

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

CARIS MPI, INC.,
Appellant

v.

FOUNDATION MEDICINE, INC.,
Cross-Appellant

2020-1886, 2020-1890, 2020-1930

Appeals from the United States Patent and Trademark
Office, Patent Trial and Appeal Board in Nos. IPR2019-
00166, IPR2019-00203.

CARIS MPI, INC.,
Appellant

v.

FOUNDATION MEDICINE, INC.,
Appellee

2020-1887, 2020-1888, 2020-1889

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2019-00164, IPR2019-00170, IPR2019-00171.

Decided: November 9, 2021

JONATHAN ELLIOT SINGER, Fish & Richardson P.C., San Diego, CA, argued for appellant. Also represented by OLIVER RICHARDS; DEANNA JEAN REICHEL, Minneapolis, MN.

MATTHEW WOLF, Arnold & Porter Kaye Scholer LLP, Washington, DC, argued for Foundation Medicine, Inc. Also represented by JENNIFER SKLENAR; WALLACE WU, Los Angeles, CA; DAVID B. BASSETT, Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY; DAVID LANGDON CAVANAUGH, THOMAS SAUNDERS, Washington, DC, VINITA FERRERA, KEVIN M. YURKERWICH, Boston, MA.

Before LOURIE, O'MALLEY, and CHEN, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Foundation Medicine, Inc. (“FMI”) petitioned for *inter partes* review of U.S. Patent 9,292,660 (the “660 patent”), owned by Caris MPI, Inc. (“Caris”). In two decisions, the United States Patent and Trademark Office Patent Trial and Appeal Board (“the Board”) held that claims 1–11 and 13–24 of the ’660 patent would have been obvious over prior art at the time the invention was made¹ but that FMI failed

¹ Because the challenged claims of the ’660 patent have an effective filing date before March 16, 2013, we apply the version of 35 U.S.C. § 103 in effect before the

to demonstrate by a preponderance of the evidence that claim 12 would have been obvious. *See Found. Med., Inc. v. Caris MPI, Inc.*, No. IPR2019-00166, 2020 WL 2478691 (P.T.A.B. May 13, 2020) (“*Decision I*”); *Found. Med., Inc. v. Caris MPI, Inc.*, No. IPR2019-00203, 2020 WL 2487140 (P.T.A.B. May 13, 2020) (“*Decision II*”).

Caris appeals (the 2020-1886 appeal) the Board’s holding that claims 1–11 and 13–24 would have been obvious and FMI cross-appeals the Board’s holding that it failed to demonstrate unpatentability of claim 12.

FMI also petitioned for *inter partes* review of claims 1–14 of U.S. Patent 8,880,350 (the “350 patent”), claims 1–14 of U.S. Patent 9,372,193 (the “193 patent”), and claims 1–14 of U.S. Patent 9,383,365 (the “365 patent”), all owned by Caris. In three decisions, the Board held that claims 1–14 of each of the ’350, ’193, and ’365 patents would have been obvious over prior art at the time the invention was made.² *See Found. Med., Inc. v. Caris MPI, Inc.*, No. IPR2019-00164, 2020 WL 2781576 (P.T.A.B. May 28, 2020) (“*Decision III*”); *Found. Med., Inc. v. Caris MPI, Inc.*, No. IPR2019-00170, 2020 WL 2789713 (P.T.A.B. May 28, 2020) (“*Decision IV*”); *Found. Med., Inc. v. Caris MPI, Inc.*, No. IPR2019-00171, 2020 WL 2789714 (P.T.A.B. May 28, 2020) (“*Decision V*”). Caris appeals (the 2020-1887 appeal).

We consolidated the two appeals for briefing and argument and decide both of them in this opinion. For the reasons detailed below, we *affirm* the 2020-1887 appeal, and *affirm-in-part, vacate-in-part, and remand* the 2020-1886 appeal to the Board for further proceedings.

adoption of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284 (2011).

² The challenged claims of the ’350, 193, and 365 patents also have an effective filing date before March 16, 2013, so the pre-AIA version of § 103 applies.

BACKGROUND

Caris owns the '660, '350, '193, and '365 patents. These patents relate to the field of personalized medicine, which uses results from molecular profiling to identify treatments for individuals. The patents describe systems and methods for identifying individualized medical intervention using molecular profiling.

A chart showing the claims that the Board addressed in each decision is shown below.

Decision	IPR	Claims	Patent
<i>Decision I</i>	2019-00166	Claims 1–16, 18, 22, 23	'660 patent
<i>Decision II</i>	2019-00203	Claims 17, 19– 21, 24	'660 patent
<i>Decision III</i>	2019-00164	Claims 1–14	'350 patent
<i>Decision IV</i>	2019-00170	Claims 1–14	'193 patent
<i>Decision V</i>	2019-00171	Claims 1–14	'365 patent

I. THE '660 PATENT

FMI petitioned for *inter partes* review of claims 1–24 of the '660 patent. Claim 1 is the only independent claim at issue, with claims 2–24 depending directly or indirectly therefrom. Claims 1 and 12 are specifically relevant to this appeal and are reproduced below.

1. A system for generating a report identifying a therapeutic agent for an individual with lung cancer comprising:
 - a. at least one device configured to assay a plurality of molecular targets in a

biological sample from the individual with lung cancer to determine molecular profile test values for the plurality of molecular targets, wherein the plurality of molecular targets comprises PTEN, CTNNB1, cKIT, BRAF and PIK3CA;

b. at least one computer database comprising:

i. a reference value for each of the plurality of molecular targets;

ii. a listing of available therapeutic agents for the plurality of molecular targets;

c. a computer-readable program code comprising instructions to input the molecular profile test values and to compare each of the molecular profile test values with a corresponding reference value from the at least one computer database in (b)(i);

d. a computer-readable program code comprising instructions to access the at least one computer database in (b)(ii) and to identify at least one therapeutic agent if present in the at least one computer database for each of the plurality of molecular targets wherein said comparison to the reference values in (c) indicates a likely benefit of the at least one therapeutic agent; and

e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the members of the plurality of molecular targets for which the comparison to the reference value indicated a likely benefit of the at least one

therapeutic agent in (d) and the at least one therapeutic agent identified in (d).

'660 patent at col. 164 l. 39–col. 165 l. 2.

12. The system of claim 1, wherein the report further comprises a listing of at least one additional molecular target for which the comparison to the reference value in (c) indicates a likely lack of benefit of at least one therapeutic agent and the at least one additional therapeutic agent.

Id. at col. 165 ll. 31–35.

Concerning the '660 patent, FMI alleged that (1) claims 1–16, 18, 22, and 23 would have been obvious over Von Hoff et al., U.S. Patent Pub. 2008/0014146 A1 (“Von Hoff”), Illumina® Gene Expression Profiling, Technical Bulletin, RNA Profiling with the DASL® Assay (2005) (“Illumina”), and Marina Bibikova et al., *Gene Expression Profiles in Formalin-Fixed, Paraffin-Embedded Tissues Obtained with a Novel Assay for Microarray Analysis*, 50 *Clinical Chemistry* 2384 (2004) (“Bibikova”); (2) claims 17 and 19 would have been obvious over Von Hoff, Illumina, Bibikova, and Ashish Guatam et al., *RRM1-induced Metastasis Suppression Through PTEN-Regulated Pathways*, 22 *Oncogene* 2135 (2003) (“Guatam”); (3) claims 20 and 24 would have been obvious over Von Hoff, Illumina, Bibikova, and Andreas Gnirke et al., *Solution Hybrid Selection with Ultra-Long Oligonucleotides for Massively Parallel Targeted Sequencing*, 27 *Nature Biotechnology* 182 (2009) (“Gnirke”); and (4) claim 21 would have been obvious over Von Hoff, Illumina, Bibikova, Guatam, and Gnirke.

The '660 patent is a continuation-in-part of Von Hoff. Von Hoff describes methods for determining individualized medical intervention for a particular disease state utilizing molecular profiling of a patient’s biological specimen. *Decision I*, 2020 WL 2478691, at *9; *Decision II*, 2020 WL

2487140, at *9. Caris has not disputed Von Hoff's status as 35 U.S.C. § 102(b) prior art based on the February 12, 2010 priority date attributed to the '660 patent. *Decision I*, 2020 WL 2478691, at *4, *9; *Decision II*, 2020 WL 2487140, at *4, *9.

illumina is a technical bulletin regarding RNA profiling with its cDNA-mediated annealing, selection, extension, and ligation ("DASL®") assay. *Decision I*, 2020 WL 2478691, at *9–11; *Decision II*, 2020 WL 2487140, at *9–10. illumina discloses a gene expression assay that can monitor up to 1536 RNA-derived sequence targets. J.A. 6887. The cancer panel targets 502 genes. J.A. 6890. The Board determined that Caris waived any argument questioning illumina's prior art status. *Decision I*, 2020 WL 2478691, at *11; *Decision II*, 2020 WL 2487140, at *10. Bibikova is an article discussing illumina's DASL® assay. *Decision I*, 2020 WL 2478691, at *9; *Decision II*, 2020 WL 2487140, at *9.

The Board instituted two trials and issued two written decisions concluding that FMI had demonstrated that claims 1–11 and 13–24 would have been obvious over the prior art, but that FMI failed to demonstrate that claim 12 would have been obvious. *Decision I*, 2020 WL 2478691, at *16; *Decision II*, 2020 WL 2487140, at *13. The Board first resolved the claim construction issue: whether claim 1 (and by extension all the challenged dependent claims) requires the claimed system to test for contraindications. The Board agreed with FMI that the claimed system does not require contraindication testing. *Decision I*, 2020 WL 2478691, at *6–8; *Decision II*, 2020 WL 2487140, at *6–9. The Board found "nothing in the language of claim 1 that requires the claimed system to specifically test for any contraindications or otherwise determine whether any therapeutic agents have a likely *lack* of benefit." *Id.*

The Board determined that the prior art disclosed all the limitations of claims 1–11 and 13–24 and that a person

of ordinary skill would have been motivated to combine the teachings to arrive at the claimed system with a reasonable expectation of success. *Decision I*, 2020 WL 2478691, at *11–15; *Decision II*, 2020 WL 2487140, at *11–12. Applying its construction, the Board found that “Von Hoff teaches most of the limitations” but “does not specifically mention lung cancer or identify the molecular targets.” *Id.* The Board determined that a person of skill in the art “would have been motivated to modify or substitute Von Hoff’s micro array analysis with the DASL Assay as taught by Illumina and Bibikova in order to provide a more comprehensive molecular profile that could be used to identify potential therapeutic agents for an individual with lung cancer.” *Id.*

The Board determined, however, that the prior art did not disclose all the limitations of claim 12. The Board construed claim 12 such that “the report generated . . . must do more than simply indicate that expression of the additional molecular target falls within a ‘normal’ range or that there is no change from the reference value for expression of that molecular target.” *Decision I*, 2020 WL 2478691, at *9. The Board required that “the report lists at least one additional molecular target (the contraindication target) for which the comparison to the reference value indicates a likely lack of benefit (contraindication) of at least one therapeutic agent as well as the additional therapeutic agent (the contraindicated agent).” *Id.*

The Board determined that FMI did not demonstrate that the prior art references disclose or render obvious the additional limitation in claim 12 “wherein the report further comprises a list of at least one additional molecular target for which the comparison to the reference value in (c) indicates a likely lack of benefit of at least one therapeutic agent and the at least one additional therapeutic agent.” The Board thus held that FMI failed to demonstrate unpatentability of claim 12. *Decision I*, 2020 WL 2478691, at *15–16. The Board also determined that Von Hoff’s system

and its report at Figures 3A–3D were insufficient to satisfy the requirements of claim 12. *Id.* at *16. The Board rejected FMI’s purported motivation to modify Von Hoff’s teachings to include “one additional target” in the report. *Id.*

Caris appealed, and FMI cross-appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

II. THE ’350, ’193, AND ’365 PATENTS

FMI petitioned for *inter partes* review of claims 1–14 of each of the ’350, ’193, and ’365 patents. Claim 1 of the ’193 patent is a representative independent claim.

1. A system for generating a report identifying at least one therapeutic agent for an individual with a cancer comprising:
 - a. at least one device configured to assay a plurality of molecular targets in a biological sample to determine molecular profile test values for the plurality of molecular targets, wherein the plurality of molecular targets comprises AR, EGFR, HER2, KIT, MLH1, PTEN, and PDGFRA; and
 - b. at least one computer database comprising:
 - i. a reference value for each of the plurality of molecular targets; and
 - ii. a listing of available therapeutic agents for each of the plurality of molecular targets;
 - c. a computer-readable program code comprising instructions to input the molecular profile test values and to compare each of the molecular profile test values with a

corresponding reference value from the at least one computer database in (b)(i);

d. a computer-readable program code comprising instructions to access the at least one computer database and to identify at least one therapeutic agent from the listing of available therapeutic agents for the plurality of molecular targets wherein the comparison to the reference values in (c) indicates a likely benefit of the at least one therapeutic agent; and

e. a computer-readable program code comprising instructions to generate a report that comprises a listing of the molecular targets for which the comparison to the reference value indicated a likely benefit of the at least one therapeutic agent in (d) and the at least one therapeutic agent identified in (d).

'193 patent at col. 17, ll. 2–32.

FMI alleged that claims 1–14 of each of the '350, '193, and '365 patents would have been obvious over Mou-Ying Fu Lu and Rong Yu, WO 03/017038 A2 (“Lu”) and Illumina. Lu teaches a computerized decision support system for selecting an optimum treatment for cancer based on a patient’s genotype. J.A. 6864. Lu’s physician interface module presents “recommendations as to the optimum drugs based on a patient genotype to the doctor” by “listing the benefits of the drug, the efficacy for the patient’s particular genotype, the drug’s side effects based upon the patient’s genotype and other relevant information.” J.A. 6876. Lu notes that the software may be “customized for a single disease or multiple diseases.” J.A. 6875. The “system can be used to identify an optimum drug for treating virtually any disease for which there exists an established correlation between a patient genotype and the efficacy

and toxicity of each of a group of drugs developed to treat the general condition.” J.A. 6879.

The Board instituted three trials and issued three written decisions concluding that FMI had demonstrated that claims 1–14 of each of the ’350, ’193, and ’365 patents would have been obvious over the prior art. *Decision III*, 2020 WL 2781576, at *23; *Decision IV*, 2020 WL 2789713, at *23; *Decision V*, 2020 WL 2789714, at *23. The Board first resolved the claim construction issue: whether the claims require a system that is cancer-lineage independent. Caris argued that “a ‘cancer-lineage independent’ system is one that ‘identif[ies] treatment options for a cancer patient independent of cancer type, based on groups of molecular targets not traditionally or conventionally associated with the patient’s specific cancer type.” *Decision III*, 2020 WL 2781576, at *8; *Decision IV*, 2020 WL 2789713, at *8; *Decision V*, 2020 WL 2789714, at *8. It is understood that the word lineage as used here means organ-based (e.g., lung, breast, kidney) as opposed to molecular target-based.

The Board, however, concluded that the claims were not restricted to a cancer-lineage independent approach. *Decision III*, 2020 WL 2781576, at *9–12; *Decision IV*, 2020 WL 2789713, at *9–12; *Decision V*, 2020 WL 2789714, at *9–12. The Board determined that nothing in the plain claim language requires the system to be a cancer-lineage independent system. *Id.* The Board also determined that the written descriptions and prosecution histories did not make clear that the claims require cancer-lineage independence. *Id.* The Board noted that adding a cancer-lineage independence requirement would result in ambiguity. *Id.*

Applying its construction, the Board determined that Lu and Illumina disclose all the limitations of the claims. *Decision III*, 2020 WL 2781576, at *15–17; *Decision IV*, 2020 WL 2789713, at *15–17; *Decision V*, 2020 WL

2789714, at *15–17. The Board noted that Caris had conceded that, if the Board “construed the claims as encompassing a ‘lineage dependent analysis,’ then the prior art taught the claimed subject matter.” *Id.* Furthermore, the Board determined that even if the claims did require a cancer-lineage approach, Lu and Illumina teach or suggest all elements of the claims because Illumina teaches a pan-cancer microarray of molecular targets and Lu, or the combination of Lu and Illumina, suggests a cancer-lineage independent system. *Id.*

Caris appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

We review claim construction *de novo* except for subsidiary factual findings based on extrinsic evidence, which we review for substantial evidence. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331–33 (2015). Obviousness is a question of law that “lends itself to several basic factual inquiries,” including the scope and content of the prior art, the level of ordinary skill in the art, and differences between the prior art and the claimed invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966) (citing *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 155 (1950)). We review the Board’s legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and the Board’s factual findings underlying those determinations for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence to support the finding. *See Consol. Edison Co. of New York v. NLRB*, 305 U.S. 197, 229 (1938).

Caris contends that the Board erred in concluding that claims 1–11 and 13–24 of the ’660 patent would have been obvious over the references. FMI asserts, in its cross-appeal, that the Board erred in concluding that FMI failed to demonstrate that claim 12 of the ’660 patent would have

been obvious. Caris also contends that the Board erred in concluding all of the '350, '193, and '365 patent claims would have been obvious. We address the parties' arguments on appeal below.

I. CARIS'S APPEAL CONCERNING THE '660 PATENT

Caris argues that the Board erred in construing the claims as not requiring utilization of contraindication information from molecular testing. Caris acknowledged that the Board's conclusion that claims 1–11 and 13–24 would have been obvious over the prior art was dependent on the Board's claim construction. *See* Appellant's Br. 32, 54. Resolution of this claim construction issue thus resolves the dispute as to whether the challenged '660 patent claims were unpatentable as obvious.

Caris contends that the Board's refusal to accept its proposed construction led to an unreasonably broad meaning, even under the broadest reasonable interpretation standard. Specifically, Caris argues that the Board's construction is inconsistent with the specification's description of the invention and with how a person of skill in the art would understand the claim language. Caris asserts that claim 1 recites testing for two markers that could only be used for contraindication testing: BRAF and PIK3CA. *See* '660 patent at col. 164, l. 46. In support of its argument, Caris points to Tables 1 and 2 and the report shown in Figures 40A–J. J.A. 199–238; J.A. 162–71.

FMI responds that the Board reasonably construed the claims as not requiring contraindication testing. Specifically, FMI argues that there is no textual basis in the claim language for requiring contraindication testing and that contraindication testing is only one of many embodiments in the '660 patent's written description. FMI also noted that Caris deleted a contraindication limitation from the claims of a parent application of the '660 patent, implying that lack of express inclusion confirms its absence. *See* Cross-Appellant's Br. 3 (describing the prosecution history

of U.S. Patent Application 12/658,770 (the '770 application)).

We conclude that the Board's construction was not unreasonably broad. Claim 1's language is not plainly limited to systems that use contraindication testing. The language of the claims and the '660 patent's written description support the Board's decision to refuse to import a contraindication requirement into all of the claims. Although the '660 patent may not describe available therapeutic agents for two of the targets recited in claim 1, claim 1 is not limited to specific assays and the '660 patent contemplates that the therapeutic agent database would be "continuously updated" as new agents and associations were discovered. '660 patent at col. 57 ll. 33–35. Although the claims may encompass systems that use contraindication information, Caris failed to demonstrate that a narrow construction is required. Considering the intrinsic evidence and the broadest reasonable interpretation standard, the Board did not err in its construction.

Regarding the parties' arguments about the prosecution history of the '770 application, although not dispositive, it is relevant that Caris previously sought claims that more clearly recited a system that identifies a treatment if a comparison "does not contraindicate the treatment for treating the cancer." *See Decision I*, 2020 WL 2478691, at *7; *Decision II*, 2020 WL , at *8. Although an exact term or phrase is not necessarily required to convey a limitation, the absence of the explicit terminology that Caris already used in a related application to claim contraindication testing further supports the Board's construction.

Given the construction of the claims, the Board's finding that FMI demonstrated that the prior art teaches or suggests all elements of claims 1–11 and 13–24 is supported by substantial evidence. As the Board noted, Caris's arguments in support of patentability are primarily dependent upon its claim construction position. J.A. 33. The

Board determined that Von Hoff teaches the identification of a therapeutic agent that is of likely benefit for a particular molecular target. *See Decision I*, 2020 WL 2478691, at *14–15; *Decision II*, 2020 WL , at *12. The Board credited the testimony of FMI’s expert in concluding that the prior art teachings are sufficient to satisfy the claim requirements and that a person of skill in the art would have been motivated to combine the prior art references. *Id.* In view of the evidence relied upon by the Board, the Board’s conclusion was well supported. Accordingly, we affirm the Board’s decision that claims 1–11 and 13–24 would have been obvious over the cited prior art. *See Decision I*, 2020 WL 2478691, at *16; *see also Decision II*, 2020 WL , at *13.

II. FMI’S CROSS-APPEAL

In its cross-appeal, FMI argues that the Board erred in construing claim 12’s “likely lack of benefit” as “contraindication.” FMI asserts that a “likely lack of benefit” means possibly not beneficial or effective. *See Cross-Appellant’s Br.* 50–51. Under a correct interpretation, according to FMI, Von Hoff discloses this claim limitation. However, FMI argues that, even under the Board’s construction, the Board’s conclusion that Von Hoff fails to disclose this limitation is unsupported by substantial evidence.

FMI argues that the Board erred by construing claim 12 to require contraindication testing. FMI argues that the intrinsic evidence does not support importing contraindication requirements into claim 12. Caris responds that the Board’s conclusion on claim 12 should be affirmed. Caris contends that there is no question that claim 12 reciting “a lack of clinical benefit” requires identification of contraindicated treatments.

We conclude that, in two respects, the Board’s construction of claim 12 was overly narrow. First, the Board construed claim 12 such that “the report generated . . . must do more than simply indicate that expression of the additional molecular target falls within a ‘normal’ range or

that there is no change from the reference value for expression of that molecular target.” However, this requirement imports extraneous detail into the claim 12 that is not supported by the intrinsic evidence. We discern no disclaimer or special definition in the intrinsic record that warrants excluding a “normal” or “no change” test value of a molecular target from the scope of claim 12.

Second, the language concerning “contraindications” was not required in claim 12’s construction. The parties do not dispute that the generally accepted meaning of a drug that is “contraindicated” is that the drug will be expected to have harmful effects on a patient. *See, e.g.*, Appellant’s Br. 8 n.2; Cross-Appellant’s Br. 16. But a “likely lack of benefit” encompasses more than merely scenarios in which an agent is harmful. The intrinsic evidence does not demonstrate the applicant’s intent to narrow the understanding of the term “likely lack of benefit.” We understand that Caris views “contraindication” to have a different meaning from the generally accepted one in the context of the specification and the Board’s construction. But we find the intrinsic evidence does not support equating “likely lack of benefit” to Caris’s specialized interpretation of “contraindication” either. It was therefore error for the Board to include the “contraindication” concept in its construction of claim 12. We therefore vacate the Board’s decision construing claim 12 and concluding that claim 12 was not unpatentable as obvious. *See Decision I*, 2020 WL 2478691, at *16.

III. CARIS’S APPEAL CONCERNING THE ’350, ’193, AND ’365 PATENTS

Caris argues that the Board erred in not construing the claims to require a cancer-lineage independent system. It argues that claim 1 does not reference any type of cancer, instead linking therapeutic agents to a group of lineage-independent targets such that a recommended therapeutic agent would necessarily be lineage independent. Caris

contends that the Board's construction is inconsistent with the specification and reads on prior art. Under a correct construction, according to Caris, the Board's conclusion that the claims would have been obvious over the prior art is unsupported by substantial evidence because the prior art only uses lineage-dependent systems.

FMI responds that there is no basis for interpreting the claims to require cancer-lineage independence. FMI asserts that the '350, '193, and '365 patents use phrases such as "independent of disease lineage diagnosis" and "not single disease restricted" to convey the concept of identifying a therapeutic agent independently of cancer lineage. *See, e.g.*, '350 patent at col. 2 ll. 28–33; *id.* at col. 2 ll. 39–47. According to FMI, there is no disclaimer or special definition in any of the written descriptions that justifies importing a requirement that the systems must be lineage independent.

We conclude that the Board's construction was consistent with the intrinsic evidence. Under the broadest reasonable interpretation standard, the Board properly analyzed the claim language and the patent specifications but found no evidence that the claims must exclude lineage-dependent systems. We thus conclude that the Board did not err in declining to construe the claims as requiring lineage independence.

Our affirmance of the Board's construction essentially requires that we affirm the Board's obviousness conclusion. Caris does not contest the Board's determination that, under the construction applied by the Board, the claims would have been obvious, and we discern no error with the Board's analysis of the prior art. In view of the evidence relied upon by the Board, we find the Board's conclusion to be supported by substantial evidence. Accordingly, we affirm the Board's decision that claims 1–14 of each of the '350, '193, and '365 patents would have been obvious over the cited prior art.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, with respect to the '660 patent, we *affirm* the portion of the Board's decision concluding that claims 1–11 and 13–24 would have been obvious and *vacate* the portion of the Board's decision construing claim 12 and concluding that claim 12 was not unpatentable as obvious (Appeal Nos. 2020-1886, -1890, -1930). We *remand* the Board's decision in IPR2019-00166 for further proceedings consistent with this opinion. With respect to the '350, '193, and '365 patents, we *affirm* the decisions of the Board (Appeal Nos. 2020-1887, -1888, -1889).

**AFFIRMED-IN-PART, VACATED-IN-PART, AND
REMANDED**

COSTS

No costs.