Trials@uspto.gov
571-272-7822

Paper 27
Date: March 10, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIFESCAN GLOBAL CORPORATION,
Petitioner,

v.

IKEDA FOOD RESEARCH, LTD. and PHC CORPORATION,
Patent Owner.

PGR2019-00032
Patent 9,976,125 B2

Before ERICA A. FRANKLIN, ROBERT A. POLLOCK, and DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

PRELIMINARY GUIDANCE
PATENT OWNER'S MOTION TO AMEND

I. INTRODUCTION

On August 15, 2019, we instituted trial as to claim 8 of U.S. Patent No. 9,976,125 B2 ("'125 patent").[1] Paper 11 ("Decision" or "Dec."). After institution, Patent Owner filed a Motion to Amend. Paper 18 ("Motion" or "Mot."). Patent Owner moves to cancel claim 8 on a non-contingent basis and to substitute proposed claim 11. *Id.* at 1. Patent Owner requests that we provide Preliminary Guidance in accordance with the Board's pilot program concerning motion to amend practice and procedures. *Id.* at 2; *see also* Notice Regarding a New Pilot Program Concerning Motion to Amend Practice and Procedures in Trial Proceedings Under the America Invents Act Before the Patent Trial and Appeal Board, 84 Fed. Reg. 9,497 (Mar. 15, 2019) (providing a patent owner with the option to receive preliminary guidance from the Board on its motion to amend) ("Notice"). Petitioner filed an Opposition to the Motion. Paper 26 ("Opposition" or "Opp.").

We have considered Patent Owner's Motion and Petitioner's Opposition to the Motion. In this Preliminary Guidance, we provide information indicating the panel's initial preliminary, non-binding views on whether Patent Owner has shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend in a post-grant review, and whether Petitioner (or the record) establishes a reasonable likelihood that the substitute claims are unpatentable. *See* 35 U.S.C. § 324(a) (2018); 37 C.F.R. § 42.221 (2018);

[1] Petitioner challenged claims 1–10 in the Petition. Prior to our decision, Patent Owner filed a statutory disclaimer under 35 U.S.C. § 253(a) disclaiming claims 1–7, 9, and 10 of the '125 patent. Accordingly, we declined to institute post-grant review with respect to disclaimed claims 1–7, 9, and 10. *See* Dec. 6–7.

Lectrosonics, Inc. v Zaxcom, Inc., IPR2018-01129, Paper 15 (PTAB February 25, 2019) (precedential).

For purposes of this Preliminary Guidance, we focus on the proposed substitute claim. *See* Notice, 84 Fed. Reg. at 9,497. Thus, we focus on the limitations added in Patent Owner's Motion to Amend, and do not address the patentability of the originally challenged claims. *Id.* Moreover, in formulating our preliminary views on the Motion and Opposition, we have not considered the parties' other substantive papers on the underlying merits of Petitioner's challenges. We emphasize that the views expressed herein are subject to change upon consideration of the complete record, including any revision to the Motion filed by Patent Owner. Thus, this Preliminary Guidance will not be binding on the Board, for example, when it renders a final written decision. *See id.* at 9,500.

II. PRELIMINARY GUIDANCE

A. Statutory and Regulatory Requirements

For the reasons discussed below, at this stage of the proceeding, and based on the current record, it appears that Patent Owner has not shown a reasonable likelihood that it has satisfied the statutory and regulatory requirements associated with filing a motion to amend.

1. Reasonable Number of Substitute Claims

Does Patent Owner propose a reasonable number of substitute claims? (35 U.S.C. § 326(d)(1)(B))
Yes. Patent Owner proposes replacing the single original claim 8 with a single amended claim (proposed claim 11). Mot. 1–3.

2. Respond to Ground of Unpatentability

Does the Motion respond to a ground of unpatentability involved in the trial? (37 C.F.R. § 42.221(a)(2)(i))
Yes. Patent Owner responds to the grounds of unpatentability at Motion 3–4. Petitioner argues that in "new substitute claim 11, P[atent] O[wner] proposes nothing more than dependent claim 8 rewritten in independent form with two proposed additional limitations, neither of which . . . address the reasons why the Board instituted this proceeding." Opp. 1. We have reviewed Petitioner's argument and find it unpersuasive. In the Petition, Petitioner argued that claim 8 failed to comply with the enablement requirement because the Specification identified a six amino acid sequence — AGVPWV — as critical, but claim 8 does not require this sequence to be present. Pet. 37–38. Patent Owner explains that "[c]laim 11 includes all of the limitations of cancelled claim 8 and also includes the six amino acid sequence AGVPWV." Mot. 3. Patent Owner's amendment thus responds to a ground of unpatentability involved in the trial.

3. Scope of Amended Claims

Does the amendment seek to enlarge the scope of the claims? (35 U.S.C. § 326(d)(3); 37 C.F.R. § 42.221(a)(2)(ii))
No. Patent Owner's amendment adds language to original claim 8 requiring the claimed polypeptide contain the amino acid sequence AGVPWV.[2] Mot. at App. Patent Owner's amendment also reduces the required enzymatic activity of the FAD-conjugated glucose dehydrogenase for maltose from 10% or less to 5% or less. *Id.* Patent Owner argues that because it has only added limitations, it has not enlarged the scope of the claims. *Id.* at 3. Petitioner argues that Patent Owner's amendment expands the scope of the claim because the added language requiring the six amino acid sequence

[2] Petitioner notes that Patent Owner does not refer to the claimed sequence by SEQ ID NO as required by 37 C.F.R. § 1.821. Opp. at 2, 6. We agree with Petitioner that the claim should comply with 37 C.F.R. § 1.821. Patent Owner may wish to address this issue in a revised motion to amend.

AGVPWV does not require the AGVPWV sequence to be encompassed within the originally claimed sequence. Opp. 1, 4–5. Put another way, Petitioner argues that the new claim encompasses a polypeptide having two amino acid sequences, one of indefinite length containing the sequence AGVPWV, and another separate sequence having 90% homology to amino acid sequence (a).

On the current record, we tend to agree with Petitioner that the substitute claim encompasses a polypeptide having two separate amino acid sequences, one containing the sequence AGVPWV and a second, separate sequence having 90% homology to amino acid sequence (a). We recognize that the Specification does not disclose the use of the sequence AGVPWV in a sequence separate from amino acid sequence (a) and, thus, it may not have been Patent Owner's intent for the substitute claim to encompass two separate sequences. However, the language of the substitute claim, on its face, is not limited to a single sequence having both AGVPWV and 90% homology to amino acid sequence (a).

While we tend to agree with Petitioner on the scope of substitute claim 11, we tend not to agree that Patent Owner's proposed amendment enlarges the scope beyond what was recited in original claim 8. In this regard, we note that original claim 8 uses the transitional term "comprises," and thus original claim 8 also encompasses a polypeptide having a second amino acid sequence separate from amino acid sequence (a). We emphasize that our construction is preliminary, and invite the parties to address this issue, as well as issues that depend on this preliminary construction (discussed below), in further briefing and/or in a revised motion to amend.

4. New Matter

Does the amendment seek to add new subject matter? (35 U.S.C. § 326(d)(3); 37 C.F.R. § 42.221(a)(2)(ii))
Yes. Petitioner argues that Patent Owner's amendment "allows for the six amino acid sequence [AGVPWV] to extend outside SEQ ID NO:1,[3] thereby enlarging the amino acid sequence to at least 599, which is . . .

[3] "SEQ ID NO:1" is the same sequence as the claimed "amino acid sequence (a)."

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.