

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**APOTEX INC. and APOTEX CORP.,
Petitioner**

v.

**AMGEN INC. and AMGEN MANUFACTURING LIMITED,
Patent Owner**

**CASE IPR2016-01542
Patent 8,952,138**

**APOTEX'S REQUEST FOR REHEARING
UNDER 37 C.F.R. § 42.71(d)**

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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I. INTRODUCTION

Petitioner respectfully requests rehearing under 37 C.F.R. § 42.71(d) of the Board's Final Written Decision ("Decision", Paper 60) finding that claim 18 is not unpatentable.

The Decision contains errors of law based on misapprehending or overlooking the record in the case as it relates to the construction of "non-aerobic conditions" in claim 18, and the application of that construction to find claim 18 not unpatentable. A proper understanding of the record, combined with application of appropriate claim-construction principles, would have provided ample basis to find that Petitioner has carried its burden of showing that claim 18 is unpatentable. 35 U.S.C. § 316(e).

Petitioners respectfully submit that the Board misinterpreted "non-aerobic conditions" in claim 18 by overlooking the express definition of that term in the specification of the '138 Patent. Decision at 40. That express definition is in the "Definitions" section of the '138 Patent specification:

As used herein, the term "non-aerobic condition" means any reaction or incubation condition that is performed *without intentional aeration* of the mixture by mechanical or chemical means.

Ex. 1001 at 7:20-37 (emphasis added). Rather than applying this broadest reasonable interpretation consistent with the specification, the Board overlooked

that definition and instead applied an inconsistent definition – “in the absence of oxygen”. As a result, the Board incorrectly found that claim 18 is not obvious over Schlegl and Hevehan.

The construction of terms not explicitly construed by Petitioner, including “non-aerobic conditions”, was previously addressed in the Petition at page 20. Petitioners and their expert, Dr. Robinson, acted accordingly and gave the term “non-aerobic conditions” its broadest reasonable construction in light of the specification in the Petition, Reply, and Dr. Robinson’s two Declarations. Pet. (paper 2) at 55; Reply (paper 26) at 17; Ex. 1002 at ¶¶ 147-148; Ex. 1056 at ¶ 67. The express definition of “non-aerobic conditions” was previously addressed in Petitioner’s Opposition to Patent Owner’s Motion to Exclude at 8-9.

When the proper definition is applied to “non-aerobic conditions”, Petitioners have met their burden of demonstrating that claim 18 is unpatentable as obvious. The Final Written Decision on claim 18 should be reconsidered using the explicit definition of “non-aerobic conditions” in the specification, and the Board should conclude that claim 18 is unpatentable over Schlegl and Hevehan.

II. LEGAL STANDARD

“A party dissatisfied with a decision may file a request for rehearing, without prior authorization from the Board.” 37 C.F.R. § 42.71(d). “The burden of showing a decision should be modified lies with the party challenging the

decision” and “[t]he request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.” *Id.*

III. ARGUMENT

A. The Board Adopted an Erroneous Construction of “Non-aerobic Conditions”

1. Relevant Legal Standards on Claim Construction

The standard for claim construction in proceedings before the U.S. Patent and Trademark Office is the broadest reasonable construction in light of the specification. *See* 37 C.F.R. § 42.100(b) (standard applies in *inter partes* reviews); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (same); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*) (standard applies in *ex parte* prosecution); 37 C.F.R. § 1.56 (same); *Leo Pharm. Prods. Ltd. v. Rea*, 726 F.3d 1346, 1352 (Fed. Cir. 2013) (standard applies in *inter partes* reexamination); *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984) (same); 37 C.F.R. § 1.550 (standard applies in *ex parte* reexamination).

Construing a patent claim, of course, begins with the claim language itself. *See, e.g., Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “Although words in a claim are given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the

term is clearly stated in the patent specification or file history.” *Id.* at 1582; *see also Phillips*, 415 F.3d at 1316 (“[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.”); *In re Bass*, 314 F.3d. 575, 577 (Fed. Cir. 2002) (“In examining a patent claim, the PTO must apply the broadest reasonable meaning to the claim language, taking into account any definitions presented in the specification. Words in a claim are to be given their ordinary and accustomed meaning unless the inventor chose to be his own lexicographer in the specification.” (citation omitted)).

2. The Inventors of the ’138 Patent Expressly Defined “Non-aerobic Condition”

The ’138 Patent specification provides an explicit definition for the term “non-aerobic condition”, a term recited in claim 18: “any reaction or incubation condition that is performed without intentional aeration of the mixture by mechanical or chemical means.” Ex. 1001 at 7:20-23. This express definition is confirmed by other portions of the specification, describing that “[u]nder non-aerobic conditions[,] oxygen can be present as long as it is naturally present and was not introduced into the system with the intention of adding oxygen to the system.” *Id.* at 7:24-26. The specification also teaches that “[n]on-aerobic conditions need not be completely free of oxygen, only that no additional oxygen other than present in the initial system is purposefully introduced.” *Id.* at 12:2-4.

In this case, there is little doubt that the inventors acted as their own lexicographers when defining this term.

As a result, it is clear that the patentees did not intend to limit the non-aerobic conditions for incubation recited in claim 18 to conditions that are completely free of oxygen.¹ Yet Patent Owner and the Board construed “non-aerobic conditions” to mean the same thing as anaerobic conditions, *i.e.*, the absence of oxygen. *See* Institution Decision (paper 10) at 29; Resp. (Paper 10) at 47-48; Decision at 40-41. This interpretation is inconsistent with the broadest reasonable interpretation of the term *in light of the specification’s* express definition and other usage, and, therefore, it is legally and factually improper.

B. When the Definition of “Non-aerobic Conditions” from the ‘138 Specification is Applied, Petitioner Has Met Its Burden to Demonstrate that Claim 18 is Obvious Over Schlegl and Hevehan

The Board concluded claim 18 was not unpatentable over Schlegl and Hevehan because “Hevehan and Schlegl fail to describe anaerobic conditions for folding.” Decision at 41. That conclusion is based on a legally and factually erroneous construction that equated “non-aerobic conditions” with “anaerobic

¹ It also follows that when using the term “aerobic conditions”, the inventors of the ‘138 Patent are referring to the intentional introduction of oxygen to the incubation conditions, rather than to conditions where oxygen from any source is naturally present.

conditions.” When the broadest reasonable interpretation of “non-aerobic conditions” *in light of the specification* is applied, however, both the Petition and the record supports the finding that claim 18 is obvious over Schlegl and Hevehan.

Patent Owner and the Board agree that Schlegl and Hevehan teach conditions where oxygen may be naturally present but was not introduced into the system with the intention of adding oxygen into the system. *See* Decision at 41; Resp. at 47. As discussed above, this is precisely how the ’138 Patent defines and discusses “non-aerobic conditions.” Ex. 1001 at 7:24-26 (“Under non-aerobic conditions oxygen can be present as long as it is naturally present and was not introduced into the system with the intention of adding oxygen to the system.”).

Patent Owner’s arguments, and the Board’s reliance, on the open-tank reactors of Schlegl and Hevehan is misplaced under the proper construction of “non-aerobic conditions.” *See* Decision at 41; Resp. at 47, (citing Ex. 1003 at Figures 1-3). An open air reactor is within the scope of the proper construction of “non-aerobic conditions,” as long as no additional oxygen is purposefully added. Moreover, one of ordinary skill knew at the time of the invention that aerobic conditions could impact the redox chemistry of the refolding reaction. Decision at 40-41; Pet. at 55, citing Ex. 1002 at ¶ 148. Yet both Schlegl and Hevehan are silent on the presence or absence of oxygen during incubation. Decision at 41; Resp. at 47-48 (citing Ex. 2019 at 82:17-20). Thus, neither Schlegl nor Hevehan

teach the intentional addition of oxygen. Consequently, the record supports the finding that claim 18 is unpatentable as obvious over Schlegl and Hevehan.

IV. CONCLUSION

The term “non-aerobic conditions” should have been construed in a manner consistent with the express definition and consistent usage in specification: “any reaction or incubation condition that is performed without intentional aeration of the mixture by mechanical or chemical means.” When that broadest reasonable interpretation in light of the specification is applied, the prior art renders claim 18 of the ’138 Patent obvious.

In view of the foregoing, Petitioner respectfully requests that the Board grant rehearing and modify its Decision to find that Apotex has shown, by a preponderance of the evidence, that claim 18 is obvious over Schlegl and Hevehan.

Date: March 16, 2018

Respectfully submitted,

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CERTIFICATION OF SERVICE

The undersigned hereby certifies that the foregoing document entitled
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