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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte AARON KEITH CHAMBERLAIN,
BASSIL DAHIYAT, JOHN R. DESJARLAIS,
SHER BAHADUR KARKI,
and GREGORY ALAN LAZAR

Appeal 2022-001944
Application 16/803,690
Technology Center 1600

Before RICHARD M. LEBOVITZ, TAWEN CHANG, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

This is a decision on Appellant's Request for Rehearing under 37 C.F.R. § 41.52 of the Decision on Appeal mailed January 10, 2023 ("the Decision" or "Dec."). Only two claims are pending and on appeal, claims 8 and 9. Claim 8 is a Jepson claim. Claim 9 is a means-plus-function claim. The Rehearing is denied.

The Decision affirmed the obviousness-type double patenting rejection of claims 8 and 9 based on the combination of U.S. Patent No. 10,336,818 B2 ("the '818 patent") and Schwaeble et al. (U.S. Pat. App. Pub. No. 2006/0018896 A1, published Jan. 26, 2006) ("Schwaeble"); reversed the obviousness-type double patenting rejection of claims 8 and 9 based on the

combination of U.S. Patent No. 8,546,543 B2 (“the ’543 patent”) and Schwaeble; and set forth new grounds of rejection of claims 8 and 9 under 35 U.S.C. § 112(a) and § 112(b) as authorized by 37 C.F.R. § 41.50(b).

CLAIM 8 REJECTION

Claim 8 is rejected under 35 U.S.C. § 112(a) as lacking a written description of the full scope of the claim. Dec. 3, 8. Claim 8 is reproduced below from the “Claims Appendix” of the Appeal Brief (dated Aug. 25, 2021).

8. In a method of treating a patient by administering an anti-C5 antibody with an Fc domain, the improvement [comprising] said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.
Appeal Br. 46 (“Claims Appendix”).

Is the preamble of claim 8 limiting?

Appellant contends that “the Board erroneously assumed that the entire preamble—reciting ‘a method of treating a patient by administering an anti-C5 antibody with an Fc domain’—is limiting and thus must be included in the written description analysis.” Req. Reh’g 3. Appellant asserts that the method of treating a patent is “an intended purpose.” *Id.* at 5. On the other hand, Appellant asserts that the phrase “administering an anti-C5 antibody with an Fc domain” is “limiting because it provides antecedent basis to the remaining claim limitations and provides the structural component (i.e., anti-

C5 antibody with an Fc domain) upon which the claimed improvement in the Fc region is implemented.” *Id.* at 4.

Appellant argues that the claim preamble is not limiting because the claim “does not require any ‘effective amount’ or efficacious result deriving, from the step of ‘administering.’” Req. Reh’g 4 (citing *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1342 (Fed. Cir. 2021)). Appellant contends that the recitation of a “method of treating a patient” “merely states an intended purpose, which the Federal Circuit has repeatedly held to be non-limiting.” *Id.* at 5 (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375–1376 (Fed. Cir. 2001); *In Re: Copaxone Consol. Cases*, 906 F.3d 1013, 1023 (Fed. Cir. 2018); *In re Montgomery*, 677 F.3d 1375, 1389–1381 (Fed. Cir. 2012)).

We initially observe that the cases cited by Appellant in support of its argument that the preamble of claim 8 is “limiting” involved claim construction for the purpose of determining whether the claims were anticipated or obvious in view of prior art. *Lilly*, 8 F.4th at 1337;¹ *Bristol-Meyers Squib*, 246 F.3d at 1374;² *Copaxone*, 906 F.3d at 1022;³

¹ In the context of determining whether the claims would have been obvious in view of three cited prior art references, “[t]he Board also discussed how the claim construction affected Lilly’s burden to demonstrate that a skilled artisan would have had a reasonable expectation of success in combining the teachings of the prior art to achieve the claimed invention.”

² “Bristol argues that the court improperly read out the phrase ‘[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity’ from claims 5, 6, 8, and 9 of the ’537 patent. . . . Bristol argues that these expressions are limitations because they distinguish the new use of the process over the prior art.”

³ “Teva contends that the district court erroneously construed certain claim terms as non-limiting and disregarded them for nonobviousness purposes.”

Montgomery, 677 F.3d at 1380–1381.⁴ In each of these cases, the determination of whether the claim preamble was “limiting” was for the purpose of ascertaining whether the preamble *limits the scope of the claim* in the context of prior art.⁵ In contrast, the issue in this appeal is whether it is necessary to consider the claim preamble when determining compliance with the written description requirement of section 112(a). The two questions are different.

The determination that a claim preamble does not limit the scope of the claim for prior art purposes does not mean the preamble can be ignored when ascertaining whether the claim complies with the written description requirement. Section 112(a) requires that “[t]he specification shall contain a written description of the invention.” Thus, when the inventors claim their invention with language that includes a preamble, we understand the statute to require that the specification describe such an invention with all the language recited in the claim, including the claim preamble. While a court

⁴ “We need not resolve this question [of whether the ‘proper interpretation of the claims would include an efficacy requirement’], however, for we agree with the Board that even if the claim includes an efficacy requirement, efficacy is inherent in carrying out the claim steps. . . . We agree with the dissent that a result is only inherent if it inevitably flows from the *prior art disclosure*, but there is no question here that treating stroke-prone patients with ramipril [*as described in the HOPE publication*] does in fact inevitably treat or prevent stroke.” (Emphasis added.)

⁵ The Board, in a new ground of rejection, found that all the claims would have been obvious in view of prior art. The court held that the claim preamble “merely recites the purpose of the process; the remainder of the claim (the three process steps) does not depend on the preamble for completeness, and the process steps are able to stand alone. . . . The Solicitor’s interpretation of the preamble would improperly broaden the scope of the claim.” *In re Hirao*, 535 F.2d 67, 70 (CCPA 1976).

may subsequently decide that the preamble is not limiting for the purpose of determining whether a claim is patentable under § 102 or § 103, etc., the statutory burden to *describe* the “invention” is still shouldered by the inventor(s) who determines the subject matter which they “regard[] as the invention.” 35 U.S.C. § 112(b) (2018) (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”). Here, where the inventors regard their invention as “a method of treating a patient by administering an anti-C5 antibody with an Fc domain,” they have the statutory burden under the written description requirement of section 112(a) to describe such a method, including the treating aspect of the claim recited in the claim preamble.

Contrary to Appellant’s arguments, the recited preamble of treating a patient is an essential part of the claimed invention and therefore necessarily limiting. As explained in *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003):

[An intended] use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates. But as we explained in *Griffin v. Bertina*, 285 F.3d 1029, 62 USPQ2d 1431 (Fed. Cir. 2002), preamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise. *Id.* at 1033, 62 USPQ2d at 1434.

To determine “the essence of the invention,” we must turn to the specification, consistent with the need to consult the specification when determining the broadest reasonable interpretation of a claim. The “correct inquiry in giving a claim term its broadest reasonable interpretation in light

of the specification is . . . an interpretation that corresponds with what and how the inventor describes his invention in the specification, i.e., an interpretation that is ‘consistent with the specification.’” *In re Smith Int’l, Inc.*, 871 F.3d 1375, 1382–1383 (Fed. Cir. 2017) (quoting from *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)) (emphasis omitted).

The improvement recited in the method of claim 8 is an “Fc domain” of an anti-C5 antibody where “said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, . . . wherein said anti-C5 antibody with said amino acid substitutions has *increased in vivo half-life* as compared to said antibody without said substitutions.” (Emphasis added.)

The Specification discloses that the reason to increase the *in vivo* half-life of an antibody is to use the antibody as a therapeutic. Spec. ¶ 10. A therapeutic is for the “treatment of diseases or disorders.”⁶ In its “Background” section, the Specification describes mutations to the Fc region of an antibody with respect to the administration of antibodies as “therapeutics”:

The administration of antibodies and Fc fusion proteins as therapeutics requires injections with a prescribed frequency relating to the clearance and half-life characteristics of the protein. Longer *in vivo* half-lives allow more seldom injections or lower dosing, which is clearly advantageous. Although the past mutations in the Fe domain have lead [sic, led] to some proteins with increased FcRn [(an Fc receptor)] binding affinity

⁶ Therapeutic: “of or relating to the treatment of disease or disorders by remedial agents or methods.” Merriam-Webster.com (last accessed May 15, 2023), www.merriam-webster.com/dictionary/therapeutic.

and *in vivo* half-lives, these mutations have not identified the optimal mutations and enhanced *in vivo* half-life.

Spec. ¶ 10.

After describing the use of antibodies “for therapeutic use” (*id.* ¶ 12), the Specification discloses that “Human IgG1 is the most commonly used antibody for therapeutic purposes,” and describes the need to improve its binding and half-life. *Id.* ¶ 14. “Additionally,” the Specification discloses “there is a need to combine variants with improved pharmacokinetic properties with variants comprising modifications to improve efficacy through altered FcγR binding [(receptor for Fc portion of antibody)]. The present application meets these and other needs.” *Id.* In other words, the purpose of increasing the binding and half-life of the Fc region of the antibody is to improve its efficacy when administered to a human as a therapeutic agent.

The Specification makes it clear from these disclosures that the “essence of the invention” is an improved Fc domain of an antibody to use the antibody therapeutically to *treat* a human patient. Consistently, the claim preamble recites “a method of treating a patient.” Treatment is not merely a context in which the Fc domain is useful, but instead it is “the *raison d’être* of the claimed method itself.” *Boehringer Ingelheim Vetmedica*, 320 F.3d at 1345. The Specification discloses that the choice of the antigen to which the antibody having the improved Fc domain binds, such as the C5 antigen, “depends on the desired application,” and “therapeutic antibodies” are the primary focus of the applications disclosed in the Specification. Spec. ¶¶ 128, 130, 131 (“A number of antibodies and Fc fusions that are approved for use, in clinical trials, or in development may benefit from the Fc variants of the present invention. These antibodies and Fc fusions are herein referred

to as ‘clinical products and candidates.’”), ¶¶ 132–139, 141 (“The present application also provides IgG variants that are optimized for a variety of therapeutically relevant properties.”), ¶¶ 144–147.

Furthermore, a court will treat a preamble as a claim limitation if it “recites essential structure or steps.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The only step in claim 8 is “administering” the antibody having the Fc domain and thus it is an “essential” step in the claim. The “administering” step, in the context of the Specification, is to treat a patient. Spec. ¶ 20 (“In another embodiment, the invention includes a method of treating a patient in need of said treatment comprising administering an effective amount of an Fc variant described herein.”); *see also* ¶ 184. For this reason, we do not agree that it was erroneous to consider the preamble in its entirety as the “essence” of the claimed invention and to “define[s] the boundaries of the claimed invention.” Req. Reh’g 6–7. Appellant’s dicing the claim preamble into “treating,” which is asserted not to be limiting, and “administering,” which is asserted to be limiting, ignores the essence of the invention and the therapeutic purpose for which the antibody is administered. *Id.* at 4.

Appellant’s attempt to circumvent the claim preamble by asserting that the claim scope is satisfied by a C5 antibody, alone, having “the claimed Fc modification” is erroneous because it construes the claim as a product, not a method which properly defines the claim scope. Req. Reh’g 7.

The preamble of a Jepson claim has been construed by the Federal Circuit. In *Rowe v. Dror*, 112 F.3d 473, 479–480 (Fed. Cir. 1997), the court

determined that the preamble of a Jepson claim was an “affirmative limitation” of the claim. The court explained:

The Jepson form allows a patentee to use the preamble to recite “elements or steps of the claimed invention which are conventional or known.” 37 C.F.R. § 1.75I (1996). When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope. . . . United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 608.01(m) (6th ed. rev. Sept. 1995) (“[The Jepson form of claim] is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination.”). Thus, the form of the claim itself indicates Rowe’s intention to use the preamble to define, in part, the structural elements of his claimed invention. The device for which the patent claims “an improvement” is a “balloon angioplasty catheter.”

Id. at 479.

Although *Catalina*, 289 F.3d at 808, acknowledged that “[n]o litmus test defines when a preamble limits claim scope,” the court recognized that “Jepson claiming generally indicates intent to use the preamble to define the claimed invention, thereby limiting claim scope” (citing *Rowe*; *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1029 (Fed. Cir. 2002)). See also *Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1426 (Fed. Cir. 1997) (“As we recognized in *Rowe*, the fact that the patentee has chosen the Jepson form of the claim evidences the intention ‘to use the preamble to define, in part, the structural elements of his claimed invention.’ [Rowe, 112 F.3d at 479.] Thus, we conclude that the invention of claim 7 consists of the maintenance machine in combination with the improvement to the maintenance assembly.”).

The court in *Artic Cat, Inc. v. GEP Power Products, Inc.*, 919 F.3d 1320, 1330 (Fed. Cir. 2019) consistently held:

We have long held that preamble language is limiting when the claim recites a combination in the way specified in the one PTO regulation on preambles, *i.e.*, by describing the “conventional or known” elements in a “preamble,” followed by a transition phrase “such as ‘wherein the improvement comprises,’” and then an identification of elements that “the applicant considers as the new or improved portion.” 37 C.F.R. § 1.75(e).

Appellant cites the analysis of a Jepson claim in *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1573 (Fed. Cir. 1996) in which the court, “when analyzing the preamble of [the] *Jepson* claim,” stated “it is ‘appropriate to determine whether the term in the preamble serves to define the invention that is claimed, or is simply a description of the prior art.’” Req. Reh’g 4. However, while the *Applied Materials* court determined that the claim preamble “[i]n a cold purge process” was stated in the “context of the state of the art,” the preamble was still considered a required “‘limitation which the accused device must meet in order to literally infringe’” the patent at issue in the proceeding. *Id.* at 1571, 1572–1573. Claim 8 is no different.

Does claim 8 have written description support even if the preamble is limiting?

Appellant contends that when the claimed limitation of “method of treating a patient” is construed as limiting, claim 8 would still have written description support. Req. Reh’g 11. Appellant argues that “[t]reating” “does not connote any effectiveness or require any particular result. It merely refers to providing care (*i.e.*, administering). And the remainder of the claim

likewise lacks any required efficacy or result deriving from the sole claimed step of ‘administering.’” *Id.*

The meaning and scope of a claim is interpreted in light of the detailed description of the invention in the specification. *Smith*, 871 F.3d at 1382–1383. The Specification discloses the “need” met by the Specification is to “combine variants with improved pharmacokinetic properties with variants comprising modifications to improve efficacy.” Spec. ¶ 14. Appellant’s statement that the claim does not require effectiveness or efficacy is incorrect because it does not consider what is described in the Specification and the stated need met by the invention. The PTAB cases cited by Appellant to support its argument are unavailing because they are based on different facts and specifications. Instead, the specification must be consulted when interpreting a claim. *Smith*, 871 F.3d at 1382–1383.

We have considered Appellant’s further arguments that Specification provides an adequate written description of claim 8, but its arguments are similar to those made in the Appeal Brief and already addressed in detail in the Decision. Req. Reh’g 7–10.

CLAIM 9 REJECTIONS

Claim 9 is rejected under 35 U.S.C. § 112(a) as lacking a written description and under 35 U.S.C. § 112(b) as indefinite. Dec. 28–29.

Claim 9 is reproduced below from the “Claims Appendix” of the Appeal Brief:

9. A method of treating a patient by administering an anti-C5 antibody comprising:
 - a) means for binding human C5 protein; and
 - b) an Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide,

wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

Appeal Br. 46.

The element of the anti-C5 antibody that binds to the human C5 protein is claimed under 35 U.S.C. § 112(f) “as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof” which is “construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” For short-hand, this element is referred to as a “means-plus-function” element or the claim as a means-plus-function claim.

Appellant argues that only one disclosed embodiment having a structure is necessary to have a valid means-plus-function claim. Req. Reh’g 12–14 (citing *Cardiac Pacemakers, Inc. v. St. Jude Med, Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002); *Crea Products, Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1346 (Fed. Cir. 2002)).

Appellant has not directed us to any cases in which § 112(f) has been applied to an antibody claim, or more broadly to a protein⁷ or DNA claim. Generally, to determine § 112(a) written description compliance for claims covering biotechnology inventions, including claims directed to proteins and DNA, we take guidance from *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) which held:

A written description of an invention involving a chemical genus, like a description of a chemical species, “requires a precise definition, such as by structure, formula, [or] chemical name,” of the claimed subject matter sufficient to distinguish it from other

⁷ An antibody is a protein.

materials. [*Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)];
In re Smythe, 480 F.2d 1376, 1383 . . . (Cust. & Pat.App.1973).
See also Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1354 (Fed.
Cir. 2010).

Further guidance comes from *Enzo Biochem, Inc. v. Gen-Probe Inc.*,
323 F.3d 956, 964 (Fed. Cir. 2002) which adopted guidelines issued by the
USPTO that the written description requirement can be met by a “*disclosed
correlation between function and structure.*”

We consider the recited “means for binding human C5 protein” to be a
chemical genus because § 112(f) construes the recited “means” as covering
the binding structure disclosed in the Specification “and equivalents
thereof.” The “equivalents thereof” broadens any structure disclosed in a
specification to a group or genus of structures.

The requirements to comply with the written description requirement
of section 112(a) are not coincident nor fully satisfied by complying with
section 112(f) for a claim in means-plus-function format. *See In re Dossel*,
115 F.3d 942, 946 (Fed. Cir. 1997) (“Paragraph 6 of § 112, which permits a
claim in means-plus-function form and specifies ‘such claim shall be
construed to cover the corresponding structure, material, or acts described in
the specification,’ does not itself implicate the requirements of section 112
¶ 1. Paragraph 1 provides the requirements for what must be contained in the
written description *regardless of whether claims are written in means-plus-
function form or not.*”) (emphasis added); *Intellectual Prop. Dev., Inc. v.
UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308, 1319 (Fed.
Cir. 2003) (In the context of a claim written in means-plus-function format,
the court held “[f]ailure to disclose adequate structure corresponding to the
recited function in accordance with 35 U.S.C. § 112, paragraph 1, results in

the claim being of indefinite scope, and thus invalid, under 35 U.S.C. § 112, paragraph 2.”). Thus, even if only one structure is required to meet section 112(f), the inquiry for compliance with section 112(a) does not end there.

In sum, we do not agree with Appellant that a different standard for compliance with the written description requirement should be applied to an antibody claim simply because the claim is written in means-plus-function format. It is inconsistent to arrive at a different result for an antibody claim comprising a means-plus-function element than for claim reciting the same antibody element without invoking § 112(f). *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021); *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech., Ltd.*, 759 F.3d 1285 (Fed. Cir. 2014) for their discussion of written description for antibody claims).

As discussed in the Decision, there is only one example disclosed in the Specification of the claimed “means for binding human C5 protein,” “5G1.1,” and no structure is disclosed for it. Dec. 29–30 (*see* Spec. ¶ 131). Appellant contends that the disclosure of the 5G1.1 antibody “is all that is required under 35 U.S.C. § 112, paragraph 6 for corresponding structure for the claimed function of ‘binding human CS protein.’” Req. Reh’g 13. Appellant argues that only one structure is required to meet the statutory requirement. *Id.* at 14. But the structure of the 5G1.1 antibody is not defined or described in the Specification. Appellant has not established that the structure of the 5G1.1 antibody was known at the time the application was filed. Equivalence under section 112(f) cannot be determined for claim 9 because there is no disclosed structure to make that determination. The failure to “disclose adequate structure corresponding to the recited function . . . results in the claim being of indefinite scope, and thus invalid, under 35

U.S.C. § 112, paragraph 2.” *Intellectual Prop. Dev.*, 336 F.3d at 1319. Thus, we discern no error in the rejection of claim 9 as indefinite under section 112(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 8 and 9 stand rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting as obvious in view of claims 1–5 of the combination of the ’818 patent claims and Schwaeble. Final Act. 17. The ’818 patent claims are directed to host cells, expression vectors, and nucleic acids for making the same Fc variant recited in instant claims 8 and 9. Dec. 30. Schwaeble discloses anti-C5 antibodies. *Id.* We affirmed the rejection. *Id.* at 34.

Appellant contends that the Examiner’s failure to provide a prima facie case of unpatentability for the nonstatutory obviousness-type double patenting rejection was “overlooked” in the Decision. Req. Reh’g 15. Appellant asserts that “the Examiner offered nothing more than a conclusory assertion without any citation support that it would have been obvious to combine the ’818 Patent and Schwaeble.” *Id.* Appellant further asserts that the Examiner “failed to explain why a person of skill in the art would have been motivated to make such a combination let alone that a person of skill in the art would have had a reasonable expectation of success in such a combination.” *Id.*

These arguments were addressed in the Decision.⁸ Dec. 31–34. We did not overlook the asserted deficiency in the prima facie case nor the Examiner’s reason to combine the ’818 patent claims and Schwaeble. The

⁸ The reference to “Appeal Br. 18” on page 32, line 2, of the Decision is an error. The correct reference is “Final Act. 18.”

Decision responded to Appellant’s same arguments⁹ made in the Appeal and Reply Briefs. *Id.* In the Request for Rehearing, Appellant does not identify an error or deficiency in our response.

CONCLUSION

The Request for Rehearing is denied.

DECISION SUMMARY

Outcome of Decision on Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Denied	Granted
8, 9	112	Written Description	8, 9	
9	112	Indefiniteness	9	
8, 9		Nonstatutory Double Patenting over '818 patent, Schwaeble	8, 9	
Overall Outcome			8, 9	

⁹ “As explained in Appellant’s Opening Brief and Reply Brief, incorporated herein, the Examiner offered nothing more than a conclusory assertion without any citation support that it would have been obvious to combine the ’818 Patent and Schwaeble but failed to explain why a person of skill in the art would have been motivated to make such a combination let alone that a person of skill in the art would have had a reasonable expectation of success in such a combination.” Req. Reh’g 15.

Final Outcome of Appeal after Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
8, 9	112	Written Description			8, 9
9	112	Indefiniteness			9
8, 9		Nonstatutory Double Patenting over '818 patent, Schwaeble	8, 9		
8, 9		Nonstatutory Double Patenting over '543 patent, Schwaeble		8, 9	
Overall Outcome			8, 9		8, 9

DENIED