

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CHARLES RIVER LABORATORIES, INC.,
Petitioner,

v.

SEIKAGAKU CORPORATION,
Patent Owner.

IPR2025-00440
Patent 11,236,318 B2

Before MICHAEL J. FITZPATRICK, JAMES A. WORTH,
TAWEN CHANG, *Administrative Patent Judges*.

Opinion for the Board filed by Administrative Patent Judge CHANG.

Opinion concurring in part and dissenting in part filed by Administrative
Patent Judge FITZPATRICK.

CHANG, *Administrative Patent Judge*.

ORDER

Granting-in-Part Patent Owner's Motion for Routine Discovery
37 C.F.R. § 42.51

Patent Owner, Seikagaku Corporation, filed an authorized Motion to Compel Routine Discovery Under 37 C.F.R. § 42.51(b)(1)(iii) (“Mot.”). Paper 12. Petitioner filed an Opposition. Paper 13 (“Opp.”). No reply was filed or authorized. *See* Paper 10. For the reasons discussed below, we grant the Motion in part.

A. Background and Requested Discovery

Petitioner asserts in this proceeding that claim 21 of the ’318 patent, which recites a *Limulus polyphemus* horseshoe crab Factor C protein recombinantly expressed from a HEK293 cell and exhibiting certain residual activity, is obvious over Mizumura in view of either the ’498 PCT or McClymont. Pet. 8. Both asserted grounds of invalidity are based on the premise that the challenged claim is entitled to an effective filing date no earlier than April 30, 2019, the ’318 patent’s actual filing date. *See, e.g., id.* at 42 (asserting that, “[i]f challenged claim 21 is entitled to an effective filing date of no earlier than April 30, 2019, then Mizumura is prior art to claim 21”).

As part of its priority arguments, Petitioner took the position that the ’767 application, which is in the priority chain of the ’318 patent, “does not demonstrate to a POSA that the inventors possessed the full scope of [claim 21] as of December 10, 2013,” or enable the full scope of the claim. Pet. 22–42. Petitioner asserts that, “[i]f the representative ’767 Application fails to describe and enable claim 21, . . . all other applications in the priority chain fail for the same reasons.” *Id.* at 22.

In its preliminary response, Patent Owner cited to a declaration from Michael A. Frohman (“Frohman Declaration”) filed in an Opposition

proceeding against European Patent No. 3530670 (“EP ’670”).¹ Prelim. Resp. 29. Patent Owner argues that “Professor Frohman’s declaration confirms a skilled artisan would not have had to unduly experiment to discover and characterize *Limulus polyphemus* Factor C and recombinantly express it in HEK293 cells.” *Id.* at 29–30.

Patent Owner further asserts that “the evidence strongly suggests that Petitioner commissioned Professor Frohman’s declaration.” Prelim. Resp. 29. Patent Owner asserts that, “[i]f so, Petitioner’s arguments here should be considered, if at all, with extreme skepticism.” *Id.*

We instituted this proceeding on September 9, 2025. Patent Owner now seeks an order compelling Petitioner to produce the following categories of information and documents as routine discovery:

- (1) confirmation whether Petitioner initiated the ’670 Opposition; and
- (2) any other relevant information of which Petitioner is aware that is inconsistent with a position Petitioner advanced in IPR2025-00440.

Mot. 1.

B. Legal Standards

In an *inter partes* review, a party must serve as “routine discovery” “relevant information that is inconsistent with a position advanced by the party during the proceeding.” 37 C.F.R. § 42.51(b)(1)(iii). Unless previously served, such information must be served “concurrent with the filing of the documents or things that contains the inconsistency.” *Id.* The

¹ The Frohman Declaration has been entered into the record in this proceeding as Exhibit 2004.

requirement of routine discovery “extends to inventors, corporate officers, and persons involved in the preparation or filing of the documents or things” but “does not make discoverable anything otherwise protected by legally recognized privileges such as attorney-client or attorney work product.” *Id.*

“Routine discovery under 37 C.F.R. § 4[2].51(b)(1)(iii) is narrowly directed to specific information known to the responding party to be inconsistent with a position advanced by that party in the proceeding, and not broadly directed to any subject area in general within which the requesting party hopes to discover such inconsistent information.” *Garmin Int’l, Inc. v. Cuozzo Speed Techs. LLC*, IPR2012-00001, Paper 26, 4 (March 5, 2013) (precedential) (“Garmin”).

As the moving party, Patent Owner bears the burden of proving that it is entitled to the requested relief. 37 C.F.R. § 42.20(c).

C. Whether Requested Information Is Subject to Routine Discovery

1. Confirmation Whether Petitioner Initiated ’670 Opposition

The ’670 Opposition is based on the grounds that the subject matter of EP ’670 “is not based on an inventive step”; “is insufficiently disclosed”; and “extends beyond the content of the application as filed.” Ex. 1048, 2; Ex. 2006, 2.

Assuming Petitioner initiated the ’670 Opposition, we are not persuaded Patent Owner has shown this fact is itself inconsistent with a position Petitioner has advanced in this proceeding. As an initial matter, the claims of EP ’670 at issue in the Opposition are different and both broader and narrower than the challenged claim in this proceeding in different respects. *Compare* Ex. 1048, 5, *with* Pet. 11. Neither has Patent Owner

explained why the grounds on which the Opposition is based are necessarily inconsistent with positions advanced by Petitioner in this proceeding.

We acknowledge Patent Owner’s argument that specific statements made during the course of the Opposition may be inconsistent with positions taken by Petitioner in this proceeding. Mot. 2. We discuss this issue separately below. We also acknowledge that whether any such inconsistent statement is made by Petitioner — rather than a third party — may implicate evidentiary issues and issues relating to, e.g., credibility. Prelim. Resp. 29. However, because of its self-executing and thus potentially onerous nature, “[r]outine discovery under 37 C.F.R. § 4[2].51(b)(1)(iii) is narrowly directed to specific information known to the responding party to be inconsistent with a position advanced by that party.” *Garmin*, 4. We are not persuaded, assuming Petitioner in fact initiated the ’670 Opposition, that such fact rises to the level of routine discovery. We emphasize, however, that this determination does not preclude Patent Owner from seeking disclosure of this information as additional discovery under 37 C.F.R. § 42.51(b)(2).

Because we determine whether Petitioner initiated the ’670 Opposition is not routine discovery, we need not, and do not, address whether this information is protected by attorney client privilege or attorney work product, as Petitioner alleges.

2. Other Relevant Information Known to the Petitioner to be Inconsistent with a Position Petitioner Advanced in This Proceeding

Even if Petitioner did not initiate the ’670 Opposition, this does not end our inquiry, because parties are required to “serve relevant information that is inconsistent with a position advanced by the party during the proceeding” so long as they are known to the party to be inconsistent, has

not been previously served, and are not otherwise protected by legally recognized privileges such as attorney-client privilege or attorney work product. 37 C.F.R. § 42.51 (b)(1)(iii); *Garmin*, 4. An order requiring production of “any other relevant information of which Petitioner is aware that is inconsistent with a position Petitioner advanced in IPR2025-00440,” as requested in the Motion, should be unnecessary, because as noted above, the requirement of 37 C.F.R. § 42.51 (b)(1)(iii) is self-executing. Nevertheless, because the parties dispute whether a specific document, the Frohman Declaration, should have been produced as routine discovery, we address this issue below to provide guidance to the parties.

a. Whether the Frohman Declaration is known to the Petitioner

The identity of the party that initiated the ’670 Opposition (“Opponent”) and submitted the Frohman Declaration is not disclosed. Paper 7 (“Prelim. Resp.”) 34; Opp. 1. However, Patent Owner has provided evidence – to date unrebutted – that Petitioner is aware of the ’670 Opposition and documents therein. Patent Owner observes that Notice of the ’670 Opposition was filed by an attorney who also is the named representative for Petitioner’s European Patent Application EP 4291648. *See* Prelim. Resp. 34; *compare* Ex. 2006 with Ex. 2007. Patent Owner also points to a reference filed in the ’670 Opposition, which bears a unique identifying footer. Prelim. Resp. 35–36. A copy of that document — including the footer — was also filed on behalf of Petitioner during the prosecution of several of Petitioner’s patent applications. *See id.* at 36–37; *compare* Ex. 2012, 1 (filed by Opponent in the ’670 Opposition) with, e.g., Ex. 2009 (filed by Petitioner in application no. 17/650,803).

Accordingly, although we make no finding as to whether Petitioner is in fact the party that initiated the '670 Opposition, we find Patent Owner has at least met its burden of showing that information relating to the '670 Opposition, including the Frohman Declaration, is known to the Petitioner.

b. Whether the Frohman Declaration is relevant and inconsistent with a position advanced by Petitioner during this proceeding

Patent Owner argues that certain portions of the Frohman Declaration, and/or its characterization by Opponent in the '670 Opposition, is inconsistent with statements in the Petition. (Mot. 2 (citing Paper 7, 30–32)). Having reviewed the Petitioner and Patent Owner's citations to the Frohman Declaration and other exhibits of record in this proceeding, and as illustrated in the chart of quotations below,² we agree that the Frohman Declaration is inconsistent at least in part with positions Petitioner has taken in this proceeding.

Petition	Frohman Declaration
The '767 Application purports to disclose experimental protocols for making—and data demonstrating that recombinant Factor C of the <i>Tachypleus tridentatus species</i> , when produced in HEK293 cells, yields—Factor C proteins with a 'residual activity' falling with the claimed range. . . . A POSA would not expect such protocols to yield	VIII. Is there any reason to believe that [<i>Limulus</i> Factor C protein] would have been difficult to express after the cDNA sequence had been obtained? 44. No.

² The quotations are by way of examples and are not intended to provide an exhaustive list of inconsistencies between the Frohman Declaration and the Petition.

recombinant proteins in soluble and functional form from a <i>different</i> species of crab (whose full sequence information was not even known as of 2013) let alone expect such unknown and uncharacterized proteins would exhibit a function—residual activity—falling in and across the full scope of the claimed range without completing the invention by sequencing the claimed proteins and engaging extensive testing to assess function or by elucidating a verified structural explanation for such function across species. Pet. 23–24.	45. Again, the cDNA sequence of the <i>Limulus</i> Factor C is very similar to the other known species of horseshoe crabs, which had been successfully expressed in Sf9, CHO DG44 and HEK 293 cells. This has been shown in e.g., D1 ('241). 46. Given that these cells were able to incorporate vectors containing cDNA for <i>T. tridentatus</i> and/or <i>C. rotundicauda</i> and express the Factor C-encoding mRNAs and Factor C proteins, there's no reason to think that they would not be equally capable of handling the <i>Limulus</i> sequence. 47. If I were to follow the example of D1 using the <i>Limulus</i> sequence, I would start with the cell exemplified in this disclosure and would not anticipate experiencing any difficulties. Ex. 2004 ¶¶ 44–47.
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In the example cited above, the Frohman Declaration suggests that, because, e.g., HEK293 cells were able to incorporate vectors containing cDNA for *T. tridentatus* to express the Factor C-encoding mRNAs and Factor C proteins, “there’s no reason to think that they would not be equally

capable of handling the *Limulus* sequence.” Ex. 2004 ¶ 46. This is inconsistent with Petitioner’s position in the Petition that an ordinarily skilled artisan would not expect experimental protocols for producing recombinant *T. tridentatus* Factor C proteins in HEK293 cells “to yield recombinant proteins in soluble and functional form from a **different** species of crab” such as *Limulus polyphemus*. Pet. 24.

We are not persuaded by Petitioner’s argument that the Petition and the Frohman Declaration are not inconsistent because the Petition relates to whether the challenged claim is adequately described and enabled as of the claimed 2013 priority date, whereas the Frohman Declaration offers testimony from the perspective of a person of ordinary skill in the art as of 2016. Opp. 2 (“There is no inconsistency between statements that explicitly refer to what was known or routine as of different points in time.”).

As an initial matter, as noted above, Petitioner took the position in the Petition that the challenged claim is entitled to an effective filing date no earlier than April 30, 2019, the ’318 patent’s actual filing date. Pet. 42. Petitioner also took the position that its arguments with respect to the ’767 Application is representative, and that, “[i]f the representative ’767 Application fails to describe and enable claim 21, . . . all other applications in the priority chain *fail for the same reasons*.” *Id.* at 22 (emphasis added). Thus, Petitioner’s arguments regarding written description and enablement do not appear to be limited to the 2013 timeframe.

Moreover, Petitioner acknowledges that “Dr. Frohman cites to earlier publications and earlier-known background information from the 1980’s and 1990’s, for example, about RACE.” Opp. 5. Petitioner argues that “this is in the context of what a skilled person would have done with such teachings

after 2016 (i.e., after the vast majority of the *Limulus polyphemus* coding sequence was public).” *Id.* However, Dr. Frohman testified, for instance, that “[i]t would have been entirely straightforward for the skilled person to design RACE primers based on the available *Limulus* sequence information listed in items (i)-(iii) above and then use any of the available RACE-PCR kits to obtain the full-length cDNA sequence.” Ex. 2004 ¶ 10; *see also id.* ¶ 17 (explaining that although Dr. Frohman “personally would have started with the genomic information in the NCBI database,” publicly available as of January 3, 2014, “any of the sources of information listed in (i)-(iii) above could have been used to design RACE primers”). As Patent Owner noted, item (iii) is a Tokunaga reference published in 1991. Prelim. Resp. 31; Ex. 1048, 3–4.

Finally, Petitioner argues that

Petitioner’s position regarding the lack of possession and experimentation required to discover and characterize the gene and amino acid sequence for *Limulus polyphemus* Factor C is tied to both the **unknown** status of the *Limulus polyphemus* Factor C gene and amino acid sequence information as of 2013, and to the **function** of the resulting protein as recited in the challenged claim.

Opp. 4. Petitioner argues that, in contrast, “Dr. Frohman’s declaration . . . explains that the gene and amino acid sequence information for the *Limulus polyphemus* genome was almost fully known by 2016 and opines about the experimentation required **from that point on** to generate recombinant Factor C protein (via the RACE procedure).” *Id.* at 4–5 (citing Ex. 2004 ¶¶ 18–19); *see also id.* at 2 (arguing that Dr. Frohman “said nothing about what a POSA would have known or expected about [producing recombinant *Limulus polyphemus* Factor C] **before such genomic information was available,**” or

“the experimentation required to produce the claimed proteins *with the full scope of residual activity function of challenged claim 21*”).

To clarify, we do not find the portion of Frohman Declaration we have excerpted above to be inconsistent with the position, also articulated in the quoted passage in the Petition, that an ordinarily skilled artisan would not expect experimental protocols for producing recombinant *T. tridentatus* Factor C proteins in HEK293 cells to yield recombinant *L. polyphemus* Factor C proteins in HEK293 “exhibit[ing] a function—residual activity—falling in and across the full scope of the claimed range.” Pet. 24. Likewise, the specifically excerpted Frohman Declaration testimony above would not be inconsistent with a position that *Limulus* Factor C protein could not have been expressed at the relevant timeframe because its cDNA sequence was not available: Indeed, the question in the excerpt explicitly assumes that such cDNA sequence had been obtained.

Nevertheless, routine discovery requires the production of “relevant information that is inconsistent with a position advanced by the party during the proceeding.” 37 C.F.R. § 42.51(b)(1)(iii) (emphasis added). Thus, the Frohman Declaration, and other similar documents, fall within its ambit even if they may not be inconsistent with all of positions advanced by Petitioner in this proceeding. In this case, a fair reading of the cited passage from the Petition shows the Petitioner to be advancing three separate reasons why an ordinarily skilled artisan would not have understood the inventors to be in possession of the horseshoe crab Factor C protein recited in claim 21 of the ’318 patent despite its disclosure of recombinant *T. tridentatus* Factor C proteins in HEK293 cells: (1) because *T. tridentatus* is a different species; (2) because the full sequence information of *L. polyphemus* is not known as

of 2013; and (3) because claim 21 requires the Factor C protein to exhibit particular ranges of residual activity. The quoted Frohman Declaration testimony is inconsistent with the first one of these reasons.

Finally, to the extent Petitioner argues that Patent Owner “is confusing issues of description and enablement with European ‘inventive step,’ which [Patent Owner] does not dispute are different,” Opp. 1–2, we are not persuaded, because Patent Owner is not asking us to adopt a legal conclusion from the ’670 Opposition in this proceeding. Rather, as discussed above, Patent Owner is directing us to testimony supporting the ’670 Opposition that is inconsistent with a position taken in the Petition.

For the foregoing reasons, Patent Owner’s Motion for Routine Discovery is granted in part.

ORDER

Accordingly, it is

ORDERED that Patent Owner’s Motion is granted in part;

FURTHER ORDERED that Petitioner must serve, within fourteen (14) days of this Order, any additional relevant, non-privileged/work product information from the ’670 Opposition known to Petitioner to be inconsistent with a position it advanced in this proceeding in the manner discussed above with respect to the Frohman Declaration.

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FITZPATRICK, *Administrative Patent Judge*, opinion concurring in part and dissenting in part.

I concur in the majority's decision as to (1) finding that the Frohman Declaration is relevant information that is inconsistent with a position advanced in the Petition and (2) ordering Petitioner to serve any additional relevant information from the '670 Opposition, of which Petitioner is aware, that is inconsistent with a position advanced in this proceeding.

However, I dissent from the majority's decision as to its finding that, if Petitioner requested the '670 Opposition (or caused it to be requested), such a fact need not be disclosed as routine discovery. In my view, such a fact would be encompassed by routine discovery because Petitioner would be advancing inconsistent positions in two separate forums. The operable language states, "[u]nless previously served, a party must serve relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents or things that contains the inconsistency." 37 C.F.R. § 42.51(b)(1)(iii).

The majority find, and I concur, that "the Frohman Declaration suggests that, because, e.g., HEK293 cells were able to incorporate vectors containing cDNA for *T. tridentatus* to express the Factor C-encoding mRNAs and Factor C proteins, 'there's no reason to think that they would not be equally capable of handling the *Limulus* sequence,'" and that such testimony is "inconsistent with Petitioner's position in the Petition that an ordinarily skilled artisan would not expect experimental protocols for producing recombinant *T. tridentatus* Factor C proteins in HEK293 cells 'to yield recombinant proteins in soluble and functional form from a *different*

species of crab’ such as *Limulus polyphemus*.” *Supra* (quoting Ex. 2004 ¶46; Pet. 24).

If Petitioner commissioned such testimony from Mr. Frohman, the fact that it did would be inconsistent with a position it is advancing before us. Further, the burden of establishing a privilege rests with the party invoking it. *See Siler v. Env’t Prot. Agency*, 908 F.3d 1291, 1297 (Fed. Cir. 2018) (“a party who seeks to withhold discovery based on privilege has the burden of showing privilege applies”). Petitioner has failed to do so here. Thus, I would order Petitioner to disclose that it requested the ’670 Opposition (if, in fact, it did, as the evidence suggests).