

v.

**ABBOTT LABORATORIES, and
ABBOTT MOLECULAR INC.,**

Defendants.

Civil Action No. 12-274-LPS

JURY TRIAL DEMANDED

ENZO'S ANSWER TO ABBOTT'S AMENDED COUNTERCLAIMS

Plaintiff Enzo Life Sciences, Inc. (“Enzo”) answers Abbott Laboratories and Abbott Molecular, Inc.’s (collectively, “Abbott’s”) Amended Counterclaims (hereinafter “Counterclaims”) as follows:

Parties

46. On information and belief, Enzo admits the allegations in Paragraph 46 of the Counterclaims.

47. On information and belief, Enzo admits the allegations in Paragraph 47 of the Counterclaims.

48. Enzo admits the allegations in Paragraph 48 of the Counterclaims.

Jurisdiction and Venue

49. Enzo admits that Abbott purports to set forth claims that arise under 28 U.S.C. §§ 2201 and 2202 and to seek declaratory relief and further relief based upon a declaratory judgment or decree. Enzo admits that Abbott states that it is seeking a judicial declaration as to non-infringement, invalidity, and unenforceability of U.S. Patent No, 6,992,180 (“the ’180 patent”).

51. Enzo admits that the '180 patent contains claims that generally relate, among other things, to oligo- or polynucleotides comprising at least one modified nucleotide or modified nucleotide analog having the formula Sig-PM-SM-BASE wherein PM is a phosphate moiety and Sig is directly or indirectly attached to the PM. Enzo denies all remaining or different allegations in Paragraph 51 of the Counterclaims.

52. Enzo admits that the '180 patent contains claims generally relating to oligonucleotide and polynucleotide compositions, and that the scope of the claims is defined by the claims themselves. Enzo denies all remaining or different allegations in Paragraph 52 of the Counterclaims.

53. Enzo admits that in an Amendment Under 37 C.F.R. § 1.116, dated July 14, 1987, applicants stated:

Applicants have determined that the examples set forth at pages 55-81, except Examples 1, 21, 22, 23, 30, 31, 40, are “Paper”, rather than “working examples” (Manual of Patent Examining Procedure § 608.01(q)) and may, therefore, be incorrectly represented by use of the past tense. By this Amendment, applicants call this inadvertent misstatement to the attention of the Examiner, and eventually to the public should this application issue as a patent.

U.S. Patent Application No. 06/674,242 (“the '352 Application”), Amendment under 37 C.F.R. § 1.116, dated July 14, 1987, at 5. Enzo admits that Dean Engelhardt (“Engelhardt”) is a co-inventor of the '180 patent. Enzo denies all remaining or different allegations in Paragraph 53 of the Counterclaims.

'352 Application, Amendment under 37 C.F.R. § 1.116, dated July 14, 1987, at 1. Enzo denies all remaining or different allegations in Paragraph 54 of the Counterclaims.

55. Enzo admits that in an Amendment under 37 C.F.R. § 1.116, dated July 14, 1987, applicants stated:

Applicants have determined that the examples set forth at pages 55-81, except Examples 1, 21, 22, 23, 30, 31, 40, are “Paper”, rather than “working examples” (Manual of Patent Examining Procedure § 608.01(q)) and may, therefore, be incorrectly represented by use of the past tense. By this Amendment, applicants call this inadvertent misstatement to the attention of the Examiner, and eventually to the public should this application issue as a patent. Although, applicants do not believe that the Examiner has relied on the tense of the examples in her examination of this application, they specifically request that the Examiner reconsider this application in view of their disclosure of these paper examples. See Robin & Haas Co. v. Crystal Chemical Co., 722 F.2d 1556, 1572 (Fed.Cir. 1983).

'352 Application, Amendment under 37 C.F.R. § 1.116, dated July 14, 1987, at 5. Enzo denies all remaining or different allegations in Paragraph 55 of the Counterclaims.

56. Enzo admits that Application No. 08/479,997 (“the ’997 application”) was filed on June 7, 1995. Enzo further admits that Ronald C. Fedus was an attorney of record. Enzo also admits that Dean Engelhardt is listed as a co-inventor of the ’180 patent. Enzo denies all remaining or different allegations in Paragraph 56 of the Counterclaims.

57. Enzo admits that the ’352 application is a parent application to the ’997 application. Enzo also admits that the ’180 patent states on its face that the ’997 application is a continuation of Application No. 08/046,004, filed on April 9, 1993, which is a continuation of Application

Fedus and Dean Engelhardt in Paragraph 43 of the Counterclaims, and therefore denies the same.

Enzo denies all remaining or different allegations in Paragraph 57 of the Counterclaims.

58. Enzo admits the allegations in Paragraph 58 of the Counterclaims.

59. Enzo admits that Engelhardt signed an inventor declaration under 37 C.F.R. 1.63 during prosecution of the applications that eventually issued as the '180 patent. Enzo lacks knowledge or information sufficient to form a belief as to the truth of the remaining or different allegations relating to Engelhardt in Paragraph 59 of the Counterclaims, and therefore denies the same. Enzo denies all remaining or different allegations in Paragraph 59 of the Counterclaims.

60. Enzo admits that during the prosecution of the '997 application, Enzo added new claims relating generally to oligo- or polynucleotides comprising at least one nucleotide having the formula "Sig-PM-SM-BASE," wherein Sig is directly or indirectly attached to a Phosphate Moiety (PM). Enzo also admits that on September 18, 1995, Enzo amended the application to seek patentability of the following claim:

-- 236. (NEW) An oligo- or polynucleotide nucleotide comprising at least one nucleotide having the formula

Sig - PM - SM - BASE

wherein PM is a phosphate moiety, SM is a sugar moiety and BASE is a pyrimidine, purine or 7-deazapurine moiety, PM being attached to the 3' or the 5' position of the sugar moiety when said nucleotide is a deoxyribonucleotide and at the 2', 3' or 5' position when said nucleotide is a ribonucleotide, BASE being attached to the 1' position of SM from the N¹ position when BASE is a pyrimidine or the N⁹ position when BASE is a purine or 7-deazapurine, and Sig is covalently attached to PM directly or via a chemical linkage, said Sig being a detectable moiety when attached to PM. ..

filed, does not provide support for the invention as is now claimed.” Enzo further admits that in a Final Office Action dated September 29, 1998, the Patent Office rejected Claims 310-372 and 405-453 under 35 U.S.C. § 112, first paragraph. Enzo denies all remaining or different allegations in Paragraph 61 of the Counterclaims.

62. Enzo admits that during prosecution of the '180 patent, Enzo Biochem, Inc. filed a November 24, 1997 Declaration by Dean L. Engelhardt. Enzo also admits that Dr. Engelhardt is a listed co-inventor for the '180 patent and, at the time the November 24, 1997 Declaration was filed, was a Senior Vice President of Enzo Biochem, Inc. Enzo denies all remaining or different allegations in Paragraph 62 of the Counterclaims.

63. Enzo admits the allegations in Paragraph 63 of the Counterclaims.

64. Enzo admits that the November 24, 1997 Engelhardt Declaration states:

In all, there are no fewer than nine (9) instances where the Sig moiety component is described in the specification as being attached to the phosphate moiety P, the sugar moiety S and/or the base moiety B! These nine separate and distinct instances include the following:”

'997 Application, Declaration of Dr. Dean L. Engelhardt in Support of Adequate Description and Enablement, dated Nov. 24, 1997, at 10, ¶ 9(B). Enzo denies all remaining or different allegations in Paragraph 64 of the Counterclaims.

65. Enzo admits that Paragraph 9B of the November 24, 1997 Engelhardt Declaration lists nine instances where the Sig moiety component is described in the '180 patent specification as

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