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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF CALIFORNIA

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CHIRON, CORPORATION
Plaintiff,

NO. CIV. S-00-1252 WBS GGH

v.

MEMORANDUM AND ORDER RE:
INDEFINITENESS

GENENTECH, INC.
Defendant.

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This patent infringement lawsuit involves Chiron's U.S. Patent No. 6,054,561 ("561 patent") for monoclonal antibodies that bind to an antigen found on human breast cancer cells and tissues. Chiron and Genentech now bring cross motions for summary judgment on the Genentech's defense that the '561 patent is invalid for indefiniteness.

I. Factual and Procedural Background

The '561 patent claims monoclonal antibodies that "bind" to the HER2 breast cancer antigen. In an order dated April 22, 2002, the court construed the term "binds" to mean "a degree of attachment that is immunologically significant, i.e. a

1 degree of attachment that is (1) above background levels; (2)
2 specific; (3) selective for cancer as opposed to normal cells
3 and/or tissues; and (4) has a useful degree of affinity." (Apr.
4 22, 2002 Order, at 42) (hereinafter "Markman order"). Genentech
5 argues that the term "binds" as the court has construed it is
6 indefinite and therefore renders the patent invalid.¹

7 I. Discussion

8 The court must grant summary judgment to a moving party
9 "if the pleadings, depositions, answers to interrogatories, and
10 admissions on file, together with the affidavits, if any, show
11 that there is no genuine issue as to any material fact and that
12 the moving party is entitled to judgment as a matter of law."
13 Fed. R. Civ. P. 56(c). The party adverse to a motion for summary
14 judgment may not simply deny generally the pleadings of the
15 movant; the adverse party must designate "specific facts showing
16 that there is a genuine issue for trial." Fed. R. Civ. P. 56(e);
17 see Celotex Corp. v. Catrett, 477 U.S. 317 (1986). Simply put,
18 "a summary judgment motion cannot be defeated by relying solely
19 on conclusory allegations unsupported by factual data." Taylor
20 v. List, 880 F.2d 1040, 1045 (9th Cir. 1989). The non-moving
21

22 ¹ In response to interrogatories served by Chiron,
23 Genentech asserted that the terms "monoclonal antibody," "strong
24 staining intensity," "normal tissues," "immunoassay," and
25 "extracellular domain" were also indefinite. Genentech, however,
26 appears to have abandoned these arguments. Chiron argued in its
27 motion for summary judgment that these terms were definite.
28 Genentech has not opposed Chiron's motion to the extent that it
concerns the definiteness of terms other than "binds," and has
moved for summary judgment that the patent is indefinite on the
sole ground that "binds" has no ascertainable meaning as the
court has defined it. Therefore, there appears to be no dispute
that the other terms of the patent meet the definiteness
requirement.

1 party must show more than a mere "metaphysical doubt" as to the
2 material facts. Matsushita Elec. Indus. Co. v. Zenith Radio, 475
3 U.S. 574, 587 (1986).

4 The claims of a patent must be definite enough so as to
5 "particularly point[] out and distinctly claim[] the subject
6 matter which the applicant regards as his invention." 35 U.S.C.
7 § 112. The claims must "inform the public during the life of the
8 patent of the limits of the monopoly asserted, so that it may be
9 known which features may be safely used or manufactured without a
10 license and which may not." United Carbon Co. v. Binney & Smith
11 Co., 317 U.S. 228, 232 (1942). A claim fails to meet this
12 requirement if one of ordinary skill in the art would not
13 understand the bounds of the claim when read in light of the
14 specification. Union Pac. Resource Co. v. Chesapeake Energy
15 Corp., 236 F.3d 684 (Fed. Cir. 2001); Morton Int'l, Inc. v.
16 Cardinal Chem. Co., 5 F.3d 1464, 1470 (Fed. Cir. 1993).

17 "A determination of claim indefiniteness is a legal
18 conclusion that is drawn from the court's performance of its duty
19 as the construer of patent claims." LNP Eng'g Plastics, Inc. v.
20 Miller Waste Mills, Inc., 275 F.3d 1347 (Fed. Cir. 2001).

21 Because an issued patent is presumed valid, the burden is on
22 Genentech to prove indefiniteness by clear and convincing
23 evidence. Morton Int'l, 5 F.3d at 1470. In evaluating the
24 sufficiency of the evidence on a motion for summary judgment, the
25 court must take this burden into consideration. See Eli Lilly &
26 Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed. Cir. 2001).

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1 A. Procedural and Legal Bars to Indefiniteness Argument

2 Chiron argues that Genentech is barred both
3 procedurally and as a matter of law from arguing that the term
4 "binds" is indefinite. First, Chiron contends that Genentech's
5 motion should be denied as an improper motion for reconsideration
6 of this court's Markman ruling. Although Genentech initially
7 raised the question of whether the term "binds" was indefinite in
8 its opening claim construction brief, it reconstituted its claim
9 construction arguments with respect to the term "binds" both
10 before the magistrate judge and before this court. In issuing
11 the Markman order, the court did not expressly consider or
12 expressly reject Genentech's arguments about the indefiniteness
13 of the term "binds." Therefore, the court does not construe
14 Genentech's motion for summary judgment as a motion for
15 reconsideration of the Markman order.

16 Chiron next argues that because the court was able to
17 construe the term "binds," the term cannot, as a matter of law,
18 be indefinite. Chiron relies on Exxon Research & Engineering Co.
19 v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001), in which
20 the Federal Circuit stated that "claims [are] indefinite only if
21 reasonable efforts at claim construction prove futile." Exxon,
22 however, did not involve a situation in which the alleged
23 infringer was attempting to challenge a claim as indefinite after
24 the court had construed it a certain way. The language upon
25 which Chiron relies comes as part of a more general discussion of
26 the indefiniteness standard; it is not the holding of the Exxon
27 case. Therefore, the court does not read Exxon to require a
28 finding in Chiron's favor on the issue of indefiniteness simply

1 because the court's effort to construe the term "binds" was not
2 futile.

3 In fact, it is not uncommon for courts to find a claim
4 term invalid for indefiniteness after construing the term. See
5 Union Pacific, 236 F.3d at 688-89, 692 (affirming district
6 court's finding that the term "comparing" was indefinite, where
7 the district court had construed the term in a separate Markman
8 ruling); Semmler v. American Honda Motor Co., 990 F. Supp. 967,
9 975 (S.D. Ohio 1997) (finding that the claim language
10 "considerable fuel saving" was indefinite despite earlier Markman
11 ruling that the language meant a fuel saving that one skilled in
12 the art in 1976 would have considered large, substantial, and
13 important). This court adopted the construction of "binds" at
14 Chiron's urging; what that term means to a person of ordinary
15 skill in the art is a separate question from whether it is
16 sufficiently definite to put others in the field on notice
17 regarding the bounds of the claims of the '561 patent.

18 B. Definiteness of "Immunologically Significant" Binding

19 Genentech acknowledges that a scientist can measure
20 whether an antibody's attachment to an antigen is "above
21 background levels" and "specific." However, Genentech contends
22 that whether binding is sufficiently "selective" or has a "useful
23 degree of affinity" to be "immunologically significant" is too
24 indefinite to apprise one of ordinary skill in the art as to the
25 boundaries of the claims.

26 1. Selectivity

27 The parties agree that whether binding is
28 "immunologically significant" depends on whether an antibody is

1 useful for the purposes contemplated by the '561 patent, which
2 include "specific binding assays, affinity purification schemes,
3 drug or toxin targeting, imaging, and genetic or immunological
4 therapeutics for various cancers" ('561 Patent, 1:27-
5 31.) As the court explained in its Markman order, "selectivity"
6 refers to the ability of an antibody to target a specific type of
7 cell or tissue to the exclusion of others. (April 22 Order, at
8 40.) As Genentech points out, how selective an antibody must be
9 for therapeutic purposes may depend on whether the therapy
10 involves conjugating the antibody to a toxin. Because a toxin
11 will kill the cell to which it attaches, it is important that a
12 conjugated antibody recognize and bind to predominately breast
13 cancer cells and tissues and not other normal cells and tissues.
14 Some antibodies against HER2, however, are useful for therapy
15 without being conjugated to a toxin. The accused product
16 Herceptin, for example, inhibits a cancer cell's ability to
17 proliferate simply by virtue of binding to the HER2 antigen. If
18 an antibody can be therapeutically useful without being
19 conjugated to a toxin, there is in theory less risk that binding
20 to tissues other than breast cancer will have an adverse effect.
21 Thus, the requisite degree of selectivity may depend on various
22 factors.

23 Even so, Genentech fails to prove that a person of
24 ordinary skill in the art, reading the claim in light of the
25 specification, would not understand when binding is "selective"
26 enough to be therapeutically useful. Union Pacific, 236 F.3d at
27 692. The specification of the '561 patent not only expressly
28 defines selective binding in terms of measurable criteria, but

1 also describes methods to test for an antibody's selectivity:

2 The selectivity and range of a given antibody is
3 determined by testing it against panels of (a) human
4 breast cancer tissues and cells and (b) normal human
5 tissues or cells of breast or other origin. . . .
6 Antibodies were deemed to bind selectively to breast
7 cancer if they bound strongly to less than about 1/3 of
8 the normal tissues and blood cell types.

9 ('561 Patent Col. 17:24-41; see also 18: 31-65 (describing how to
10 test for selectivity in an immunoperoxidase staining assay).)

11 Thus, a person skilled in the art is given considerable direction
12 regarding when a monoclonal antibody should be "deemed selective"
13 for purposes of coming within the scope of the patent's claims.

14 2. Useful Degree of Affinity

15 As with selectivity, whether an antibody has a useful
16 degree of affinity appears to depend on several factors.
17 Genentech's expert, Dr. Unkeless, testified at his deposition
18 that the affinity value required for an antibody to work for
19 purposes of diagnosis may vary depending on the type of assay
20 that is used. (Unkeless Dep. at 71-72 ("[T]here are antibodies
21 that will not immunoprecipitate but are wonderful for Western
22 blotting. So for an antibody to be useful, you can't say it has
23 to have these particular properties.")) In addition, Dr.
24 Unkeless testified that for purposes of therapy or in vivo²
25 diagnosis, "you can't pin a number affinity or avidity of an
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27 ² In vivo diagnosis involves administering a labeled
28 monoclonal antibody to a patient and tracking it in the patient's
body. In vitro diagnosis tests for breast cancer by running
assays and other tests in the laboratory.

1 antibody to say, above this it will work, below that it won't."³
2 (Id. at 72.)

3 Dr. Unkeless also testified, however, that he is not
4 aware of any therapeutically or diagnostically useful antibodies
5 having an affinity of less than 10^6 or 10^7 . (Unkeless Dep. at
6 74.) Consistent with this testimony, the specification of the
7 '561 patent discloses that the affinity values for the monoclonal
8 antibodies exemplified in the specification range from 1.6×10^6
9 to 1.9×10^9 . ('561 Patent at 25:46-48; Cert. of Corr. at 4.)
10 The specification also discusses specific binding assays in which
11 the monoclonal antibodies should be useful, as well as how to
12 test an antibody's affinity value. (See '561 Patent at 9:55-
13 10:5.)

14 Rather than demonstrate that the term "binds" is
15 indefinite, Dr. Unkeless's testimony supports the opposite
16 conclusion. "[I]f the language is as precise as the subject
17 matter permits, the courts can demand no more." Shatterproof
18 Glass Corp. v. Libbey-Owens Ford, Co., 758 F.3d 613, 624 (Fed.
19 Cir. 1984); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802
20 F.2d 1367 (Fed. Cir. 1986). If, as Dr. Unkeless suggests, it is
21 impossible to define a useful level of affinity by reference to a

22
23 ³ Chiron urges the court to ignore Dr. Unkeless's
24 testimony, alleging that it is outside the scope of his expert
25 report and deposition testimony and violates a case management
26 order of January 18, 2001. First, the court notes that Dr.
27 Unkeless's deposition testimony cannot be outside the scope of
28 his deposition testimony. Second, the January 2001 order
precludes an expert from testifying at trial regarding any
information gathered, or an opinion formed after his deposition.
Finally, Dr. Unkeless's expert report states: "there is no
threshold for avidity or affinity," which is consistent with the
evidence submitted by Genentech in support of its summary
judgment motion.

1 particular numerical value, the '561 patent cannot be expected -
2 and is not required as a matter of law - to list every possible
3 affinity value that might be useful for every possible purpose of
4 the invention.

5 Moreover, simply because a broad range of affinities
6 may be useful does not make the claims indefinite. It is well
7 settled that "[b]readth is not to be equated with
8 indefiniteness." Union Pacific, 236 F.3d at 691 (quoting In re
9 Miller, 441 F.2d 689, 693 (CCPA 1971)). Thus, the claims may
10 permissibly encompass a wide range of affinity values (indeed,
11 according to the specification the exemplary antibodies range in
12 affinity value from 1.6×10^6 to 1.9×10^9). The relevant
13 question is whether a person of ordinary skill in the art would
14 understand when a monoclonal antibody has an affinity value that
15 is "useful" for the purposes described in the specification.

16 Importantly, Dr. Unkeless did not testify that it would
17 be impossible for a person of ordinary skill in the art to
18 consider the factors he identified to ascertain whether an
19 antibody has a useful degree of affinity and therefore falls
20 within the scope of the claims. Rather, he testified that "I can
21 only say that, that in looking to the effect that any antibody
22 has in any given system, you have to try it," which, if anything,
23 suggests that one of ordinary skill in the art could determine
24 whether an antibody binds with a useful degree of affinity in a
25 particular application. (Unkeless Dep. at 73.) See LNP Eng'g
26 Plastics, 275 F.3d at 1356, 1360 (Fed. Cir. 2001) (claim term
27 "substantially and completely wetted" was not indefinite, where
28 tests to determine wettedness were known in the art and mentioned

1 in the specification); Exxon, 265 F.3d at 1379 (Fed. Cir.
2 2001) (finding the term "period sufficient to increase
3 substantially the initial catalyst activity" definite where
4 expert testimony established that the "period sufficient" could
5 be ascertained by conducting activity checks).

6 In fact, Dr. Unkeless's testimony that he is not aware
7 of a useful antibody having an affinity value lower than 10^6 or
8 10^7 indicates not only that scientists have been able to
9 recognize the circumstances in which an antibody binds with a
10 useful degree of affinity for diagnosis and therapy, but also
11 that the inquiry is not completely boundless. Contrast STX v.
12 Brine, Inc., 37 F. Supp. 2d 740 (D. Md. 1999) (finding claim for a
13 lacrosse stick with "improved handling and playing
14 characteristics" indefinite because the standard was subjective
15 on so many different levels it was impossible to determine the
16 scope); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed.
17 Cir. 1991) (finding claims covering a drug with an activity level
18 of "at least about 160,000" units of potency indefinite where
19 measuring activity was imprecise, the inventors themselves had
20 questioned whether a specific affinity value fell within the
21 scope of the claims, and there was no suggestion in the
22 specification, prosecution history, or prior art regarding what
23 range of activity was covered).

24 Genentech's use of similar terminology without apparent
25 difficulty in arguing that the '561 patent is invalid in light of
26 prior art, and in its own patent applications, is yet another
27 indication that what is meant by a "useful degree of affinity" is
28 not indefinite. For example, in performing an experiment to

1 demonstrate that Chiron's patent was invalid in light of prior
2 art, Genentech's expert Dr. Frackelton was able to test whether
3 an antibody known as 2G8 bound to HER2 with a "useful degree of
4 affinity" in an immunoprecipitation assay so as to identify and
5 isolate the HER2 protein. (See Genentech's Mem. of P & A in Opp'n
6 to Chiron's Mot. S.J. Re: Sections 102 and 103 Invalidity, at 6,
7 10; Emery Decl. Ex. P); Rosemount, Inc. v. Beckman Instruments,
8 Inc., 727 F.2d 1540, 1547 (Fed. Cir. 1984) (refusing to invalidate
9 patent where the party asserting indefiniteness had no trouble
10 applying the terms of the claim to prior art references). Dr.
11 Frackelton's experiment demonstrates that persons of ordinary
12 skill in the art are equipped to determine when an antibody has a
13 degree of affinity that is "useful" for the purposes described in
14 the patent.

15 In addition, one of Genentech's own patent applications
16 uses the term "affinity" in the same supposedly ambiguous manner
17 that the court has used the term. Genentech's application,
18 entitled "Humanized Anti-ErbB2 Antibodies and Treatment with
19 Anti-ErbB2 Antibodies," states:

20 An antibody "which binds" an antigen of interest, e.g.
21 ErbB2 antigen, is one capable of binding that antigen
22 with sufficient affinity such that the antibody is
useful as a therapeutic agent in targeting a cell
expressing the antigen.

23 (Jorjani Decl. Ex. 13) (emphasis added). Genentech's use of the
24 phrase "sufficient affinity" in its own patent application belies
25 its contention that one of ordinary skill in the art would not
26 understand when an antibody has sufficient affinity to be
27 "useful" for therapy. See Rosemount, 727 F.2d at 1547 (Fed. Cir.
28 1984) (finding a term definite where the party asserting

1 invalidity used the allegedly indefinite term in describing its
2 own products); Bausch & Lomb, Inc. v. Alcon Labs., Inc., 79 F.
3 Supp. 2d 243, 250-51 (W.D.N.Y. 1999) (finding term "substantially"
4 not indefinite because, among other things, the defendant had
5 used it in its own patents); W.R. Grace & Co. v. Intercat, Inc.,
6 7 F. Supp. 2d 425, 467 (D. Del. 1997), aff'd 155 F.3d 572 (Fed.
7 Cir. 1998) (finding the defendant's indefiniteness defense
8 "especially unavailing" given the defendant's "own ease, prior to
9 this litigation," in using the supposedly indefinite term).

10 Genentech argues that its patent application is
11 different from the '561 patent because its application requires
12 that the antibody either (1) reduce the number of cancer cells or
13 tumor size, or (2) inhibit cancer cell infiltration of peripheral
14 organs, tumor metastasis of tumor growth, or (3) relieve cancer
15 symptoms. However, these additional requirements provide no more
16 information about what degree of affinity is useful; the same
17 factors that might influence the range of affinity values of the
18 monoclonal antibodies claimed in Chiron's patent could influence
19 the range of affinity values of the antibodies claimed in
20 Genentech's patent application.

21 Genentech has failed to show by clear and convincing
22 evidence that a person of ordinary skill in the art would not
23 understand when an antibody has a "useful degree of affinity"
24 such that it falls within the scope of the claims of the '561
25 patent. Nor has Genentech shown that the "selectivity" required
26 for immunologically significant binding is indefinite in light of
27 the specification. The court accordingly finds that the term
28 "binds" is not indefinite.

