

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

IMPOSSIBLE FOODS INC.,

*Plaintiff,*

v.

MOTIF FOODWORKS, INC., and  
GINKGO BIOWORKS, INC.,

*Defendants.*

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Civil Action No. 22-311-WCB

**MEMORANDUM OPINION AND ORDER**

In this patent case, plaintiff Impossible Foods Inc. has moved to amend its infringement contentions against Motif Foodworks, Inc., and Ginkgo Bioworks, Inc (collectively “Defendants”). Defendants oppose the motion. For the reasons set forth in this opinion, Impossible’s motion is GRANTED.

**1. Background**

Impossible’s initial complaint asserted 162 claims across seven different patents against Motif. Ginkgo was later added as a defendant, after which I ordered that the claims of infringement of U.S. Patent Nos. 10,273,492 and 10,689,656 (collectively the “yeast patents”) be tried separately from claims of infringement of the other five patents in the case. Dkt. No. 161. I set a new schedule for the “yeast patents” case, in which the following case narrowing procedures apply:

By February 9, 2024, Impossible should reduce the number of asserted claims against Ginkgo and Motif in the Yeast Patent case to 14. By March 1, 2024, Ginkgo and Motif should reduce the number of asserted prior art references in the Yeast Patent case to 18. By April 5, 2024, Impossible should reduce the number of asserted claims against Ginkgo and Motif in the Yeast Patent case to 6. By May 17, 2024, Ginkgo and Motif should reduce the number of asserted prior art references in the Yeast Patent case to 10. Either party may move to deviate from the above procedures upon a showing of good cause, including but not limited to subsequent events such as IPR institution decisions or the court’s claim construction order.

*Id.* at 8.

Defendants served their initial Identification of Asserted Prior Art References in early March 2024. Dkt. No. 373 (Ginkgo notice of service); Dkt. No. 382 (Motif notice of service); *see also* Dkt. No. 527-1, Ex. 2 at 2 (Motif references); *id.*, Ex. 3 at 2 (Ginkgo references). Both lists include a paper by Krainer et al., which is attached as Exhibit 1 to this Order. The Krainer study sought to increase the availability of “cofactors” in the heme protein production process. Cofactors, in this context, are proteins other than the heme proteins themselves, that assist in the production of the heme proteins. To achieve that goal, Krainer engineered yeast cells to produce those proteins under a strong constitutive promoter,<sup>1</sup> and a methanol inducible promoter.<sup>2</sup> Ex. 1 at 2–3. All yeast strains in Krainer “were based on the *P. pastoris* wildtype strain CBS 7435.” *See* Ex. 1 at 6.

On March 22, 2024, the court issued an order construing various claim terms used in the yeast patents. Dkt. No. 414. One of the critical terms in that order was “a Mxr1 transcriptional activator sequence.” The parties disputed whether that phrase refers to the DNA or RNA encoding the Mxr1 protein, or to the DNA sequence to which Mxr1 binds when it is doing its job as a transcriptional activator. I agreed with Impossible that the term refers to the DNA sequence to which Mxr1 binds.

On April 19, 2024, Defendants served their Final Invalidity Contentions, which included arguments based on the CBS 7435 *P. pastoris* strain. Dkt. No. 486 (notice of service); Dkt. No.

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<sup>1</sup> A promoter is the portion of a gene that determines the degree to which the gene is expressed, i.e., how much protein the gene makes. A constitutive promoter is a promoter that is active all the time, regardless of environmental condition. A strong constitutive promoter is one with a high degree of expression.

<sup>2</sup> A methanol inducible promoter is one which regulates gene expression based on the presence of methanol.

527-1, Ex. 1 (contentions). Specifically, Defendants argued that claim 5 of the '492 patent would cover naturally existing CBS 7435 *P. pastoris* under the court's claim construction, rendering the claim invalid under 35 U.S.C. § 101.<sup>3</sup> See Dkt. No. 527-1, Ex. 1 at 47–49 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)). On May 17, 2024, Defendants reduced their asserted invalidity references from two lists of 18 references to a single list of 10 references. See Dkt. No. 527-1, Ex. 4 at 2. While the total number of references was reduced, the CBS 7435 *Pichia pastoris* strain was added as an asserted reference for the first time in the list of 10 references.

On May 6, 2024, Impossible moved to add claim 11 of the '492 patent to its infringement contentions. Defendants did not oppose that motion, and the court granted the motion. See Dkt. No. 498; Dkt. No. 507. Four days later, Impossible notified Defendants' counsel that it intended to seek leave to amend its infringement contentions by adding claim 5 and dropping claim 2 of the '492 patent. Claims 2 and 5 both depend from claim 1. Those claims recite:

1. A methylotrophic *Pichia* yeast cell comprising:

a nucleic acid molecule encoding a heme-containing protein operably linked to a promoter element from *P. pastoris* and a Mxr1 transcriptional activator sequence from *P. pastoris*; and

a nucleic acid molecule encoding at least one polypeptide involved in heme biosynthesis operably linked to a promoter element from *P. pastoris* and a Mxr1 transcriptional activator sequence from *P. pastoris*.

2. The yeast cell of claim 1, wherein the heme-containing protein is Leghemoglobin (LegH).

5. The yeast cell of claim 1, wherein the promoter element from *P. pastoris* is a constitutive promoter element from *P. pastoris* or a methanol-inducible promoter element from *P. pastoris*.

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<sup>3</sup> Impossible also represents that Defendants' contentions introduce a new argument based on the CBS 7435 strain and 35 U.S.C. § 102. Only excerpts of Defendants' Final Invalidity Contentions were attached to Impossible's motion, and those excerpts do not contain any argument relating to CBS 7435 and section 102.

Impossible filed its motion to amend on June 5, 2024, approximately seven weeks after receiving the Final Invalidity Contentions, and approximately three weeks after the CBS 7435 strain was formally identified as a prior art reference. Defendants oppose the substitution of claims.

## **2. Analysis**

The scheduling order in this case provides that a party may amend its contentions for good cause. *See* Dkt. No. 161 at 8; *see also* Fed. R. Civ. P. 16(b)(4) (“A schedule may be modified only for good cause and with the judge's consent.”). “In determining whether a party has demonstrated good cause to amend its contentions, the key factor that courts have considered is whether that party has shown diligence both in discovering that an amendment was necessary and in moving to amend after that discovery.” *Brit. Telecomms. PLC v. IAC/InterActiveCorp*, No. CV 18-366, 2020 WL 3047989, at \*2 (D. Del. June 8, 2020) (citing *O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366–67 (Fed. Cir. 2006) and *Bayer Cropscience AG v. Dow AgroSciences LLC*, No. CV 10-1045, 2012 WL 12904381, at \*2 (D. Del. Feb. 27, 2012)). Even if a party can establish good cause, however, “substantial or undue prejudice to the non-moving party is a sufficient ground for denial of leave to amend.” *See Cureton v. Nat’l Collegiate Athletic Ass’n*, 252 F.3d 267, 273 (3d Cir. 2001) (discussing amendments to a complaint).

Impossible’s core theory is that it has good cause to amend because it acted quickly upon learning that Defendants had raised new arguments in their final invalidity contentions and that defendants were asserting a new prior art reference, the CBS 7435 strain. Defendants in turn argue (1) that Impossible had all the necessary facts to assert claim 2 once it learned that some of Defendants’ products contain leghemoglobin, (2) that Impossible was not diligent because it waited to disclose its intention to assert a new claim until after Defendants agreed not to oppose a

separate amendment to the contentions, and (3) that the proposed amendment would be prejudicial to Defendants at this stage in the case.

Prior to Defendants submitting their Final Invalidity Contentions, Impossible had no way of anticipating that *P. pastoris* strain CBS 7435 would be used as a reference to argue the invalidity of claim 5 under section 101. The fact that the CBS 7435 strain is referenced in Krainer did not put Impossible on notice that the CBS 7435 strain might itself be used as a reference. Claim 1, from which claim 5 depends, recites “a nucleic acid molecule encoding a heme-containing protein.” ’492 patent at col. 77, ll. 50–51. Krainer, on the other hand, discusses a “*P. pastoris* strain recombinantly producing the heme protein HRP,” meaning that the naturally occurring CBS 7435 strain was genetically modified to produce the heme protein. Ex. 1 at 3. Impossible cannot have been expected to understand Krainer as disclosing a naturally occurring yeast strain meeting the requirements of claim 1 because the strain in Krainer was modified to express the claimed protein. A claim to a modified organism with “markedly different characteristics” is not invalid under section 101. *See generally Chakrabarty*, 447 U.S. at 310.

Krainer primarily relates to a different portion of claim 1, which addresses “polypeptide[s] involved in heme biosynthesis.” ’492 patent at col. 77, ll. 54–55. Those are the polypeptides that Krainer refers to as “cofactors.” The inclusion of Krainer in Defendants’ Initial Invalidity Contentions therefore did not place Impossible on notice of a potential section 101 argument based on *P. pastoris* strain CBS 7435 meeting all limitations of the claim.

After learning about Defendants’ new position on April 19, 2024, Impossible acted reasonably promptly to amend its contentions. It informed Defendants of its intentions on May 10, 2024, three weeks after receiving the invalidity contentions containing the new argument. Impossible formally moved to amend on June 5, 2024, approximately seven weeks after receiving

the final invalidity contentions. Whereas I previously held that Impossible was not diligent where it took four months to initiate testing of sample after the sample was produced and did not begin that process until after the deadline to amend had passed, *see* Dkt. No. 572 at 5, in this instance Impossible acted with reasonable promptness upon learning of the new argument. Impossible could not have made the change prior to the deadline to submit final infringement contentions because the deadline had already passed at the time Impossible learned of Defendants' new argument. For that reason, I find that Impossible was diligent and therefore has good cause to amend.

Defendants' arguments to the contrary are not persuasive. Although it is true that Impossible knew that some of Defendants' products produced soy leghemoglobin, and thus had information relevant to infringement, Impossible did not learn critical information relevant to invalidity until Defendants submitted their Final Invalidity Contentions. By its nature, the case narrowing procedure in the scheduling order invited Impossible to assert only the claims it believed to be strongest. In making that determination, Impossible was entitled to decide which claims it believed to be the strongest with the benefit of knowing what invalidity positions Defendants would be taking. Defendants deprived Impossible of that opportunity by raising a new invalidity position in their final contentions, based on a previously unlisted reference. As such, Defendants cannot properly be said to have "narrowed" their contentions or "reduced" the number of asserted invalidity references as contemplated by the scheduling order. *See generally* Dkt. No. 161 at 8. Because they supplemented their invalidity references in substance while reducing them in number, Defendants are partly responsible for Impossible's need to reevaluate its position.

Defendants also argue that Impossible engaged in gamesmanship by waiting to inform Defendants of its intention to amend until after the Defendants had agreed to permit a similar

amendment. While Defendants might have opposed both motions to amend if Impossible had raised them together, Impossible would have been in the same position with respect to the present motion, which Defendants have opposed. With respect to the motion at hand, Defendants were not prejudiced by Impossible's seriatim filing of its motions. The only difference in Defendants' position is that they might have opposed the first motion as well as the current one. And the fact that Defendants did not oppose the first motion is the best indication that they did not regard that motion as prejudicial to them. The fact that Defendants may have behaved differently had Impossible raised the issue sooner does not warrant denial of the present motion.

Similarly, although Defendants may suffer some prejudice from allowance of the amendment, the prejudice is likely to be quite modest. Claims 2 and 5 both depend from the same independent claim, so the overwhelming majority of Defendants' work will be transferrable. That is particularly true because Defendants' invalidity contentions already address leghemoglobin, the additional limitation added by claim 2, in some capacity. *See generally* Dkt. No. 527-1, Ex. 1. At 121; *id.* at 211. Additionally, the parties recently stipulated to extend the close of expert discovery by almost a month. Dkt. No. 591. Defendants will have three weeks from the filing of this order until the close of discovery, which will be sufficient time to adapt their positions from claim 5 to claim 2. In short, the prejudice to Defendants weighs slightly in favor of denying the motion, but not enough to overcome the arguments in favor of granting it.

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For the foregoing reasons, Impossible's motion is GRANTED. The briefs regarding this issue were submitted under seal. For that reason, I have filed this opinion under seal. Within three business days of the issuance of this order, the parties are directed to advise the court by letter whether they wish any portions of this order to remain under seal, and if so which portions. Any

request that portions of the order remain under seal must be supported by a particularized showing of need to limit public access to those portions of the order.

IT IS SO ORDERED.

SIGNED this 26th day of July, 2024.

Handwritten signature of William C. Bryson in cursive script.

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WILLIAM C. BRYSON  
UNITED STATES CIRCUIT JUDGE