

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENZO LIFE SCIENCES, INC., :
 :
 Plaintiff/Counterclaim :
 Defendant, :
 :
 v. : Civil Action No. 02-212 JJF
 :
 DIGENE CORPORATION, :
 :
 Defendant/Counterclaim :
 Plaintiff, :
 :
 v. :
 :
 ENZO BIOCHEM, INC., :
 :
 Additional Counterclaim :
 Defendant/Declaratory :
 Plaintiff. :

Josy W. Ingersoll, Esquire of YOUNG, CONAWAY, STARGATT & TAYLOR, LLP, Wilmington, Delaware.
Of Counsel: Richard L. DeLucia, Esquire and Paul M. Richter, Jr., Esquire of KENYON & KENYON, New York, New York.
Attorneys for Plaintiff/Counterclaim Defendant Enzo Life Sciences, Inc., and Counterclaim Defendant/Declaratory Plaintiff Enzo Biochem, Inc.

Richard D. Kirk, Esquire of MORRIS, JAMES, HITCHENS & WILLIAMS LLP, Wilmington, Delaware.
Of Counsel: Marc R. Labgold, Ph.D., Esquire and Kevin M. Bell, Esquire of PATTON BOGGS LLP, McLean, Virginia.
Richard J. Oparil, Esquire of PATTON BOGGS LLP, Washington, D.C.
Attorneys for Defendant/Counterclaim Plaintiff Digene Corporation.

MEMORANDUM OPINION

February 19, 2004

Wilmington, Delaware

Farnan, District Judge.

Presently before the Court is the Motion Of Digene Corporation ("Digene") For Partial Summary Judgment Of Invalidity (By Reason Of Indefiniteness). (D.I. 36.) For the reasons discussed, the Court will deny the Motion.

CONTENTIONS

Digene contends that claims 16-29 and 44-56 of U.S. Patent No. 6,221,581 (the "'581 patent") are invalid for indefiniteness under 35 U.S.C. § 112, paragraph two. Specifically, Digene contends that an inherent contradiction in the claims makes them indefinite. Digene contends that claims 16's and 44's requirement that the first entity have one or both of the signaling or capturing domains is impermissibly inconsistent with the next two entities that require the presence of both domains.

In response, Enzo Life Sciences ("Life Sciences") contends that Digene has manufactured an inconsistency in the language of claims 16 and 44 by reading them separately. Life Sciences contends that claims 16 and 44 follow the common method of claim drafting, wherein drafting attorneys start with broader claims and then subsequently add limitations. Further, Life Sciences contends that Digene has failed to satisfy its burden of proof because it has not produced evidence that the claims of the '581 patent would be indefinite to one of ordinary skill in the art. Life Sciences also contends that Digene incorrectly assumes that

if independent claims 16 and 44 are held invalid for indefiniteness, their dependent claims must also be invalid. Life Sciences contends that well-established law provides that each claim is presumed valid independent of the validity of other claims.

STANDARD OF REVIEW

Rule 56(c) of the Federal Rules of Civil Procedure provides that a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a triable dispute of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000). Thus, to properly consider all of the evidence without making credibility determinations or weighing the evidence, the "court should give credence to the evidence favoring the [non-movant] as well as that 'evidence supporting the moving party that is uncontradicted and unimpeached, at least to the extent

that that evidence comes from disinterested witnesses.'" Id.
(quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 254
(1986)).

To defeat a motion for summary judgment, Rule 56(c) requires
the non-moving party to:

do more than simply show that there is some
metaphysical doubt as to the material facts. . . . In
the language of the Rule, the non-moving party must
come forward with "specific facts showing that there is
a genuine issue for trial." . . . Where the record
taken as a whole could not lead a rational trier of
fact to find for the non-moving party, there is "no
genuine issue for trial."

Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S.
574, 586-87 (1986) (quoting Fed. R. Civ. P. 56). Accordingly, a
mere scintilla of evidence in support of the non-moving party is
insufficient for a court to deny summary judgment. Liberty
Lobby, Inc., 477 U.S. at 252 (1986).

DISCUSSION

The second paragraph of 35 U.S.C. § 112 provides, "The
specification shall conclude with one or more claims particularly
pointing out and distinctly claiming the subject matter which the
applicant regards as his invention." Id. The Federal Circuit
has interpreted Section 112, paragraph two as containing two
requirements: 1) the claim must set forth what the patentee
regards as his invention, and 2) do so with sufficient
particularity and definiteness. Allen Eng'r Corp. v. Bartell
Indus., 299 F.3d 1336, 1348 (Fed Cir. 2002) (citing Solomon v.

Kimberly-Clark Corp., 216 F.3d 1372, 1377 (Fed. Cir. 2000). In determining whether a claim is sufficiently definite, a court must analyze whether "one skilled in the art would understand the bounds of the claim when read in light of the specification." Id. (interior quotation omitted). However, a court must remain mindful that granted claims are "accompanied by a presumption of validity based on compliance with . . . § 112 ¶ 2." S3 Inc. v. Nvidia Corp., 259 F.3d 1364, 1367 (Fed. Cir. 2001). Therefore, in order to be successful, a party challenging validity must do so by clear and convincing evidence. Budde v. Harley Davidson, Inc., 250 F.3d 1369, 1376 (Fed. Cir. 2001).

I. Whether Digene's Failure To Produce Evidence Of One Of Ordinary Skill In The Art Defeats Its Motion For Summary Judgment

Life Sciences contends that Digene's motion should fail because Digene has presented the Court with no evidence of whether one of ordinary skill in the art would view the claims at issue as indefinite. (D.I. 50 at 16.) In response, Digene contends that the question of indefiniteness is a legal question, and thus, it has no obligation to present testimony from an individual skilled in the art.

When the issue of invalidity due to indefiniteness is appropriate for resolution by summary judgment is less than clear. The Federal Circuit has repeatedly stated that indefiniteness is a legal question, and, at the same time, held

that in certain circumstances, "evidence beyond the claims and written description may be reviewed." Solomon, 216 F.3d at 1379 n. 4. Derived from such statements is an inherent tension as to the appropriateness of resolving indefiniteness questions as a matter of law. See, e.g., Sys. Mgmt. Art v. Avesta Tech., 137 F. Supp. 2d 382, 399 (S.D.N.Y. 2001) (noting the conflict in authorities over whether a determination of invalidity due to indefiniteness is a pure question of law or a question involving underlying issues of fact that preclude the entry of summary judgment). Notwithstanding this conflict in authority, the facts in this case permit the Court to decide the question of indefiniteness without resolving disputed questions of fact. The claims at issue do not have technical or relational terms that may be understood differently by one of ordinary skill in the art. Instead, Digene's arguments of indefiniteness involve allegations of internal contradiction based upon the wording of the claims. Thus, as the construer of patent claims, the Court may reach the merits of the indefiniteness question. See Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1376 (Fed. Cir. 2001) (citing Personalized Media Communications, LLC v. Int'l Trade Comm'n, 161 F.3d 696, 705 (Fed. Cir. 1998); Union Pacific Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 685 (Fed. Cir. 2001)).

II. Whether The Claims At Issue Are Invalid Due To Indefiniteness

Claims 16 and 44 are independent claims in the '581 patent and the focus of the parties' dispute. Claim 16 reads:¹

A composition of a matter which comprises three entities:
the first entity comprising:

(i) one or more oligo- or polynucleotides (i) and said nucleic acid of interest (ii) form a first complex or complexes comprising at least one signaling domain, or at least one capturing domain, or both;

the second entity comprising:

(iii) one or more capturing entities fixed or immobilized to a solid support, said capturing entities characterized in being (A) complexed or capable of complexing with said capturing domain in said first complex or complexes; and (B) substantially incapable of hybridizing with either said one or more polynucleotides (i), or said nucleic acid of interest (ii); and

the third entity comprising:

(iv) one or more complex forming moieties which are capable of complexing with said signaling domain in said first complex or complexes and generating a signal.

(D.I. 37, Ex. A.)² As noted above, Digene contends that these claims are invalid due to indefiniteness because it is contradictory to have a first entity requiring at least one or both of two optional components and then to have a second and third entity requiring the presence of the optional components. In support of its contention, Digene relies upon Allen Engineering Corp. v. Bartell Industries, 299 F.3d 1336 (Fed. Cir.

¹ The Court has highlighted the disputed language.

² The disputed language in claims 14 and 44 is identical. Thus, the Court will not recite the entirety of claim 44.

2002), and In re Cohn, 438 F.2d 989 (C.C.P.A. 1971).³ Digene contends that Allen and Cohn require a finding of indefiniteness in this case because, as in those cases, there is an irreconcilable contradiction in claims 16 and 44. The Court disagrees.

In Allen, the court was faced with a patent involving concrete riding trowels powered by a combustion engine and controlled with a steering mechanism. In the steering mechanism was a gearbox that was the subject of the court's discussion on indefiniteness. Claims 1-4 and 13 of the patent in Allen limited the "pivoting of the gear box only in a plane perpendicular to said biaxial plane." Id. at 1349 (emphasis in original). The specification, however, described the same structure in "'contrary terms,' stating that "rotation . . . cannot pivot in a plane perpendicular to the biaxial plane.'" Id. (emphasis in original). Based upon this contradiction, the Allen court held that the claims were indefinite. Id.

In Cohn, the Court of Customs and Patent Appeals held that a patent for producing nonmetallic-appearing finishes on aluminum

³ Digene also relies upon a recently reversed district court case Omega Engineering, Inc. v. Cole-Parmer Instrument Co., 198 F. Supp. 2d 152, 159 (D. Conn. 2002). However, as the Federal Circuit reversed the court's grant of summary judgment due to indefiniteness because of an erroneous claim construction, the Court will not engage in further analysis of Digene's contentions regarding the applicability of Omega to the instant case.

surfaces was invalid due to indefiniteness. The court held that the specification and the claims were "inherently inconsistent." 438 F.2d at 993. The specification taught that one could obtain an "opaque finish" without the use of an alkali metal silicate as a sealant. However, the claims of the patent in Cohn required the sealing of the surface with an alkali silicate in order to obtain this same "opaque finish." The court held that reading the claims in light of the example in the specification resulted in a "inexplicable inconsistency," and therefore, required rejection under 35 U.S.C. § 112, paragraph two.

Allen and Cohn thus require a finding of invalidity when there is an irreconcilable contradiction within the patent. However, the Court concludes that Allen and Cohn do not require a finding of invalidity in this case as both are distinguishable from the claims at issue. In claim 16 of the '581 patent, the first entity must contain a signaling domain, a capturing domain, or both. The second and third entities then require the presence of both a signaling and capturing domain. Accordingly, the language in claims 16 and 44 is distinguishable from the claims of the patents in Allen and Cohn because the language in claims 16 and 44 does not at the same time require and prohibit the presence of the same elements. The last phrase of the first entity in claims 16 and 44 is permissive - it permits the existence of both a signaling and capturing domain. Thus, the

requirement of the second and third entities that the signaling and capturing domain be present is not irreconcilable with the first entity.

In sum, the Court concludes that the claims at issue are not invalid due to indefiniteness because there is no irreconcilable contradiction in claims 16 and 44.⁴ Therefore, Digene's Motion will be denied.

An appropriate Order will be entered.

⁴ Based upon this conclusion, the Court concludes that the remaining dependent claims, 17-29 and 45-56, are also not invalid due to indefiniteness. Digene contends that these dependent claims are invalid for the same reasons as claims 16 and 44. However, as the Court has determined that claims 16 and 44 are not invalid due to indefiniteness, the Court must also reject Digene's claims concerning the remaining claims.

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ORDER

At Wilmington, this 19th day of February, 2004, for the reasons discussed in the Memorandum Opinion issued this date;

NOW THEREFORE, IT IS HEREBY ORDERED that the Motion Of Digene Corporation For Partial Summary Judgment Of Invalidity (By Reason Of Indefiniteness) (D.I. 36) is **DENIED**.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE