Trials@uspto.gov
571-272-7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALTAIRE PHARMACEUTICALS, INC.,
Petitioner,

v.

PARAGON BIOTECK, INC.,
Patent Owner.

Case PGR2015-00011
Patent 8,859,623 B1

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Institution of Post-Grant Review
37 C.F.R. § 42.208

INTRODUCTION

Altaire Pharmaceuticals, Inc. ("Petitioner") filed a Petition for a post-grant review of claims 1–13 of U.S. Patent No. 8,859,623 B1 ("the '623 patent," Ex. 1001). Paper 1 ("Pet."). Paragon Bioteck, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Thereafter, at our request (Paper 8), Petitioner filed a Reply, addressing the issue of whether the Petition properly identifies all real parties in interest (Paper 11). We have jurisdiction under 35 U.S.C. § 324, which provides that post-grant review shall not be instituted unless it is determined that "the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the challenged claims in the petition is unpatentable." 35 U.S.C. § 324(a).

For the reasons provided below, we determine that Petitioner has demonstrated that it is more likely than not that at least one claim of the '623 patent is unpatentable. Because Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 324(a), we institute a post-grant review of claims 1–13 of the '623 patent.

Related Proceedings

Patent Owner identifies two district-court cases involving the parties. Paper 5, 1. Those cases, however, appear to involve issues unrelated to the '623 patent. Prelim. Resp. 6 n.7.

The '623 Patent

The '623 patent "is directed to methods and compositions of stabilizing phenylephrine formations." Ex. 1001, Abstract. "Phenylephrine is a selective α1-adrenergic receptor agonist used primarily as a decongestant, as an agent to dilate the pupil, and to increase blood pressure." *Id.* at 1:6–8. Specifically, the '623 patent provides "a composition comprising at least 95% R-phenylephrine hydrochloride and an aqueous buffer, wherein the composition substantially maintains an initial chiral purity of R-phenylephrine hydrochloride for at least 6 months stored between –10 to 10 degree Celsius." *Id.* at 1:16–21. It also discloses "methods of dilating the pupil comprising administering a composition comprising R-phenylephrine hydrochloride topically to a mammal, wherein the composition substantially maintains the initial chiral purity of R-phenylephrine hydrochloride for at least 6 months." *Id.* at 1:38–42.

At the time of the '623 patent invention, it was known that R-phenylephrine, but not S-phenylephrine, was useful to dilate the pupil. *Id.* at 6:21–30. Thus, "it is important that an eye drop containing Phenylephrine Hydrochloride used for dilation of the pupil contains predominantly the R-isomer in order to maintain maximum efficacy of the ophthalmic solution." *Id.* at 6:30–33.

According to the '623 patent, generally, commercially available phenylephrine hydrochloride ophthalmic solutions were stored at 20 to 25 degree Celsius, with the container tightly closed. *Id.* at 2:60–65. A solution under such condition, however, often turns brown over time and cannot be

used. *Id.* at 2:66–3:3. The '623 patent states that it "provides the improvement to overcome such instability problem." *Id.* at 3:4–5.

Illustrative Claim

Claims 1 is the sole independent claim. It reads:

> 1. A method of using an ophthalmic composition for pupil dilation, the composition comprising R-phenylephrine hydrochloride having an initial chiral purity of at least 95% and an aqueous buffer, wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months, the method comprising:
>
> administering the composition into an eye of an individual in need thereof, wherein the composition is stored between –10 to 10 degree Celsius prior to administration, and wherein the composition comprises R-phenylephrine hydrochloride having a chiral purity of at least 95% when administered after storage.

Asserted Ground of Unpatentability

Petitioner asserts the following grounds of unpatentability:

1. claims 1–13 as anticipated by, or in the alternative, rendered obvious over, Altaire's Product ("the Altaire's Product ground");

2. claims 1–13 as anticipated by, or in the alternative, rendered obvious over, Altaire's Package Insert,[1] "or alternatively, in view of common knowledge in the art or, alternatively or in addition, in view of U.S.

[1] Sterile Phenylephrine Hydrochloride Ophthalmic Solution, USP (Revised August 2010) (Ex. 1018).

Patent No. 3,966,749[2] and in further view of Syn-Tech's Commercially Available product ("the Altaire's Package Insert ground");

3. claims 1–13 as "obvious in view of Applicants' Admitted Prior Art ('AAPA'), Altaire's Commercial Product, and/or the common knowledge in the art or, alternatively or in addition, in view of U.S. Patent No. 3,966,749" ("the AAPA ground"); and

4. claims 1–13 as unpatentable "under 35 U.S.C. § 112(b) for failing to particularly point out and distinctly claim the subject matter which the joint inventors regard as the invention" ("the indefiniteness ground").

In support of its patentability challenge, Petitioner relies on the Declaration of Assad Sawaya. Ex. 1003.

ANALYSIS

Eligibility for Post-Grant Review

The '623 patent issued on October 14, 2014, from an application filed on November 14, 2013. Ex. 1001, (22). It does not claim the benefit of any earlier filing date. Because it issued from an application that contains a claim with an effective filing date after March 16, 2013, the '623 patent is available for post-grant review. *See* Leahy-Smith America Invents Act (Pub. L. No. 112-29, 125 Stat. 284 (2011), §§ 3(n)(1), 6(f)(2)(A).

The Petition was filed on May 11, 2015 (Pet. 69), within 9 months of the grant of the '623 patent. *See* 35 U.S.C. § 321(c). Petitioner further

[2] U.S. Patent No. 3,966,749, issued on June 29, 1976 (Ex. 1011).

certifies that it has standing to seek a post-grant review of the '623 patent. Pet. 2.

Real Party in Interest

Patent Owner requests that we dismiss the Petition because Petitioner should have identified Sawaya Aquebogue, LLC ("Saw Aque") as a real party in interest. Prelim. Resp. 2. Based on the current record, we are not persuaded.

A petitioner for a post-grant review must identify all real parties in interest. 35 U.S.C. § 322(a)(2); *see also* 37 C.F.R. § 42.8(b)(1). The real party in interest may include not only the named petitioner, but also "the party or parties at whose behest the petition has been filed." Office Patent Trial Practice Guide ("Trial Practice Guide"), 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012). Whether a non-party is a real party in interest is a highly fact-dependent question. *Id.*

Patent Owner argues that Saw Aque and Petitioner "are related companies under the common control, and are even run by the same individual – Assad Sawaya." *Id.* at 3. According to Patent Owner, Mr. Sawaya serves as both the President of Petitioner and the General Manager of Saw Aque. *Id.* (citing Ex. 2001 ¶ 3). In addition, the two companies share the same address, and Petitioner's General Counsel accepts service of legal documents for both companies at this same address. *Id.* at 3–4 (citing Exs. 2002, 2003, 2005). Patent Owner refers to an Air State Facility permit issued by the New York State Department of Environmental

Conservation. *Id.* at 4 (citing Ex. 2005). Although the permit was issued to Saw Aque, the facility bore Petitioner's name. *Id.* at 4 (citing Ex. 2005, 1).

Patent Owner also refers to a 2011 agreement between itself and Petitioner, which allegedly involves the "manufacturing, marketing, and distribution of a selection of products and subject matter of the '623 patent." *Id.*; Ex. 2001, Ex. A. Saw Aque is not a party to the agreement. Ex. 2001 ¶ 21. Pursuant to that agreement, however, Patent Owner "agreed to provide certain consideration to Saw Aque." *Id.*, Ex. A. All the evidence, Patent Owner contends, shows that Saw Aque "has a direct interest in this proceeding and has the motivation and ability to control this proceeding." Prelim. Resp. 6.

Citing the testimony from Mr. Sawaya, Petitioner asserts that "Petitioner and Saw Aque are separate and distinct entities that have no ownership interest in one another." Reply 4 (citing Ex. 1022 ¶ 6).[3] According to Mr. Sawaya, the two companies "do not have a parent/subsidiary relationship," and are not under common control. Ex. 1022 ¶ 6. Petitioner also emphasizes that the two companies are in different fields of businesses—while Petitioner "is in the business of pharmaceutical research, development, manufacturing, supply and

[3] We recognize that we rely on Mr. Sawaya's testimony regarding real party in interest while Patent Owner has not had an opportunity to cross-examine him on this issue. Upon institution, Patent Owner, should it wishes to pursue the issue, can cross-examine Mr. Sawaya through routine discovery. *See* 35 U.S.C. § 326(a)(5); 37 C.F.R. § 42.51.

distribution," Saw Aque is a holding company that holds, among others, real properties. Reply 5 (citing Ex. 1022 ¶¶ 4, 8). According to Petitioner, the two companies "share the same address merely because Saw Aque owns property that it leases to Petitioner at arm's length rates." *Id.* (citing Ex. 1022 ¶ 13).

Mr. Sawaya testifies that "Saw Aque does not have an ownership interest in any entity that could infringe the '623 patent," and "does not have the capabilities to manufacture or sell products that allegedly could be covered by the '623 patent." Ex. 1022 ¶ 9. As a result, Petitioner contends, Saw Aque "has no interest in challenging the claims of the '623 patent." Reply 5.

To determine whether Saw Aque is a real party in interest to this post-grant review, we analyze whether Saw Aque "exercised or could have exercised control" over Petitioner's participation in this proceeding. Trial Practice Guide, 77 Fed. Reg. at 48,759. In this inquiry, we are persuaded by Mr. Sawaya's testimony that Saw Aque, a company unrelated to Petitioner and in a line of business different from Petitioner's, "did not direct, control, or fund the preparation or filing of the Petition." *See* Prelim. Resp. 8 (citing Ex. 1022 ¶ 12). Therefore, based on the current record, we determine that Petitioner has complied with the statutory requirement to identify the correct real party in interest.

Claim Construction

In a post-grant review, we interpret a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.200(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015) (concluding that "Congress implicitly adopted the broadest reasonable interpretation standard in enacting the AIA"). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner proposes constructions for the following terms: (1) "chiral purity" and "initial chiral purity;" (2) "wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months;" (3) "administering the composition into an eye of an individual in need thereof, wherein the composition is stored between -10 to 10 degree Celsius prior to administration;" and (4) "allowed to be." Pet. 31–33. Patent Owner challenges the first two constructions. Prelim. Resp. 21–22.

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). For purposes of this Decision, we determine that no terms require express construction.

The Altaire's Product Ground

Petitioner argues that claims 1–13 of the '623 patent are unpatentable as obvious over Altaire's Product.[4] Pet. 33–45.

Petitioner relies on two lots of Altaire's products: Lot # 11578 and Lot # 11581. Pet. 34. According to Mr. Sawaya, Lot # 11578, a 2.5% phenylephrine hydrochloride ophthalmic solution, was manufactured in December 2011, and sold and distributed to an Altaire customer in October 2012. Ex. 1003 ¶¶ 4, 36; Ex. 1007. Lot # 11581, a 10% phenylephrine hydrochloride ophthalmic solution, was manufactured in January 2012, and sold and distributed to another Altaire customer in October 2012. Ex. 1003 ¶¶ 5, 6, 36; Ex. 1009. In other words, these products were "in public use, on sale, or otherwise available to the public" before November 14, 2013, the effective filing date of the challenged claims. *See* 35 U.S.C. § 102(a)(1). Therefore, they qualify as prior art.

Relying on the package insert, Petitioner points out that Altaire's Product contains R-phenylephrine hydrochloride[5] and an aqueous buffer, as claim 1 requires. Pet. 38 (citing Ex. 1018, 1). The package insert directs the user to place one drop of the solution in each eye for pupil dilation, also as

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[4] Petitioner asserts two different challenges of claims 1–13 under this single ground: anticipation, "or, in the alternative," obviousness. Pet. 33. We exercise our discretion and do not address the anticipation challenge. *See* 37 C.F.R. § 42.108.

[5] Petitioner asserts that "(-) m-Hydroxy-α-[(methylamino)methyl] benzyl alcohol hydrochloride is the same as R-phenylephrine hydrochloride." Pet. 48.

claim 1 requires. *Id.* at 37 (citing Ex. 1018, 1), 39 (citing Ex. 1018, 2). Furthermore, the package insert instructs that the Altaire's Product should be stored at 2–8 degree Celsius, within the temperature range recited in claim 1. *Id.* at 40 (citing Ex. 1018, 2).

Petitioner refers to Exhibits 1012, 1016, and 1019 for teaching the chiral-purity limitations of claim 1. *Id.* at 35–39. According to Mr. Sawaya, Lot # 11578 in Exhibit 1012 and Lot # 11581 in Exhibit 1019 were tested after cold storage for over 13 months and over 12 months, respectively. Ex. 1003 ¶¶ 37, 38. In Exhibit 1012, the optical rotation data showed the chiral purity of Lot # 11578 was 101.5% of the R-phenylephrine hydrochloride control. Pet. 35 (citing Ex. 1012, 8). In Exhibit 1019, the HPLC data showed that no S-form of phenylephrine was detected in Lot # 11581. *Id.* at 37, 39; Ex. 1019. Thus, Petitioner argues, Altaire's Product meets the limitation of claim 1, requiring "the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months." Pet. 39.

Mr. Sawaya further states that both Lot # 11578 and Lot # 11581 in Exhibit 1016 were tested after room-temperature storage for 37 months. Ex. 1003 ¶ 24; Ex. 1016. In both cases, no S-form of phenylephrine was detected using the HPLC method. Ex. 1003 ¶ 25; Ex. 1016. Because the chiral purity of R-phenylephrine hydrochloride remained undiminished after months of storage under either cold or room temperature, Petitioner contends that the initial chiral purity would have been essentially 100%, meeting the

initial-chiral-purity requirement of claim 1. Pet. 36, 39. We find Petitioner's argument persuasive based on the evidence of record so far.

Patent Owner challenges the methodology Petitioner used in determining chiral purity. Prelim. Resp. 12–18. First, according to Patent Owner, only those methods disclosed in the '623 patent, and not the USP standard HPLC protocol used by Petitioner, can reliably detect chiral impurity. *Id.* at 12–15. For support, Patent Owner points us to a declaration submitted during prosecution, by Mr. Patrick H. Witham, one of the inventors of the '623 patent, in which he states that "[n]on-chiral reverse phase column chromatographs (currently published USP HPLC method) show no or little chemical degradation of R-Phenylephrine hydrochloride in both formulations (i) and (ii)." *Id.* at 14 (citing Ex. 1002, 110). The significance of this statement, however, is not immediately clear to us. Read in context, the sentence appears to indicate neither storing a commercially available R-Phenylephrine hydrochloride at room temperature for six months (as in (i)), nor storing an R-Phenylephrine hydrochloride of the '623 patent at 2–8 degree Celsius (as in (ii)), led to detectable degradation. Ex. 1002, 109–10. We are not persuaded, at this stage, that Mr. Witham's statement serves to discredit the USP standard HPLC method utilized by Petitioner as a reliable method to detect chiral impurity.

Patent Owner also presents Exhibit 2014, purportedly "a study designed specifically to address whether the currently published USP method could reliably detect S-phenylephrine." Prelim. Resp. 14. Exhibit 2014 appears to be pages from a laboratory notebook with handwritten

information and certain test results. At this stage of the proceeding, with only attorney argument and no other explanation from Patent Owner, we find Petitioner's evidence sufficient for institution.

Second, Patent Owner contends that the optical rotation method used by Petitioner in Exhibit 1012 provides not quantitative, but rather relative, measurements. *Id.* at 16–17. Patent Owner points out that Petitioner's study relied on phenylephrine hydrochloride obtained from Sigma Aldrich as a control. *Id.* at 17 (citing Ex. 1012, 3). As a result, Patent Owner asserts, "[k]nowing the chiral purity of the Sigma control is critical to drawing any conclusions from the study regarding the absolute chiral purity of Lot # 11578." *Id.* According to Patent Owner, the data showing a chiral purity of 101.5% for the tested R-phenylephrine hydrochloride demonstrates the impurity of the control. *Id.* at 18.

We understand Exhibit 1012 shows data generated by Petitioner on behalf of Patent Owner, which was submitted to the FDA. *See* Pet. 9–11 (citing Ex. 1003 ¶¶ 9–10). Petitioner asserts that the study was performed during Patent Owner's New Drug Application, and in response to the FDA's request for "adding a chiral purity test to the drug product specification." *Id.* at 9–10. We recognize that Patent Owner has raised legitimate concerns about the purity of the Sigma control used, and how that may affect the chiral purity data relied upon by Petitioner. At this stage of the proceeding, however, there is an insufficient basis to conclude that such data are unreliable. Thus, based on the current record, even though Patent Owner's

argument here may be reasonable, we find Petitioner's evidence sufficient to go forward with trial.

Patent Owner argues that Petitioner's witness, Mr. Sawaya, is a fact witness, and not an expert. Prelim. Resp. 18–20. We agree. Mr. Sawaya states that he makes the Declaration "based upon [his] personal knowledge of the facts stated [t]herein." Ex. 1003 ¶ 1. In his Declaration, he does not explain his "knowledge, skill, experience, training, or education" that would provide the bases for his qualification as an expert. *See* Fed. R. Evid. 702. Because Mr. Sawaya is not shown to be an expert witness, we accord no weight to his opinion in that capacity.

That said, the lack of expert testimony is not, as Patent Owner argues, fatal to the Petition. *See* Prelim. Resp. 24. Where the technology is simple, where the references are easily understandable without the need for expert explanatory testimony, or where the factual inquiries underlying the obviousness determination are not in material dispute, expert testimony, though it might be helpful, may not be indispensable. *Allergan, Inc. v. Barr Labs., Inc.*, 501 F. App'x 965, 972 (Fed. Cir. 2013); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1239 (Fed. Cir. 2010) ("[T]he legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony.").

Patent Owner further challenges portions of Mr. Sawaya's Declaration, in which he testifies to the temperature and duration of the product storage. Pet. 26–27. According to Patent Owner, Mr. Sawaya fails to corroborate his statement about storing Altaire's Product at cold

temperature for over six months before testing in the studies. *Id.* at 19, 26–27. Patent Owner's position is not unreasonable. But, at this stage of the proceeding, Patent Owner's argument does not persuade us that we should decline to go forward with a trial. We emphasize that, upon institution, a post-grant review proceeding provides the opportunity for discovery of "evidence directly related to factual assertions advanced by either party in the proceeding." *See* 35 U.S.C. § 326(a)(5); 37 C.F.R. § 42.51. As a result, factual challenges, like this one, would be better resolved after the parties have had an opportunity to cross-examine each other's declarants.

In sum, based on the current record, we find that Petitioner has offered sufficient evidence to show that it is more likely than not that claim 1 is unpatentable as obvious over Altaire's Product. After considering Petitioner's arguments and evidence with respect to the remaining claims (Pet. 42–45), we determine that Petitioner has made a sufficient showing as to those claims, as well.

The Altaire's Package Insert Ground

> Petitioner asserts that claims 1–13 of the '623 patent are unpatentable under 35 U.S.C. § 102, or in the alternative, 35 U.S.C. § 103 as anticipated or rendered obvious in view of Altaire's Package Insert, or alternatively, in view of common knowledge in the art or, alternatively or in addition, in view of U.S. Patent No. 3,966,749 and in further view of Syn-Tech's Commercially Available product.

Pet. 45.

Patent Owner argues that this ground of unpatentability "is not presented with the requisite degree of clarity or particularity and could be interpreted as including no fewer than eight separate grounds." Prelim. Resp. 29. We agree with Patent Owner.

Under the statute, a petition for a post-grant review must identify "with particularity, each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim." 35 U.S.C. § 322(a)(3). In addition, a petition must include a "full statement of the reasons for the relief requested, including a detailed explanation of the significance of the evidence." 37 C.F.R. § 42.22(a)(2). The Petition fails to comply with the requirements specified in the statute and the rules. We decline to identify or analyze all possible permutations of prior art combinations that Petitioner may have sought to include in this ground. We, thus, exercise our discretion and do not institute trial on this ground. *See* 37 C.F.R. § 42.108.

The AAPA Ground

Petitioner contends that claims 1–13 of the '623 patent are unpatentable "under 35 U.S.C. § 103 as being obvious in view of Applicants' Admitted Prior Art ("AAPA"), Altaire's Package Insert, and/or the common knowledge in the art or, alternatively or in addition, in view of U.S. Patent No. 3,966,749." Pet. 57.

The AAPA ground also fails to comply with the requirements specified in 35 U.S.C. §322(a)(3) and 37 C.F.R. § 42.22(a)(2). First, though

presented as a single ground, with language "and/or" and "alternatively or in addition," the AAPA ground actually represents numerous different grounds. *Id.* Second, Petitioner asserts this unpatentability ground based on its analysis of the originally filed claim 1, a claim different from the challenged claim 1. *Id.* Because the Petition does not identify with sufficient particularity either the claim challenged, or the grounds on which the challenge is based, we, again, exercise our discretion and do not institute trial on this ground.

The Indefiniteness Ground

Petitioner argues that claim 1 fails to particularly out and distinctly claim the subject matter of the invention. Pet. 66–68. Petitioner asserts claim 1 does not require storage at cold temperature for any minimum duration before use, even though the preamble refers to chiral purity after six months. *Id.* at 32–33, 66–67. According to Petitioner, however, during prosecution, both the applicants and the examiner relied on cold storage for six months to distinguish claim 1 from the prior art. *Id.* at 67 (citing Ex. 1002, 110–13, 167). Thus, Petitioner argues, "claim 1 is unclear as to what it encompasses," and thus, is indefinite. *Id.* We are not persuaded.

To satisfy the requirement under 35 U.S.C. 112(b), "claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms." *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014). Petitioner is correct that claim 1 does not require cold storage for six months before administering the composition to a patient. Indeed, the only step of claim 1

recites that the composition is "stored between –10 to 10 degree Celsius prior to administration." Ex. 1001, 12:45–48. It does not specify how long the storage must be at that cold temperature.

Patent Owner contends that claim 1 requires cold storage for six months, "such that the chiral purity after said storage is at least 95% of the initial chiral purity." Prelim. Resp. 37. Patent Owner, however, relies on not the step of the claim, but the preamble, which explicitly recites the chiral purity "is at least 95% of the initial chiral purity *after 6 months*." Ex. 1001, 12:42–44 (emphasis added).

This language of the preamble is also consistent with the prosecution history, which both parties emphasize. *See* Pet. 67 (citing Ex. 1002, 110–13, 167); Prelim. Resp. 37–38 (citing Ex. 1002, 110, 113, 167). During prosecution, the applicants argued, and the examiner agreed, that claim 1 was patentable because the chiral purity remained at least 95% of the initial chiral purity after cold storage for six months. Ex. 1002, 110, 113, 167.

Maintaining at least 95% of the initial chiral purity after six months, however, simply describes a property of the composition to be administered. The characteristic, defined in the preamble, does not add a limitation on the duration of storage at cold temperatures recited in the "administering" step. This is especially so because the preamble requires that, after the six-month storage, the chiral purity is only at least 90.25% (i.e., "at least 95% of the initial chiral purity," which is already "at least 95%"). *See id.* at 12:41–44. In contrast, the step of claim 1 requires "a chiral purity of at least 95% when administered after storage." *Id.* at 12:49–50.

Based on the current record, we determine that claim 1 is directed to a method of administering a composition—wherein the composition comprises R-phenylephrine hydrochloride that exhibits the property of having at least 95% of the initial chiral purity after six months—as long as the composition is stored in cold temperature before the administration. Although perhaps not articulately stated, claim 1 is cast in clear terms. *See Packard*, 751 F.3d at 1313. We accordingly deny Petitioner's indefiniteness ground.

CONCLUSION

For the foregoing reasons, the information presented in the Petition and accompanying evidence establishes that it is more likely than not that claims 1–13 of the '623 patent are unpatentable as obvious over Altaire's Product.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of claims 1–13 or the construction of any claim term.

ORDER

Accordingly, it is

ORDERED that pursuant to 35 U.S.C. § 324(a), a post-grant review is hereby instituted to determine whether claims 1–13 of the '623 patent are unpatentable as obvious over Altaire's Product;

FURTHER ORDERED that no other grounds raised in the Petition are

instituted;

FURTHER ORDERED that pursuant to 35 U.S.C. § 324(d) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision.

PETITIONER:

Dipu A. Doshi
DICKSTEIN SHAPIRO LLP
doshid@dicksteinshapiro.com

PATENT OWNER:

Michael Rosato
Steven W. Parmelee
WILSON SONSINI GOODRICH & ROSATI
mrosato@wsgr.com
sparmelee@wsgr.com