

PUBLIC VERSION

Trials@uspto.gov
571-272-7822

Paper No. 8
Entered: June 27, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

JENNEWEIN BIOTECHNOLOGIE GmbH
Petitioner,

v.

GLYCOSYN LLC,
Patent Owner.

Case PGR2019-00023
Patent 9,970,018 B2

Before ERICA A. FRANKLIN, JACQUELINE T. HARLOW, and
RICHARD J. SMITH, *Administrative Patent Judges*.

HARLOW, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324(a)

ORDER
Denying Patent Owner's Motion to Seal (Paper 7) without Prejudice
37 C.F.R. § 42.55

PUBLIC VERSION

PGR2019-00023
Patent 9,970,018 B2

I. INTRODUCTION

Petitioner, Jennewein Biotechnologie GmbH, filed a Petition requesting post-grant review of claims 1–28 of U.S. Patent No. 9,970,018 B2 (Ex. 1001, “the ’018 patent”) pursuant to 35 U.S.C. §§ 321–329. Paper 1 (“Pet.”). Patent Owner, Glycosyn LLC, filed a Preliminary Response. Paper 5 (“Prelim. Resp.”).¹ Patent Owner also filed a Motion to Seal Exhibit 2002, designated by Petitioner as confidential in a related proceeding before the International Trade Commission, as well as portions of the Preliminary Response referring to Ex. 2002. Paper 7.

We have authority, acting under the designation of the Director, to determine whether to institute post-grant review. 35 U.S.C. § 324; 37 C.F.R. § 42.4(a). Post-grant review may be instituted only if “the information presented in the petition . . . demonstrate[s] that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a). Upon consideration of the Petition and Preliminary Response, as well as all supporting evidence, we determine that the Petition fails to demonstrate that it is more likely than not that the ’018 patent is eligible for post-grant review. Accordingly, we deny institution of post-grant review. We also deny, without prejudice, Patent Owner’s Motion to Seal.

¹ Patent Owner filed unredacted (Paper 5) and redacted (Paper 6) versions of the Preliminary Response. Our citations are to Paper 5, the unredacted version.

PUBLIC VERSION

PGR2019-00023
Patent 9,970,018 B2

A. Related Matters

The '018 patent is the subject of an investigation before the U.S. International Trade Commission, captioned *Certain Human Milk Oligosaccharides and Methods of Producing the Same*, Inv. No. 337-1120 (USITC) (“the related ITC Investigation”). Pet. 3; Paper 3, 1. The parties additionally identify as a related matter *Glycosyn LLC v. Jennewein Biotechnologie GmbH*, Case 1:18-cv-10423 (D. Mass.), which is stayed in view of the aforementioned investigation, and concerns U.S. Patent No. 9,453,230 B2 (“the '230 patent”), to which the '018 patent claims priority. Pet. 3; Paper 3, 1.

B. The '018 Patent

The '018 patent is titled “Biosynthesis of Human Milk Oligosaccharides in Engineered Bacteria.” Ex. 1001, (54). As its title suggests, the '018 patent discloses methods for producing purified human milk oligosaccharides (“HMOs”), including, in particular, fucosylated oligosaccharides, that are typically found in human milk. *Id.* at 1:26–30.

The '018 patent explains that HMOs, although unimportant for infant nutrition, play a critical role in establishing a healthy microbiome, preventing disease, and developing immune function. Ex. 1001, 1:34–39. According to the patent, however, known methods for producing HMOs at scale were limited by “stereo-specificity issues, precursor availability, product impurities, and high overall cost.” *Id.* at 1:40–44.

To overcome these challenges, the '018 patent discloses a method for manipulating certain genes and pathways within *Escherichia coli* (“*E. coli*”)

PGR2019-00023
 Patent 9,970,018 B2

bacteria to produce purified fucosylated oligosaccharides. Ex. 1001, 2:28–31. In particular, the patent teaches genetically modifying *E. coli* bacteria to generate the “enhanced cellular pool of both lactose and GDP-fucose” required for biosynthesis of fucosylated HMOs. *Id.* at 16:27–29; *see also id.* at 16:29–18:60. Figure 3 of the ’018 patent, illustrating such an engineered bacterium is reproduced below.

FIG. 3 Metabolic engineering for 2'-FL production in *E. coli*

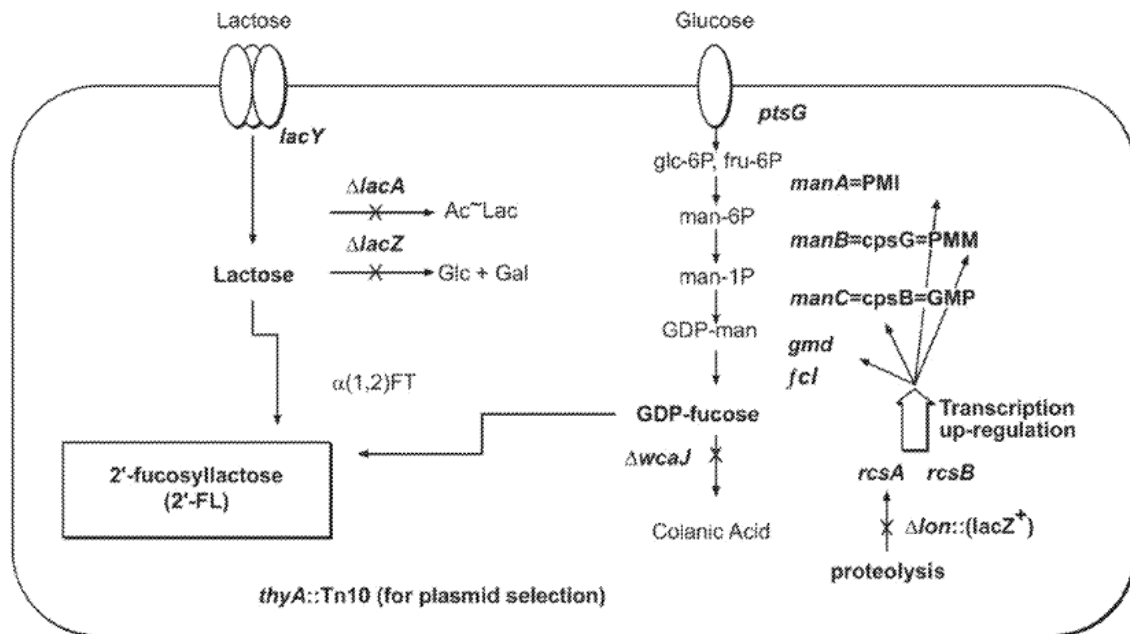


Figure 3 “is a schematic demonstrating metabolic pathways and the changes introduced into them to engineer 2'-fucosyllactose (2'-FL) synthesis in *Escherichia coli* (*E. coli*).” *Id.* at 12:20–30. As illustrated in Figure 3, the ’018 patent discloses genetically modifying the host bacterium to decrease β-galactosidase (“lacZ”) activity, thereby increasing the intracellular pool of lactose available for syntheses of 2'-FL. *Id.* at Fig. 3.

PUBLIC VERSION

PGR2019-00023
Patent 9,970,018 B2

C. Illustrative Claim

Claim 1, the sole independent claim of the '018 patent, reproduced below, is illustrative of the claimed subject matter.

1. A method for producing a fucosylated oligosaccharide in a bacterium, comprising

providing an isolated *E. coli* bacterium comprising,

(i) a deletion or functional inactivation of an endogenous β -galactosidase gene;

(ii) an exogenous functional β -galactosidase gene comprising a detectable level of β -galactosidase activity that is reduced compared to that of a wild-type *E. coli* bacterium, *wherein the level of β -galactosidase activity comprises between 0.05 and 200 units*;

(iii) an inactivating mutation in a colanic acid synthesis gene; and

(iv) an exogenous lactose-accepting fucosyltransferase gene;

culturing said bacterium in the presence of lactose; and

retrieving a fucosylated oligosaccharide from said bacterium or from a culture supernatant of said bacterium.

Ex. 1001, 111:41–57 (emphasis added).

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.