UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/320,431	06/30/2014	Derek Lee Lindstrom	20130226-02	6113

22878 7590 02/21/2019

Agilent Technologies, Inc.
Global IP Operations
5301 Stevens Creek Blvd
Santa Clara, CA 95051

EXAMINER
SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
02/21/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com
Agilentdocketing@cpaglobal.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte DEREK LEE LINDSTROM

Appeal 2018-000914
Application 14/320,431
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and ULRIKE W. JENKS, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1,2] under 35 U.S.C. § 134 involving claims to methods of combining nucleic acid fragments. The Examiner rejected the claims as failing to comply with the written description requirement, as lacking utility, and as failing to comply with the enablement requirement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

---

[1] Appellant identifies the Real Party in Interest as Agilent Technologies, Inc. (*see* App. Br. 2).

[2] We have considered and herein refer to the Specification of June 30, 2014 ("Spec."); Final Office Action of Nov. 21, 2016 ("Final Act."); Appeal Brief of Apr. 6, 2017 ("App. Br."); Examiner's Answer of Sept. 6, 2017 ("Ans."); and Reply Brief of Nov. 6, 2017 ("Reply Br.").

Statement of the Case

Background

"Many methods have been developed to ligate double stranded DNA fragments into larger molecules. Assembly methods that allow the user to dictate the order and orientation of the assembled fragments . . . rely on the specific hybridization of short single-stranded overhangs" (Spec. 1).

The Claims

Claims 1 and 3–20 are on appeal. Independent claim 1 is representative and reads as follows:

> 1. A method of combining nucleic acid fragments, comprising:
>
> (a) providing two double-stranded DNA molecules having a common sequence, wherein the common sequence is at the end of each molecule;
>
> (b) nicking one strand in the common sequence of both molecules at a respective nicked site with one or more Cas9 nicking enzymes;
>
> (c) moderately denaturing both molecules to remove a single-stranded fragment from the nicked site to said end of each molecule, wherein the single-stranded fragment includes 4-30 bases of the common sequence, resulting in an overhanging sequence in each molecule, and the overhanging sequences in both molecules are complementary to each other; and
>
> (d) allowing the overhanging sequences of both molecules to anneal to each other, and ligating the molecules.

The Issues

A. The Examiner rejected claims 1 and 3–20 under 35 U.S.C. § 112(a), written description (Final Act. 3–8).

B. The Examiner rejected claims 1 and 3–20 under 35 U.S.C. § 101 and 112(a) enablement as lacking utility (Final Act. 12–16).

A. 35 U.S.C. § 112(a), written description

The Examiner rejected the claims as lacking a written description of the claimed genus of double-stranded DNAs. The Examiner finds:

> While an applicant is not required to teach each and every possible embodiment encompassed by the claims, the specification still must provide a full, clear, and concise description of the genus encompassed by the claims so that one would be readily able to determine if a species fell within the claims' scope, and to also reasonably suggest that applicant had possession of the invention at the time of filing.

(Final Act. 6).

We find that the Examiner erred. As Appellants correctly point out, the claims are drawn to "a platform technology for combining nucleic acids, which technology is not dependent on particular sequence requirement" (App. Br. 4). *See Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006). "[T]he determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue." *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

There can be no reasonable dispute that the method would function with any DNA sequence containing a protospacer adjacent motif (PAM), whether one of the millions described in the publicly available literature or one newly sequenced today (*see* Spec. 9). Appellants are not claiming that the genus of DNA molecules are new, but rather the application of the method to ordinary double-stranded DNA. The genus of DNA molecules are thus fully described since it is the double-stranded structure which is necessary for the method to work. Thus, we can discern no reason why a

description of the DNA molecules is lacking. Similarly, the Specification teaches that any Cas9 nickase enzyme among those described and well-known would function (*see* Spec. 10).

B. 35 U.S.C. § 101 and 112(a), enablement

The Examiner finds:

> the claimed method can result in the production of a nucleic acid having "any sequence." The fact that the end product can be virtually any nucleic acid is not considered to satisfy the specific utility requirement of MPEP 2107.01 II A. The case at hand is deemed to be analogous to scenario set forth in MPEP 2107.01 II B (D) in that method of making a material that itself has no specific, substantial, and credible utility is not considered to satisfy the substantial utility requirement.

(Final Act. 15–16).

We find the Examiner erred. As Appellants correctly point out the "present methods are, *inter alia*, useful research tools as well - as would be apparent to one skilled in the art, the present methods represent a step forward in genetic engineering, as they provide new techniques for combining two DNA molecules that have a common sequence" (App. Br. 7).

"[T]o satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

There can be no reasonable dispute that a general method that joins two nucleic acids, whether by restriction enzyme cleavage followed by ligation with DNA ligase, fusion polymerase chain reaction, or the instantly claimed Cas9 process, has specific, substantial, and credible utilities

immediately recognizable by the ordinary molecular biologist for use in cloning and other procedures.

Therefore, because there is substantial, specific, and credible utility in performing the generic method of ligation using a Cas9 nicking enzyme, we reverse the Examiner's erroneous utility and enablement rejections.

SUMMARY

In summary, we reverse the rejection of claims 1 and 3–20 under 35 U.S.C. § 112(a), written description.

We reverse the rejection claims 1 and 3–20 under 35 U.S.C. § 101 and 112(a) enablement as lacking utility.

REVERSED