

United States District Court,
D. Delaware.

ENZO LIFE SCIENCES, INC,
Plaintiff/Counterclaim Defendant.

v.

DIGENE CORPORATION,
Defendant/Counterclaim Plaintiff.

v.

ENZO BIOCHEM, INC,
Additional Counterclaim Defendant/Declaratory Plaintiff.

No. Civ.A.02-212 JJF

June 10, 2004.

Josy W. Ingersoll, Young, Conaway, Stargatt & Taylor, Wilmington, DE, for Plaintiff and Counter-Defendant.

Richard D. Kirk, Morris, James, Hitchens & Williams, Wilmington, DE, for Defendant and for Counter-Claimant.

MEMORANDUM ORDER

FARNAN, J.

Presently before me are the Motions for Claim Construction (D.I.229, 233) filed by the parties regarding United States Patent No. 6,221,581 (the " '581 patent"). After consideration of the arguments advanced by the parties in their papers and at the *Markman* hearing held on June 8, 2004, I construe the disputed terms as follows:

I. "*Entity*"

The parties agree that the term "entity" should be construed pursuant to its ordinary and customary meaning. Accordingly, I construe entity to mean: "something that has a real existence; a thing." *Random House College Dictionary Revised Edition* 441 (Jess Stein, ed.1984).

II. "*One or More Oligo- or Polynucleotides*"

A. "*Polynucleotides*" & "*Oligonucleotides*"

1. *Parties' Contentions*

Enzo asserts that polynucleotides should be construed to mean a "linear sequence of nucleotides" without any numerical limitation. At the *Markman* hearing, Enzo advised that it does not dispute Digene's proposed construction of the term oligonucleotides. (Markman Hearing Transcript ("Tr.") at 22.)

Digene responds that oligonucleotides should be construed according to its ordinary and customary meaning of "a chain of nucleotides ranging from 2 to 20." Digene asserts that polynucleotides should be construed to have the same definition as oligonucleotides.

2. Court's Construction

I conclude that neither the claims nor the intrinsic record of the '581 patent establish that the term "polynucleotide" should be construed in a manner different than its ordinary and customary meaning. Thus, I conclude that "polynucleotide" means "[a] linear sequence of nucleotides." *McGraw-Hill Dictionary of Scientific and Technical Terms* (5th ed., Sybil P. Parker, ed.1994). Additionally, I conclude "oligonucleotide," according to its ordinary usage as agreed by the parties, means: "a chain of 2 to 20 nucleotides."

B. Whether the Claims of the '581 Patent are Limited to the Use of At Least Two Polynucleotide Segments

1. Parties' Contentions

Enzo contends that "one or more oligo- or polynucleotides" should be construed according to its ordinary meaning. Enzo contends that Digene cannot overcome the heavy presumption that the claim term "one or more" requires its ordinary meaning. Moreover, Enzo maintains that the specification and the prosecution history support the ordinary meaning of the terms at issue, and do not justify a limitation of the claim "one or more" polynucleotide segments to "at least two" single stranded polynucleotide segments.

Digene responds that the specification and the prosecution history make clear that "one or more" polynucleotide segments should be limited to mean "at least two" polynucleotide segments. Digene contends that the specification does not support the broader construction and, further, that Enzo disavowed "one or more" polynucleotide segments during the prosecution of the '581 patent.

2. Interpretation

I conclude that the phrase "one or more" single stranded polynucleotide segments should be construed in accordance with its ordinary and customary meaning. I note that the ordinary and customary meaning of "one or more" single stranded polynucleotide segments is not limited to Digene's proposed construction of at least two single stranded polynucleotide segments. Thus, in order to prevail on its proposed construction which is contrary to the ordinary and customary meaning of the claim term at issue, Digene must establish that Enzo prescribed a narrower construction of "one or more" in the intrinsic record. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1326 (Fed.Cir.2003) (citing *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1301 (Fed.Cir.2001) and *Biodex Corp. v. Loredan Biomedical, Inc.*, 946 F.2d 850, 863 (Fed.Cir.1991)).

With respect to the specification, I find that the detailed description of the '581 patent provides support for the ordinary and customary meaning of the term "one or more" single stranded polynucleotide segments. *See* (D.I. 230, Ex. A at col. 8 ll. 37-42; col. 6 ll. 8-12.) Also, I agree with Enzo that although it submitted an

amendment of its claims in response to a rejection by the Examiner due to lack of support in the specification that would have disavowed claim coverage of one single stranded polynucleotide segments, on the record before me, it appears that the Examiner never acted on this amendment. Instead, as indicated by the Office Action Summary dated August 11, 1999, I find the Examiner accepted the explanation offered by Dr. Engelhardt in the April 9, 1999, Declaration, wherein Dr. Engelhardt averred that the specification of the '581 patent was sufficient to support use of the claim language "one or more" single stranded polynucleotide segments and did not require Enzo to amend its claims. (D.I. 250, Ex. A9 at 2.) Thus, I conclude that Enzo's proposed construction does not violate the rule that a party may not "construe[claims] one way in order to obtain their allowance and in a different way against accused infringers." *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed.Cir.1995) (citing *Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed.Cir.1991)).

In sum, I conclude that based on the lack of evidence demonstrating that Enzo prescribed a meaning contrary to the ordinary and customary meaning in the specification or limited the meaning of the term in the prosecution history, the claim language "one or more" single stranded polynucleotide segments is not limited to "at least two" single stranded polynucleotide segments.

C. Whether the Claims of the '581 Patent are Limited to Labeled Polynucleotide Segments

1. Parties' Contentions

Digene contends that the specification of the '581 patent limited the claims of the patent to labeled polynucleotide segments. Digene also contends that Enzo limited the '581 patent to labeled polynucleotide segments in its prosecution of the patent by distinguishing prior art with this limitation.

Enzo responds that there is support in the specification for its contention that it did not limit the '581 patent to labeled polynucleotide segments and that the Examiner was aware that it did not so limit the '581 patent.

2. Interpretation

I conclude that the '581 patent should not be limited to labeled polynucleotide segments. I find that the specification of the '581 patent supports an interpretation without the limitation of labeled polynucleotide segments. *See* (D.I. 230, Ex. A at col. 8, 11, and 6.) Additionally, I am not persuaded by the citations by Digene to the prosecution history in support of its contention that Enzo's distinguishing of prior art operated to limit all of the '581 patent claims to labeled polynucleotide segments. *Id.*, Ex. H at 14-16 (related application 005,327, now U.S. Patent No. 4,894,325.) For these reasons, I conclude that the '581 patent is not limited to labeled polynucleotide segments.

III. "Hybridized to"

The parties agree that the term "hybridized to" should be construed according to its ordinary and customary meaning. Therefore, I conclude that "hybridized to" means: "the bonding between nucleotide bases on one nucleic acid with the complementary nucleotide based on another acid."

IV. "Nucleic acid of interest"

The parties agree that this term should be construed pursuant to its ordinary and customary meaning. Accordingly, I conclude that "nucleic acid of interest" means: "the particular DNA or RNA sequence that is

the subject of the detection method."

V. "First complex or complexes" and "complexed with"

The parties agree that the proper construction of complex is "an entity that is formed by such non-covalent binding." Further, the parties agree that "complexing with" should be construed to mean "the formation of such non-covalent bonds between complementary molecules." Accordingly, I adopt these constructions.

VI. "Signaling domain" and "capturing domain"

A. Parties' Contentions

Enzo contends that I should construe the claim language "signaling domain" and "capturing domain" according to their ordinary meaning. Enzo contends that one of ordinary skill in the art would recognize these terms as having their ordinary meaning. Further, Enzo contends that I should not construe these terms to be means plus function elements because it did not use the term "means ."

Digene contends that if I do not construe these terms as means plus function elements, I should limit the definition of these terms to a binding between a specific discrete and identifiable portion of the "complex" and the "capturing entity" because, during prosecution of the '581 patent, Enzo overcame a prior art reference with this definition of the claim terms.

B. Interpretation

I conclude that the terms "signaling domain" and "capturing domain" are not properly construed as means plus function elements. The claim language of the '581 patent does not use the term "means," and therefore, a presumption arises that 35 U.S.C. s. 112, para. 6 does not apply. *See Mas-Hamilton Group v. Lagard, Inc.*, 156 F.3d 1206, 1213 (Fed.Cir.1998). Moreover, I agree with Enzo that the claims recite sufficient structure, material, and acts necessary to perform the functions described by the terms, and therefore, do not invoke Section 112 para. 6. *See Sage Prods. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427-28 (Fed.Cir.1997).

I find that the term "domain" has an ordinary and customary definition to one of ordinary skill in the art. The ordinary meaning of "domain" is "[a] structurally and/or functionally discrete portion of a protein, nucleic acid, or membrane." *The Encyclopedia of Molecular Biology* 296 (Sir John Kendrew ed.1994). Further, I am persuaded that one of ordinary skill in the art would be able to determine sufficient structure of "capturing domain" and "signaling domain" by observing the "discrete portion" of the first complex or complexes that complexes with the second entity, i.e. the domain in the first complex where the second entity binds (capturing domain), or with a complex forming moiety (signaling domain), as described in the claims of the '581 patent.

Additionally, I conclude that Digene has not demonstrated that Enzo's distinguishing U.S. Patent No. 4,724,202 (the "Dattagupta et al. reference") to overcome the Examiner's rejection narrowed the scope of "capturing domain" and "signaling domain" to a binding between a specific discrete and identifiable portion of the "complex" and "capturing entity." In reaching this conclusion, I have found the Declaration of Enzo's consultant, Dr. James G. Wetmur persuasive in setting forth the distinctions between the capturing or collection described in the '581 claims and those of Dattagupta's direct and non-specific immobilization. (D.I. 231, Ex. X at 5, 6, 7, and 8.) In sum, I accept Enzo's proposed construction of the terms "capturing domain" and "signaling domain."

VII. "Second entity" and "third entity"

The parties agree that "second entity" and "third entity" should be construed according to their ordinary and customary meaning, and therefore, I adopt this construction.

SO ORDERED.

D.Del.,2004.

Enzo Life Sciences, Inc. v. Digene Corp.

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