

CASE NO. 15-61631-CIV-COHN/SELTZER  
(CONSOLIDATED WITH 15-62081-CIV-COHN/SELTZER)

AMGEN INC. and AMGEN  
MANUFACTURING LIMITED,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.,

Defendants.

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**PARTIAL FINDINGS REGARDING  
APOTEX'S ASSERTION OF INVALIDITY OF THE '138 PATENT**

Apotex Inc. and Apotex Corp. (collectively, "Apotex") concluded its presentation of evidence on July 14, 2016 in this nonjury, patent infringement matter. Plaintiffs Amgen Inc. and Amgen Manufacturing Limited (collectively, "Amgen") have moved pursuant to Federal Rule of Civil Procedure 52(c) for partial findings on Apotex's Fifth Affirmative Defense (Invalidity) and Second Counterclaim (Declaratory Judgment on Invalidity of the '138 Patent) in each of Apotex's Answers, Affirmative Defenses, and Counterclaims in this consolidated action (ECF Nos. 47, 64). In particular, Amgen moved for partial findings regarding Apotex's claim that the '138 Patent is invalid for anticipation, lack of written description, indefiniteness, and obviousness. Having "fully heard" Apotex pursuant to Rule 52(c), the Court hereby finds in favor of Amgen and against Apotex on each of these issues and makes the following partial findings of fact and conclusions of law.

Amgen Exhibit 2004

## STANDARD

Rule 52(c) provides that “[i]f a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.” Fed. R. Civ. P. 52(c). A Rule 52(c) motion is properly granted when a party presents “no evidence” in support of a claim or defense. See, e.g., *Cueva v. Allstate Ins. Co.*, 142 F.3d 442 (9th Cir. 1998). Further, courts grant “partial findings under Rule 52(c) with respect to . . . patent invalidity defense[s].” *Elan Corp. v. Andrx Pharm., Inc.*, No. 98-7164, 2008 WL 4709251, at \*8 (S.D. Fla. Aug. 13, 2008).

Amgen’s ’138 patent is presumed to be valid. 35 U.S.C. § 282. To prevail on any of its invalidity defenses, Apotex must provide clear and convincing evidence that Amgen’s patent is invalid. See *Finnigan Corp. v. Int’l Trade Comm’n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999) (“The burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence.” (citation and quotation marks omitted)).

## PARTIAL FINDINGS

### **A. Anticipation**

Anticipation is a question of fact. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). A reference is anticipatory under § 102(b) when it discloses each and every element of the claimed invention, whether it does so explicitly or inherently. *Id.* The reference must “enable one of ordinary skill in the art to make the invention without undue experimentation.” *Impax Labs., Inc. v. Aventis*

*Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008); see *In re LeGrice*, 49 C.C.P.A. 1124, 301 F.2d 929, 940–44 (1962).

The Court finds that Apotex failed to meet its burden of establishing by clear and convincing evidence that the '138 patent is invalid for anticipation. The Court thus finds that each of the asserted claims 1-3, 6, 7, 13, 15-17, 22-23 of the '138 Patent is not invalid for anticipation under 35 U.S.C. § 102.

**B. Written Description**

“[C]ompliance with the ‘written description’ requirement of § 112 is a question of fact.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). For a claim to be invalid for lack of written description, the specification must fail to convey to one skilled in the relevant art that the inventors were in possession, at the time the specification was filed, of the claimed subject matter. See *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (Fed. Cir. 2003). Inventors are not required to disclose in their patent specification every species encompassed by their claims, even in an unpredictable art. See *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (“If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met.”).

The Court finds that Apotex failed to meet its burden of establishing by clear and convincing evidence that the '138 patent is invalid for lack of written description. The Court thus finds that each of the asserted claims 1-3, 6, 7, 13, 15-17, 22-23 of the '138

Patent is not invalid for lack of written description under 35 U.S.C. § 112, first paragraph.

### **C. Indefiniteness**

A claim can only be held invalid for indefiniteness when those skilled in the art could not reasonably understand its meaning in light of the patent specification, such that it is not capable of any reasonable construction and the scope of the claim cannot be determined. See, e.g., *Marley Mouldings Ltd. v. Mikron Indus., Inc.*, 417 F.3d 1356, 1359 (Fed. Cir. 2005); *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366 (Fed. Cir. 2004).

The Court finds that Apotex failed to meet its burden of establishing by clear and convincing evidence that the '138 patent is invalid for indefiniteness. The Court thus finds that each of the asserted claims 1-3, 6, 7, 13, 15-17, 22-23 of the '138 Patent is not invalid for lack of definiteness under 35 U.S.C. § 112, second paragraph.

### **D. Obviousness**

A party seeking to challenge the validity of a patent based on obviousness must prove that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). Establishing prima facie obviousness requires the Court to engage in a two-part inquiry. The Court must determine: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of

success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

The Court finds that Apotex failed to meet its burden of establishing by clear and convincing evidence that the '138 patent is invalid for obviousness. The Court thus finds that each of the asserted claims 1-3, 6, 7, 13, 15-17, 22-23 of the '138 Patent is not invalid for obviousness under 35 U.S.C. § 103.

### **CONCLUSION**

For the reasons given above, it is hereby **ORDERED AND ADJUDGED** that:

Each of the asserted claims 1-3, 6, 7, 13, 15-17, 22-23 of the '138 Patent is not invalid for (i) anticipation under 35 U.S.C. § 102, (ii) lack of written description under 35 U.S.C. § 112, first paragraph, (iii) indefiniteness under 35 U.S.C. § 112, second paragraph, and (iv) obviousness under 35 U.S.C. § 103. Accordingly, the Court enters judgment in favor of Amgen and against Apotex on Apotex's Fifth Affirmative Defense (Invalidity) and Second Counterclaim (Declaratory Judgment on Invalidity of the '138 Patent) in each of Apotex's Answers, Affirmative Defenses, and Counterclaims in this consolidation action (ECF Nos. 47, 64) solely with respect to the matters addressed in these partial findings. The Court notes that no judgment is rendered herein with respect to any claim or defense of invalidity based on lack of enablement.

**DONE AND ORDERED** in Chambers at Fort Lauderdale, Broward County, Florida, this 14th day of July, 2016.

  
JAMES I. COHN  
United States District Judge

Copies provided to:  
Counsel of record via CM/ECF