

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

OSSEO IMAGING, LLC,

Plaintiff,

v.

PLANMECA USA, INC.,

Defendant.

C. A. No. 1:17-cv-01386-LPS-CJB

PUBLIC REDACTED VERSION

**PLAINTIFF OSSEO IMAGING, LLC'S ANSWERING BRIEF IN OPPOSITION  
TO PLANMECA'S USA, INC.'s MOTION FOR SUMMARY JUDGMENT OF  
INVALIDITY DUE TO LACK OF WRITTEN DESCRIPTION AND  
ENABLEMENT**

Dated: October 11, 2019

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Plaintiff OSSEO IMAGING, LLC (“Osseo”) hereby opposes the Motion for Summary Judgment of Invalidity Due to Lack of Written Description and Enablement (D.I. 92, the “Motion”), filed by Defendant PLANMECA USA, INC. (“Planmeca” or “Defendant”) in the above-captioned action on September 23, 2019.

**I. Nature and stage of the proceedings**

Plaintiff Osseo Imaging, LLC (“Osseo”) filed this lawsuit against Planmeca USA, Inc. (“Planmeca”) on October 3, 2017 alleging infringement by Planmeca of U.S. Patent No. 6,381,301 (“the ’301 patent”), U.S. Patent No. 6,944,262 (“the ’262 patent”), and U.S. Patent No. 8,498,374 (“the ’374 patent”) (collectively “the Patents-in-Suit”). The Court issued a Claim Construction Order and Opinion on November 2, 2018. D.I. 44-46. The Parties have completed fact and expert discovery, and trial is scheduled to begin on May 18, 2020. D.I. 18. Each party filed motions to exclude the other party’s expert reports and Planmeca filed two motions for summary judgement of invalidity and noninfringement. D.I. 92-100, 102-104.

**II. Summary of Arguments**

Planmeca’s motion for summary judgment of invalidity based on the written description and enablement requirements under 35 U.S.C. § 112, ¶ 1 is on its face inadequate. Planmeca failed to produce any evidence to support its contentions that the Asserted Claim are not described or enabled by the specification, let alone show that there is no genuine issue of material fact regarding the requirements of 35 U.S.C. § 112, ¶ 1. Indeed, the parties’ experts do not agree on any of the issues of fact relevant to the § 112, ¶ 1 inquiries. This disagreement stems primarily from Planmeca’s refusal to accept the Court’s construction, applying instead interpretations that were rejected by the Court. Planmeca made little effort to address the requirements of § 112, ¶ 1 separately, at times

even conflating the disparate requirements applicable under § 112. Planmeca’s lack of attention in this respect broadcasts its true motivation, which is to relitigate claim construction to include requirements in the claim terms at issue that the Court rejected. Dispositive motions are not an opportunity to relitigate claim construction and the evidence of record clearly shows that there are genuine issues of material fact that must be resolved by the jury. For these and the reasons discussed herein, Planmeca’s motion for summary judgement must be denied on all grounds.

### **III. Factual Background**

Planmeca’s motion for summary judgment of invalidity alleges that certain terms of the Asserted Claims lack written description and enablement under 35 U.S.C. § 112, including with respect to (i) the densitometry requirement, (2) the energy source limitations, (3) the 3D model limitations, and (4) the comparing model claims. *See Op. Br.* at 1-2 (D.I. 93). The Parties exchanged expert reports that address the requirements of 35 U.S.C. § 112, ¶ 1 with respect to these claim terms, including reports by Dr. Pelc for Planmeca (Ex. A (Pelc Opening Invalidity Report) and Ex. B (Pelc Reply Invalidity Report)), and by Dr. Kia for Osseo (Ex. C (Rebuttal Invalidity Report)). Both experts provided relevant testimony in their respective depositions. *See Ex. D-E.*

### **IV. Legal Standards**

“Summary judgment is appropriate where the court is satisfied ‘that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.’” *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986) (quoting Fed. R. Civ. P. 56(a)). The burden to show the nonexistence of a “genuine issue” rests on the moving party. *Id.* (citation omitted). This burden has two distinct components, which includes an initial burden of production and the ultimate burden of persuasion. *Id.* “The

burden of production ... requires the moving party to make a prima facie showing that it is entitled to summary judgment.” *Id.* at 331 (citation omitted). Where “the moving party [bears] the burden of persuasion at trial, that party must support its motion with credible evidence ... that would entitle it to a directed verdict if not controverted at trial.” *Id.* (citation omitted).

Invalidity for lack of written description and enablement under 35 U.S.C. § 112, ¶ 1 must be proven by the moving party by clear and convincing evidence. *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682-684, (Fed. Cir. 2015). The written description requirement requires that the specification “clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” *Ariad Pharm., Inc., v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (internal quotation marks omitted). “Compliance with this requirement is an issue of fact.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 962-962 (Fed. Cir. 2002) (citation omitted).

Enablement is a question of law that is determined based on underlying factual determinations. *Vasudevan Software, Inc.*, 782 F.3d at 684. (citation omitted). A claim is not enabled when “undue experimentation” is necessary to practice the claimed invention. *Id.* Conclusions on undue experimentation are determined based on a number of factors that “include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Id.* (quoting *In re Wands*, 858 F.2d 731, 737 (Fed.Cir.1988)).

In determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007).

**V. ARGUMENT**

**A. The Specification Provides Sufficient Support for the “*comparing model*” Terms**

The specification provides adequate written support to satisfy both requirements under 35 U.S.C. § 112 ¶ 1 for the “comparing model” terms.

The Court concluded that the term “comparing” requires no construction. D.I. 46 at 3. In doing so, the Court rejected Planmeca's contention that the comparing the claimed model terms required “comparing quantitative data used to create each of the claimed models.” D.I. 44 at 14. In construing the single means plus function limitation of the Asserted Claims (“means for comparing...”), the Court acknowledged that the specification disclosed the function comparing tomographic models, including with respect to the embodiment involving “comparing diagnostic parameters” thereof. *Id.* at 15 (citing to '301 patent at 2:13-36, 2:41-45, 4:43-55, 4:59-5:25, 5:18-21, Figs. 1-2). Further, it is well established that the claims themselves provide written support for the comparing model terms. *In re Benno*, 768 F.2d 1340, 1346 (Fed.Cir.1985) (acknowledging that “a claim is part of the disclosure”).

Osseo's technical expert, Dr. Omid Kia confirmed that the specifications provide adequate support for the “comparing model” terms. For example, Dr. Kia explained that “Pelc has not shown that the Patents-in-Suit fail to meet the requirements under 35 U.S.C. § 112” and that in his opinion, the specifications of the Patents-in-Suit meet these requirements. Ex. C at 29 (¶¶88-89). Dr. Kia also identified exemplary disclosures in the

specifications that provide written description support for the “comparing model” claims. *Id.* at 33 (¶95 (citing the ’262 Patent, at 2:48-3:5 and 5:64-6:9 and FIG. 6A-6B)). Indeed, during claim construction Planmeca gleaned from the specification sufficient written description to argue that the “comparing model” terms require “comparing quantitative data used to create each of the claimed models.” D.I. 37 at 2, 16-18 (quoting the “comparing diagnostic parameters” discussion at 5:16–23 of the ’301 Patent), D.I. 44 at 14.

Against this backdrop, Planmeca has not and cannot satisfy its burden to demonstrate there is no genuine factual dispute regarding the written description and enablement requirements with respect to the “comparing models” terms. Dr. Pelc alleged in his reports—without any evidentiary [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. But the claims do not recite an algorithm as a

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<sup>1</sup> Planmeca’s Opening Brief cites to Pelc’s Declaration (OP. Br. Ex. F), which Pelc purports is a summary of the opinions in his reports and which includes the relevant portions of those reports as exhibits. *See* Planmeca’s Op. Br. Ex. F at ¶3. To avoid any conflicting that may arise from this convention, Osseo cites directly to the reports, relevant portions of which have been attached as Exhibits A-D to this brief.

requirement and there is therefore no need for the specification to provide such disclosure. *Vasudevan Software, Inc.*, 782 F.3d at 684 (“A specification must ‘enable’ a person of skill in the art to make and use the *claimed* invention.”) (citing 35 U.S.C. § 112 ¶ 1) (emphasis added), *Ariad Pharm., Inc.*, 598 F.3d at 1351 (noting with respect to the written description requirement that “the test for sufficiency is whether the disclosure ... reasonably conveys to those skilled in the art that the inventor had possession of the *claimed* subject matter as of the filing date”) (emphasis added).

In arguing that “comparing” requires the disclosure of an algorithm, Planmeca conflates the various paragraphs of 35 U.S.C. § 112. That is, Planmeca attempts to invoke 112, ¶ 6, which governs means-plus-function terms. Ex. A at 208 (¶508), Op. Br. at 2-3 (citing D.I. 44 at 16, the Court’s findings regarding the algorithm requirement for the only claim in this case that used a means-plus-function limitation.). But when a claim term lacks the word “means”, a rebuttable presumption arises that Section 112, ¶ 6 does not apply. *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1007-8 (Fed. Cir. 2018) (declining to construe as MPF term where defendant offered “no evidentiary support” to carry the burden to overcome presumption) (internal quotations omitted). “[T]he presumption can be overcome and § 112, para. 6 will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015).

Courts regularly reject attempts to invoke Section 112, ¶ 6, where, as here, the term has “a reasonably well understood meaning in the art”. *TQ Delta, LLC v. 2Wire, Inc.*, No. 1:13-cv-01835-RGA, 2018 WL 4062617, at \*10 (D. Del. Aug. 24, 2018)

(declining to apply Section 112, ¶6). The “comparing models” terms do not use the word “means,” and therefore the presumption against applying Section 112, ¶ 6 applies in this case. Defendant has offered no evidence to overcome this presumption, nor did Defendant propose that these terms should be governed by Section 112, ¶ 6, during claim construction. Thus, this attempt to resurrect issues this Court already resolved during claim construction must be rejected.

Additionally, even though [REDACTED], he does not at all discuss enablement with reference to any of the “*Wand*” factors for undue experimentation. Ex. A at 12 (¶33), *see In re Wands*, 858 F.2d at 737, *supra*. In short, Planmeca has not provided any credible evidence to show that it is entitled to a directed verdict regarding the written description and enablement requirements. *Celotex Corp.*, 477 U.S. at 330-331, *supra*. To the contrary, Dr. Pelc’s admissions regarding the ’301 Patent’s disclosure of the “comparing” terms alone show that the written description requirement is indeed met. Ex. A at 207-208 (¶¶507-508).

The disagreement between the experts stems from Dr. Pelc’s misrepresentation of the scope of the claims, which is even narrower than the interpretation that Planmeca proposed during claim construction (which this Court rejected). Op. Br. at 3, Ex. B at 25-26 (¶¶43) (arguing that “[p]ointing to a computer having software does not provide any guidance regarding how to compare the claimed models, e.g., what algorithm or method the software implements and applies.”), D.I. 44 at 13 (rejecting Planmeca’s “comparing quantitative data” requirement). Although it is clear, as set forth above, that Planmeca has not offer sufficient evidence to meet its burden to show that the “comparing models”

terms are invalid, that there is this disagreement between the experts establishes that there is a genuine issue of material fact in dispute and this motion for summary judgment must be denied. *Fuji Machine Mfg. Co. Ltd. v. Hover-Davis, Inc.*, 60 F.Supp.2d 111, 120 (W.D.N.Y. 1999) (where experts disagree, credibility determinations “should not be made by the court on a motion for summary judgment.”) (citing *Allied Colloids Inc. v. American Cyanamid Co.*, 64 F.3d 1570, 1575 (Fed. Cir. 1995)).

**B. The Specification Provides Sufficient Support for the “densitometry model” Terms**

The Court construed “densitometry” to mean ‘quantitatively calculated bone density’. D.I. 44 at 8. The Court rejected Planmeca’s argument that this term should be limited to dual energy, because even though the specification discloses dual energy measuring techniques, there are other patents incorporated by reference therein that describe single energy imaging. *Id.* at 9 (citing the ’301 Patent at 5:6-23 and D.I. 41 (Tr.) at 23-24). Planmeca’s counsel confirmed as much during the Markman hearing. D.I. 41 at 33 (“And then from the perspective of the other patent, one of the other patents is incorporated by reference to the ’755 Patent, the Gershman patent. *There is some discussion in there of whether you can use a single energy level or dual energy level.*”) (emphasis added).

Notwithstanding the forgoing, Planmeca argues that because the claims could capture single-energy measuring techniques, they fail to meet the written description and enablement requirements because “there is no description or explanation [in the Patents-in-Suit] of how to generate a densitometry model from single energy level measurements that are used to quantitatively calculate bone density.” Op. Br. at 4-5 (quoting Dr. Pelc at ¶¶ 14–15). First, this is not the test for either of the requirements at issue here. *See*

Section IV, *supra*. Second, “the specification need not necessarily describe how to make and use every embodiment of the invention because the artisan’s knowledge of the prior art and routine experimentation can often fill in the gaps.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007) (internal citation and quotation marks omitted). Third, Planmeca acknowledged that the Gershman patent, which was incorporated in the Patents-in-Suit by reference, discusses the use of single energy level measurements. 37 C.F.R. 1.57(b)-(c), D.I. 41 (Tr.) at 23-24.

Planmeca does not provide any evidence to show that it is entitled to a judgment on either of the requirements of § 112, ¶ 1. Indeed, the only support for its arguments is a single paragraph in [REDACTED]. [REDACTED]. Op. Br. at 4-5 (citing Ex. A at 205 (¶503)). Not only does Planmeca neglect to disclose its admission regarding the Gershman patent, it also misrepresents Dr. Kia’s testimony, *i.e.*, that Dr. Kia “does not dispute that the Patents-in-Suit lack written description or enablement for densitometry using a single energy level....” Op. Br. at 5 (citing Kia Validity Report ¶92). Kia made no such admission in the cited ¶ 92, which is reproduced below:

The Opening Invalidity Report argues that there is no disclosure for “how to generate a densitometry model from a single energy level measurement that are used to quantitatively calculate a bone density” and “how to produce such models if they need to be tomographic or 3D”. (Pelc Report, at p. 205). The claims in the Patents-In-Suit are not limited to only a single energy level and this inquiry is therefore irrelevant.

Ex. C at 30. Thus, *Trs. of Boston University v. Everlight Elecs. Co.* does not apply to the facts of this case. 896 F.3d 1357, 1362 (Fed. Cir. 2018), Op. Br. at 4. That is, in *Trs. of Boston University*, both parties’ experts testified at trial that the species at issue was physically impossible, and the claims directed to the genus were therefore not enabled as

a matter of law. *Trs. of Boston University v. Everlight Elecs. Co.*, 896 F.3d 1357, 1362 (Fed. Cir. 2018). There is no such agreement in this case and that case is inapt.

Planmeca has the burden to show that it is entitled to summary judgment (*Celotex Corp.*, 477 U.S. at 330-331), but it has acknowledged that specification provides a written description for at least the embodiment that uses “dual energy techniques” (Br. at 4) and admits that there is at least some discussion of the single energy techniques incorporated by reference into the specification (D.I. 33). Regarding enablement, claims are entitled to their full breadth, and are not limited to disclosed embodiments. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). The appropriate standard for enablement is whether the full scope of the claims would require undue experimentation. *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed.Cir.2009) (citation omitted). But, Dr. Pelc did not offer testimony to show that it would require one of ordinary skill in the art to undertake undue experimentation to use single-energy level techniques. Ex. A at 205 (¶503).

Accordingly, Planmeca has not shown that it is entitled to a judgement on either ground under § 112, ¶ 1. Additionally, that the parties and their experts disagree on what the specification discloses and enables, demonstrates that there is a genuine issue of material fact. Summary judgment on invalidity is therefore improper.

**C. The Specification Provides Sufficient Support for the “*Electron Beam Source*” and “*3D model*” Terms.**

Planmeca’s “electron beam source” and “3D model” arguments are no better than any of its other arguments.

On one hand, Planmeca admits that the “electron beam source” embodiment is disclosed in the specification, but on the other that there is no written description. Op.

Br. at 5. There is no doubt, therefore, that the “electron beam source” satisfies the written description requirement. Regarding enablement, Pelc explained that to achieve this function, “the electron beam would have to be very, very energetic and would deliver a huge radiation dose to the patient. Creating, focusing, and steering such an electron beam would requires [sic] powerful magnets and very significant amounts of electrical power, yet the specification states that such sources could be intra-oral and wireless.” Op. Br. at 6 ( [REDACTED] ). Dr. Kia stated similarly that such systems would be complicated, but the test for enablement is not premised on practicality. *Id.* Rather, Planmeca must produce clear and convincing evidence that undue experimentation is required, but Dr. Pelc did not offer any testimony in this regard, nor is there any evidence in the record to resolve the *Wands* factors. *See Martek Biosciences Corp.*, 579 F.3d at 1378 (citation omitted).

Planmeca’s arguments regarding the “3D model” term are even more puzzling. For instance, Planmeca argues that the ’301 Patent lacks written description for the 3D model (Op. Br. at 6-7), but the ’301 Patent does not claim 3D models (*see* Planmeca Op. Br., Ex. A at 5:26-8:26), only the ’374 Patent expressly claims 3D models (*see* Planmeca Op. Br. Ex. C at 5:31-8:21). Additionally, Planmeca did not dispute that the citations to the ’374 Patent in Dr. Kia’s report provide written support for the 3D model. Instead, Planmeca argues that “[n]one of these portions [cited to by Kia] explain how to create a three-dimensional model from quantitative calculations of bone density.” (Op. Br. at 7.) Written description and enablement are separate requirements, which Planmeca’s arguments fail to appreciate. *Ariad Pharm., Inc.*, 598 F.3d at 1351. Moreover, the written description requirement is not violated simply because “the Patents-in-Suit as of

the claimed priority date did not *use* the term 3D or three-dimensional” as Planmeca argues. Op. Br. at 7 (emphasis added), *see Atmel Corp. v. Information Storage Devices, Inc.*, 198 F. 3d 1374, 1385 (Fed. Cir. 1999) (“claims may use language that those skilled in the art understand without the need for explicit, detailed definitions in the written description.”) (citation omitted). Rather, the key inquiry is possession of the claimed invention, which Planmeca did not address and which Dr. Kia’s testimony refuted. Ex. E at 50 (194:6-195:14 (discussing the inherent requirement of 3D in the tomographic model disclosure)).

Finally, Planmeca argues that the ’301 Patent is not entitled to its claimed priority date. Op. Br. at 7. But, Planmeca makes this argument without identifying any intervening art, or otherwise asserting that the ’301 Patent would be invalid if not entitled to its earliest claimed priority date. *Id.* There is therefore no need for the Court to address this issue, as it is not material to the issues in dispute.

Regarding enablement, Planmeca argues that “Dr. Kia admitted that there is no algorithm in the Patents-in-Suit for how to do the calculations necessary to get to a three-dimensional model based on densitometry.” But Planmeca again bases its argument on limitations that are not in the claims, attempting to relitigate claim constructions that were rejected by the Court over one year ago. *See* Section IV(A), *supra*. Additionally, Planmeca’s expert consistently failed to even mention whether undue experimentation was required, let alone discuss the facts to support this conclusion. Ex. A at 205-206 (¶504). Finally, Dr. Kia offered testimony that 3D models are enabled, which precludes summary judgement on this issue. Ex. A at 30 (¶ 93) (citing 374 Patent, at 2:51-3:4; 4:37-4:60 and FIG. 2).

**VI. Conclusion**

In view of the forgoing, Planmeca has not met its burden to show that there is no genuine issue of material fact regarding the requirements of 35 U.S.C. § 112, ¶ 1 for any of the Asserted Claims. Indeed, the parties' experts do not agree on any of the material issues of fact relevant to the § 112, ¶ 1 inquiries, as discussed above, precluding disposition of this case on summary judgement. Finally, Planmeca has not shown that it can apply the tests under 35 U.S.C. § 112 correctly, let alone that it is entitled to a directed verdict. For these reasons, Planmeca's motion for summary judgement must be denied on all grounds.

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**CERTIFICATE OF SERVICE**

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