

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GE HEALTHCARE LTD.,
Petitioner

v.

THE JOHNS HOPKINS UNIVERSITY,
Patent Owner

Case PGR2025-00059
U.S. Patent No. 12,115,233

**PATENT OWNER'S OPPOSITION TO PETITIONER'S
MOTION FOR ADDITIONAL DISCOVERY**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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TABLE OF CONTENTS

I.	GE’s Request Is a Belated Attempt to Cure its Petition’s Deficiencies.....	1
II.	<i>Garmin</i> Factor 1 – GE Has Not Demonstrated That the Requested Items Would be Useful	3
III.	<i>Garmin</i> Factor 3 – GE Had Access to Equivalent Information	7
IV.	<i>Garmin</i> Factor 4 – GE’s Requests Are Not Sufficiently Clear	8
V.	<i>Garmin</i> Factor 5 – GE’s Requests Are Overly Burdensome	8
VI.	<i>Garmin</i> Factor 2 – Litigation Positions	10

TABLE OF AUTHORITIES

Cases

<i>ACCO Brands Corp. v. Fellowes, Inc.</i> , IPR2013-00566 (P.T.A.B. Apr. 24, 2014)	4
<i>Apple Inc. v. Singapore Asahi Chem. & Solder Indus. PTE Ltd.</i> , IPR2019-00377 (P.T.A.B. Oct. 21, 2019)	6, 7
<i>Arctic Cat, Inc. v. Polaris Indus., Inc.</i> , IPR2014-01428 (P.T.A.B. July 17, 2015)	5, 6, 7, 10
<i>Corning Inc. v. DSM IP Assets B.V.</i> , IPR2013-00043 (P.T.A.B. June 21, 2013)	6, 7
<i>Douglas Dynamics, L.L.C. v. Meyer Prod. LLC</i> , IPR2015-01839 (P.T.A.B. July 26, 2016)	3
<i>Garmin Int’l v. Cuzzo Tech. LLC</i> , IPR2012-00001 (P.T.A.B. Mar. 5, 2013)	5
<i>Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.</i> , IPR2014-00309 (P.T.A.B. Sept. 4, 2014)	5, 6
<i>Mylan Pharm. Inc. v. Allergan, Inc.</i> , IPR2016-01127 (P.T.A.B. May 21, 2017)	2

Petitioner GE Healthcare Ltd.’s (“GE”) Motion is belated and lacks merit.

GE should have grappled with the relevant intrinsic evidence before filing its Petition. Even now, GE fails to explain how the requested discovery would be useful. And contrary to the Board’s guidance, GE has not materially or specifically narrowed its requests. Paper 15, 2. Indeed, its requests are overbroad, burdensome, vague, and nothing more than a fishing expedition. The Motion should be denied.

I. GE’s Request Is a Belated Attempt to Cure its Petition’s Deficiencies

GE seeks additional discovery regarding inventor Dr. Pomper’s §1.132 declaration submitted in 2024 during prosecution of the challenged patent and in 2023 during prosecution of its parent. *Id.*, 1. GE alleges that it is entitled to that discovery because Patent Owner “JHU and [its expert] Dr. VanBrocklin have put” the declaration “at issue in this proceeding.” *Id.*, 6. But, GE was first to put the declaration at issue, citing cherry-picked portions of it in GE’s petition. Pet., 20-23, 48, 107-108. The declaration is also ***part of the challenged patent’s intrinsic record*** and was submitted during prosecution to show that the claimed compounds have unexpectedly better FAP-selectivity compared to prior-art FAP inhibitors (“FAPis”). EX1002, 173-176; Paper 12, 48-54. Thus, from the outset, GE should have expected JHU to rely on the declaration, and GE should have fully addressed this intrinsic evidence of unexpected results in its petition. But GE ignored it. Pet., 106. GE also could have indicated at the outset that it would need the requested

discovery if trial were instituted; but it did not. *Id.* And GE could have generated equivalent information by making and testing the claimed compounds; but it did not. *Id.* The Motion is thus a belated attempt to cure deficiencies GE left unaddressed from the start.

GE's failure to address this intrinsic evidence and its Motion's belatedness are underscored by the very *Mylan* decision GE cites to justify its requests. Paper 15, 1, 4 (citing *Mylan Pharm. Inc. v. Allergan, Inc.*, IPR2016-01127, Paper 28 (P.T.A.B. May 21, 2017)). In *Mylan*, the petitioner ***timely raised across ten pages of its petition*** that data in §1.132 declarations submitted during prosecution “failed to demonstrate unexpected results because it failed to provide parameters necessary for scientific interpretation, including raw data values and error rates” to determine “whether the reported data are statistically significant or material.” *Mylan*, Paper 3 at 47-57. And the *Mylan* institution decision stated “it [was] more appropriate to allow further evidence to be developed during trial” regarding those results should they be relied upon. *Id.*, Paper 8 at 18 n.4. That is not the case here.

Here, GE selectively chose ***not to address*** in its petition the unexpected results demonstrated in Pomper's declaration—even though GE was aware of those results. GE then waited until 3 months after issuance of the Board's decision to institute, 2 weeks after being served JHU's Patent Owner Response, and 5 days after JHU offered a date for Dr. VanBrocklin's deposition to raise GE's discovery

request in an email to JHU. EX1058, 5-6. GE's actions, thus, are not on all fours with those in *Mylan*. GE's untimely motion, thus, should be denied given "the substantial delay between when [it] learned of [the §1.132 declaration], and when it first made its request" to JHU. *Douglas Dynamics, L.L.C. v. Meyer Prod. LLC*, IPR2015-01839, Paper 29 at 5 (P.T.A.B. July 26, 2016) (requests belated when documents sought were known of before the proceeding); *see also* 37 C.F.R. §42.25(b) ("Delay in seeking relief may justify a denial of relief sought.").

Additionally, the requests lack merit, as set forth below.

II. *Garmin* Factor 1 – GE Has Not Demonstrated That the Requested Items Would be Useful

GE cannot satisfy *Garmin* Factor 1 because it has not demonstrated that something *useful* will be uncovered. Rather, GE's Motion shows that it is on an impermissible fishing expedition.

First, GE invokes 37 C.F.R. § 42.65(a) as a basis for its request, asserting that "[t]he records [it] seeks are those necessary to investigate and assess Dr. VanBrocklin's opinions and JHU's arguments that rely on Dr. Pomper's tests." Paper 15, 2. But §42.65(a) does not create an automatic right to additional discovery, particularly when Dr. VanBrocklin did not rely on the documents GE seeks. Indeed, accepting GE's position would eviscerate the limits on additional discovery, rendering it *per se* available for *any* intrinsic-record data—including the data underlying a patent's examples. Dr. VanBrocklin and JHU, nevertheless,

complied with §42.65(a) by citing the underlying material they relied on here:

Pomper's declaration in the intrinsic record.

GE questions the accuracy of Pomper's data (Paper 15, 5) but has not identified any reason why it is inaccurate or unreliable, nor why that data is purportedly insufficient. The §1.132 declaration is sworn and subject to the Office's duty of candor, underscoring its reliability. Moreover, Dr. Pomper is a well-established and respected researcher—a member of the National Academy of Medicine and a recognized thought leader in the field—and he conducted his research at JHU, an equally well-established and respected institution.

Additionally, Pomper's declaration identifies the tested compounds, provides the resulting FAP-selectivity, and explains the conclusions drawn from that data.

EX1002, 174-175. Contrary to the petitioner in *Mylan* that identified error rate calculations that were needed “for scientific interpretations,” GE has not tied any of the data and materials it seeks to a specific alleged deficiency in Pomper's declaration or the PCT that renders the information uninterpretable, unreliable, or misleading. *Mylan*, Paper 28 at 3. Instead, GE solely seeks additional materials to allegedly probe the underlying experimentation more deeply—precisely the type of “fishing expedition” that *Garmin* prohibits. *ACCO Brands Corp. v. Fellowes, Inc.*, IPR2013-00566, Paper 20 at 5 (P.T.A.B. Apr. 24, 2014). Nothing undermines the evidentiary value or trustworthiness of Pomper's declaration, and nothing justifies

departing from the AIA's carefully circumscribed limits on discovery.

Second, GE offers no evidence beyond a "mere allegation that something useful will be found." *Garmin Int'l v. Cuzzo Tech. LLC*, IPR2012-00001, Paper 26 at 6 (P.T.A.B. Mar. 5, 2013). GE asserts that it seeks this discovery to "evaluate the completeness and accuracy of Dr. Pomper's and Dr. VanBrocklin's testimony" and "test the reliability and accuracy of Dr. Pomper's representations." Paper 15, 6. But those are generalized, exploratory aims, not a showing that the requested materials will yield information useful to a specific issue. Indeed, "[i]nformation that is useful for 'exploring' testimony is not information that has a clear use; rather, it only has a possible use." *Arctic Cat, Inc. v. Polaris Indus., Inc.*, IPR2014-01428, Paper 35 at 4 (P.T.A.B. July 17, 2015); *Intri-Plex Techs., Inc. v. Saint-Gobain Performance Plastics Rencol Ltd.*, IPR2014-00309, Paper 40 at 7-8 (P.T.A.B. Sept. 4, 2014) (Factor 1 not satisfied because movant sought information to "evaluate" its contentions). Both of GE's requests also broadly seek "other documents," without limiting that phrase in any meaningful way. Paper 15, A-1. As the attached Appendix shows, that phrase could encompass many document types across the subcategories GE identifies, underscoring GE's fishing expedition.

Third, contrary to the Board's Order, GE does not explain, "***for each item of requested discovery***, the purpose for seeking the item and how the information sought, in the best of circumstances, would assist in the presentation of [GE's]

reply.” Paper 14, 4 (emphasis added). GE merely says it “intends to use the requested documents to rebut JHU’s arguments and evidence in its Reply” and needs them “to prepare for and afford a fair rebuttal of Dr. VanBrocklin’s opinions and JHU’s contentions.” Paper 15, 4. But those general statements do not comply with the Board’s Order to show that *each item* of discovery outlined in the Appendix’s table will “in the best of circumstances ... assist in the presentation of [GE’s] reply.” Paper 14, 4; *see also Arctic Cat* at 4; *Intri-Plex* at 7-8. GE also appears to seek information on compounds “not covered by the [] claims.” Paper 15, 2 (citing EX1002, 174). Pomper’s declaration, however, identifies the unclaimed prior-art compounds he tested, and GE fails to show how underlying information on B-L-FAPi compounds outside the claims has any bearing on this proceeding. GE is simply fishing.

GE’s reliance on *Corning* and *Apple* to assert that the requested materials are “‘per se useful’” is also misplaced. Paper 15, 3-4. In *Corning*, the petitioner’s expert replicated the prior art to support **inherency** arguments—i.e., to prove that a particular result necessarily occurs. *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00043, Paper 27 at 2 (P.T.A.B. June 21, 2013); *see, e.g., id.*, Paper 3 at 24-25. That particular context can justify access to the underlying materials because inherency turns on whether the precise experimental conditions inevitably yielded the claimed result. But inherency is not at issue here. And in *Apple*, the experiments

were run *at the direction of* an expert, but the expert provided only summaries to challenge the asserted art's teachings. *Apple Inc. v. Singapore Asahi Chem. & Solder Indus. PTE Ltd.*, IPR2019-00377, Paper 22 at 2 (P.T.A.B. Oct. 21, 2019). The scenario is fundamentally different here: Pomper's declaration was not litigation-driven, and Dr. VanBrocklin relies on the data itself—not a curated summary Dr. VanBrocklin prepared.

III. *Garmin* Factor 3 – GE Had Access to Equivalent Information

The relevant question for *Garmin* Factor 3 “is not whether the[] *exact documents* can be generated by other means, but whether *equivalent information* can be generated by other means.” *Arctic Cat* at 4-5 (emphases in original). GE's Motion fails that test. GE's claim that it “cannot replicate the Pomper lab's own records and experimental results” is beside the point. Paper 15, 7. GE could have synthesized and tested compounds within the challenged claims to assess FAP-selectivity and generate equivalent information. In fact, Dr. Zeglis has admitted that making the claimed compounds requires only routine skill. EX1003, ¶¶121, 172. The Jansen reference GE relies on in its Petition also provides protocols for assessing FAP-selectivity. EX1006, 3809-3091. Paper 15, 5. GE's reliance on *Apple* and *Corning* is likewise misplaced, as discussed. *Id.*, 7. GE is also wrong that the PCT omits assay methods or controls. *Id.*, 5. The PCT includes a “*Competitive inhibition assays*” section describing the methods and materials used

to assess FAP-selectivity and identifying FAPI-04 as the “positive control.”

EX1057, 110:16-27. The PCT provides equivalent information to what GE seeks.

IV. *Garmin* Factor 4 – GE’s Requests Are Not Sufficiently Clear

GE seeks “other documents,” a term broad and vague enough to cover many document types depending on the information sought. Nor is it clear what is encompassed by “protocols” and “compounds and reagents,” which could include materials used either to synthesize the compounds and/or to perform the inhibition assays. Moreover, the scope of what GE is asking for is unclear because its stated requests in the Motion’s Appendix, which are limited to the testing of the specificity of a number of FAP imaging agents (Paper 15, A-1), are inconsistent with the body of its Motion, which also seeks other “discovery into the protocols and procedures used to generate those compounds.” *Id.*, 6. None of that is useful: GE has not shown that synthesis would affect ultimate activity, and the art and Pomper’s PCT already disclose how to perform the inhibition assays.

V. *Garmin* Factor 5 – GE’s Requests Are Overly Burdensome

GE fails to satisfy *Garmin* Factor 5. Its belated, speculative, and broad requests would substantially and unjustifiably burden JHU and the case schedule. Although GE characterizes its requests as “narrowed,” they still sweep broadly, seeking any notebooks, protocols, raw data, analyses, materials on controls and reagents, and compound-selection criteria tied to Pomper’s “lab test[ing] the

specificity of a number of FAP imaging agents.” Paper 15, 2 (citing EX1002, 174-75), A-1. GE’s assumption that these materials “invariably [still] exist” and can be readily located and reviewed is baseless. *Id.*, 3. The PCT and Dr. Pomper’s declaration are several years old, and JHU would have to reconstruct the requested information anew, especially in view of the breadth of the requests.

JHU’s internal inquiries to comply with the Board’s Order to “indicate with particularity the burden the discovery request imposes” show substantial burden. Paper 14, 4. JHU has identified at least seven involved laboratory personnel, most no longer at JHU. It would also need a vendor to scan and ingest at least 25 lab notebooks, each containing hundreds of pages and a variety of work, including different projects, then manually review them to tie entries to the relevant experiments because the handwritten notebooks cannot be OCR’d. Indeed, by requesting lab notebooks, GE has asked for information at the highest level of granularity that is the most burdensome to produce, without justifying its usefulness. A shared lab computer would also have to be searched on-site because it is not internet-connected. JHU further expects to need: (1) 5-10 hours from one or two remaining lab members, neither of whom is available until well into June; (2) 5-10 hours from a university paralegal and 3-5 hours from university counsel to supervise collection; (3) 1-3 hours from an administrator to access stored materials because Dr. Pomper’s lab is no longer at JHU; and (4) an unknown amount of

outside-counsel time to review and redact non-responsive materials and business-confidential materials, given the request's uncertain scope. GE's overbroad and vague requests would also substantially burden JHU in showing compliance with any production order and increase its costs in this unilaterally initiated proceeding. Granting GE's Motion would impose burdensome district-court-style discovery, contrary to the AIA's design of "a quick and cost-effective alternative to litigation." *Arctic Cat* at 2.

GE's belated requests also burden the schedule. GE's Reply is currently due July 1, and because collection likely could not begin until well into June, the requested materials cannot feasibly be collected, reviewed, and produced in the current window. Although the parties might move GE's Reply to August 10, so that Dr. VanBrocklin can be deposed on July 29, the breadth and vagueness of GE's requests still render production likely infeasible before the deposition (as GE requests) without moving the current Oral Argument date, which could delay the Final Written Decision. That prejudices JHU, which is entitled to timely resolution of this proceeding within the statutory period, given the lack of good cause here.

VI. *Garmin* Factor 2 – Litigation Positions

GE's claim that JHU put Pomper's declaration at issue is undermined by the declaration being in the intrinsic record. Even so, JHU views this factor as neutral.

Under *Garmin*, GE's belated and burdensome Motion should be denied.

Respectfully submitted,

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APPENDIX

The table below provides the types of “other documents” that, at least, could be encompassed across the subcategories GE identifies in its requests.

Stated in GE’s Requests	Types of Possible “Other Documents”
Protocols (Paper 15, A-1, Request 1)	Computer files, emails, handwritten files, third-party journal articles, printouts, lab manuals, memoranda, slide decks, checklists, instrument instructions, grant applications, published and draft manuscripts
Sources of compounds and reagents (Paper 15, A-1, Request 1)	Invoices, certificates of analyses, emails, photographs, purchase orders, receipts, packing slips, inventory records, stockroom logs, catalogs, safety data sheets, labels, spreadsheets
Compound selection criteria (Paper 15, A-1, Request 1)	Handwritten notes, meeting minutes, slide decks, emails, memorandums, grant applications, published and draft manuscripts, spreadsheets, reports, research plans
Raw data, including compilations and analyses of such data (Paper 15, A-1, Request 2)	Computer files, emails, printouts, slide decks, instrument output files, spreadsheets, drawings, figures, memorandums

CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))

I certify that the above-captioned **PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION FOR ADDITIONAL DISCOVERY** was served in its entirety on May 26, 2026, upon the following parties via electronic mail:

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