one set of statements by Novo's attorney in the 1996 Amendment are inconsistent with the totality of the prosecution history, and are not entitled to the dispositive effect that Becton gives it. As a result, this Court construes the language "Pen-type insulin syringe ... which accepts cartridges" to apply both to durable pen syringes which accept replaceable pre-filled cartridges and disposable pre-filled insulin pen syringes.

3. "Thinner than G-29"

The dispute here is whether the claim language "thinner than G-29" and "[a] needle thinner than a G-29

needle" FN5 means all needles thinner than 29 Gauge. Novo argues that this Court should construe the term "thinner than G-29" according to its plain meaning. Becton argues that there is no plain meaning for this claim, because it is an "open-ended range" with no defined upper limit on the needle's thickness. That is, this limitation might read on a 35 gauge needle, a 50 gauge needle, or even a 100 gauge needle, etc., as they are all "thinner than 29 gauge."

FN5. "A needle thinner than a G-29 needle." (Claims 1-10 of the '906 patent.) "[A] thinner than G-29 needle." (Claims 11-14 of the '906 patent.)

Novo's support for this limitation is the originally-claimed 30 gauge needle, and one phrase of a single sentence in Novo's patent which states: "The present invention is based on the surprising recognition that needles thinner than G 29 may be used for injecting insulin." However, this is only a generalized statement referring to a range which cannot be seen as corresponding to the content of the application at that time, because only one single value of this range, G30, has been consistently defined. Construing the patent, this Court comes to the same conclusion as the European Patent Office: that the aim of the application was to use needles thinner than G-29, and the result of this "wish" was the possibility of having a G-30 needle. Only a G-30 needle is allowable in this context. As a result, this Court construes "thinner than G-29" to be thinner than 29 gauge, but not thinner than 30 gauge.

SO ORDERED:

S.D.N.Y.,2000.
Novo Nordisk A/S v. Becton Dickinson and Co.