PUBLIC VERSION

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Paper 107
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS LLC,
Petitioner,

v.

LONGHORN VACCINES & DIAGNOSTICS, LLC,
Patent Owner.

IPR2021-00847 (Patent 8,084,443 B2)
IPR2021-00850 (Patent 8,293,467 B2)
IPR2021-00854 (Patent 8,669,240 B2)
IPR2021-00857 (Patent 9,212,399 B2)
IPR2021-00860 (Patent 9,683,256 B2)[1]

Before GEORGIANNA W. BRADEN, ZHENYU YANG, WESLEY B. DERRICK, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PER CURIAM

BRADEN, *Administrative Patent Judge*, CONCURRING.

ORDER
Granting Petitioner's Motions for Sanctions
37 C.F.R. §§ 42.5, 42.11, and 42.12

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[1] This Order addresses issues that are the same in each of the above-listed proceedings unless otherwise indicated. We issue one Order to be filed in each proceeding. The listing of all the Judges here does not expand any of the panels. The parties are not authorized to use this heading style in any subsequent papers.

INTRODUCTION

The above-captioned proceedings involve parties Spectrum Solutions LLC ("Petitioner") and Longhorn Vaccines & Diagnostics ("Patent Owner"). In these proceedings, we determine that Patent Owner, through its counsel, failed to meet its duty of candor and fair dealing in its actions before the Board. Patent Owner conducted, and relied on, biological testing in an attempt to distinguish the asserted Birnboim reference in each proceeding, but selectively and improperly withheld material results that were inconsistent with its arguments and the patentability of both original and proposed substitute claims. Finding Patent Owner's actions wholly inconsistent with meeting the duty of candor and fair dealing, we determine the sanctions of adverse judgment as to all challenged claims and denial of revised motions to amend are appropriate.

PROCEDURAL POSTURE

Petitioner sought *inter partes* review as set forth in its Petitions, on which we instituted review,[2] for U.S. Patent Nos.: 8,084,443 B2 (IPR2021-00847, Papers 1 (petition challenging claims 1–51)), 13 (institution decision, "the '847 Dec."); 8,293,467 B2 (IPR2021-00850, Papers 1 (petition challenging claims 1–42)), 13 (institution decision, "the '850 Dec."); 8,669,240 B2 (IPR2021-00854, Papers 1 (petition challenging claims 1–35)), 12 (institution decision, "the '854 Dec.")); 9,212,399 B2 (IPR2021-

[2] Petitioner also filed a Petition for *inter partes* review of U.S. Patent No. 8,415,330 B2, for which we denied institution. IPR2021-00851, Papers 1, 13.

00857, Papers 1 (petition challenging claims 1–35), 12 (institution decision, "the '857 Dec.")); and 9,683,256 B2 (IPR2021-00860, Papers 1 (petition challenging claims 1–20), 12 (institution decision, "the '860 Dec.")). Thereafter, in each instituted IPR,[3] Longhorn Vaccines & Diagnostics, LLC ("Patent Owner") filed a Patent Owner's Response,[4] Petitioner filed a Reply to Patent Owner's Response,[5] and Patent Owner filed a Sur-Reply to Petitioner's Reply.[6]

In each proceeding, Patent Owner also filed a Contingent Motion to Amend (*see, e.g.*, IPR2021-00847, Paper 21 ("original MTA")), and Petitioner filed an Opposition to the Motion to Amend (*see, e.g.*, *id.*, Paper 40). We issued Preliminary Guidance on the original MTA, for each proceeding, indicating our initial, preliminary, non-binding views that Petitioner had established a reasonable likelihood that the proposed substitute claims are unpatentable. *See* Paper 49. Thereafter, Patent Owner

[3] We cite throughout this decision to Papers filed in the IPR2021-00847 IPR, as representative, when appropriate, of corresponding Papers filed in each case. Unless otherwise noted, papers and exhibits cited are from IPR2021-00847.

[4] Patent Owner originally filed its Response on February 11, 2022. IPR2021-00847, Paper 22. It later sought, and we granted, leave to amend the Patent Owner Response. *Id.* Papers 52, 61. After filing the Amended Patent Owner Response (Paper 65), Patent Owner again sought, and we granted, leave to correct certain citations therein (Ex. 3009). Patent Owner filed a corrected Amended Patent Owner Response. Paper 105.

[5] IPR2021-00847, Paper 39.

[6] Patent Owner originally filed the Sur-Reply on June 17, 2022. IPR2021-00847, Paper 54. It later sought, and we granted, leave to correct certain citations therein (Ex. 3009). Patent Owner filed a corrected Sur-Reply. Paper 106.

filed a Revised Contingent Motion to Amend (Paper 90, "revised MTA"),[7] Petitioner filed an Opposition to the revised MTA (Paper 67), Patent Owner filed a Reply in support of its revised MTA in each case (Paper 78, "MTA Reply"), and Petitioner filed a Sur-Reply to the MTA Reply (Paper 95).

Patent Owner engaged Assured Bio Labs, LLC ("ABL" or "Assured Bio"), to conduct biological testing in support of its Response and MTA. Ex. 2019, 1 ("Assured Bio has been tasked by Remenick PLLC with testing nuclease inactivation and antimicrobial activity of 2 different solutions.") (filed Feb. 11, 2022). In connection with Petitioner's deposition of Assured Bio employees, the parties contacted the Board with a dispute as to the attorney work product objections Patent Owner raised in these depositions. The objections were discussed during a conference call on March 30, 2022, with the parties and Judges Braden, Derrick, Pollock, and Yang. *See* Exs. 3004–3006. After authorized briefing on the issue (IPR2021-00847, Papers 28, 32), we issued an Order authorizing additional questioning on certain testing and ordering Patent Owner to serve any relevant inconsistent information as required by 37 C.F.R. § 42.51(b)(iii) (Paper 34, "Order").

Patent Owner made three Assured Bio witnesses available for further cross examination and served Petitioner additional documents relating to its testing. *See* Exs. 1069, 1072–1073 (deposition transcripts), 1201–1211 (documents filed as exhibits by Petitioner after service by Patent Owner).

[7] Patent Owner originally filed its Revised Contingent Motion to Amend on June 17, 2002. Paper 55. It later sought, and we granted, leave to "make two clerical corrections to its revised contingent Motion to Amend." IPR2021-00847, Ex. 3010.

Petitioner sought authorization to file a motion for sanctions, and in compliance with Rule 42.11(d)(2) (requiring that "[a]t least 21 days prior to seeking authorization to file a motion for sanctions, the moving party must serve the other party with the proposed motion."), served Patent Owner with a copy of its motion prior to filing and, in turn, Patent Owner served Petitioner an Amended Response and exhibits; authorization for Petitioner to file its motion was discussed during a conference call on June 13, 2023. *See, e.g.*, Ex. 1081. During the conference call, we authorized Petitioner to file a Motion for Sanctions absent any substantive revision to Patent Owner's Amended Response and exhibits served on Petitioner. *Id.* 21:1–22:9.

As authorized, Petitioner filed a Motion for Sanctions. *See, e.g.*, IPR2021-00847, Paper 56. Petitioner requested: (1) entering judgment against Patent Owner; (2) holding that a particular reference meets particular claim limitations and precluding Patent Owner from contesting otherwise; and (3) providing Petitioner compensatory expenses, including attorney fees. *Id.* at 1–2. Patent Owner filed an Opposition to the Motion for Sanctions. Paper 76. Patent Owner contends that Patent Owner's conduct does not warrant sanctions, and that the requested sanctions are improper and disproportionate given the lack of harm. *Id.* An oral hearing on the issue of sanctions was held on August 16, 2022 ("Motions Hearing"), a transcript of which is of record. Paper 104. An oral hearing as to the merits of the cases was held on August 19, 2022 ("Merits Hearing"), and the transcript of that hearing is also of record. Paper 108.

PARTIES' DUTY OF CANDOR AND GOOD FAITH

It is well established that parties and individuals involved in any proceeding before the Board "have a *duty of candor and good faith* to the Office during the course of a proceeding" (emphasis added). 37 C.F.R. § 42.11(a); *see also Patent Quality Assurance, LLC v. VLSI Tech. LLC*, IPR2021-01229, Paper 102 ("*PQA*") at 23 (PTAB Dec. 22, 2022) (precedential) (quoting same); *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Paper 102 ("*OpenSky*") at 17 (PTAB Oct. 4, 2022) (precedential) (quoting same). Rule 42.11 further sets forth that, a practitioner, "[b]y presenting to the Board a petition, response, written motion, or other paper" "attests compliance with . . . § 11.18(b)(2)." 37 C.F.R. § 42.11(c). Rule 11.18(b)(2) states that

> (2) *To the best of the party's knowledge, information and belief*, formed after an inquiry reasonable under the circumstances,
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> (i) The paper is not being presented for any improper purpose,
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> . . .
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> (iii) The *allegations and other factual contentions have evidentiary support* or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and
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> (iv) The *denials of factual contentions are warranted on the evidence*, or if specifically so identified, are reasonably based on a lack of information or belief.

37 C.F.R. § 11.18(b)(2) (emphasis added).

Rule 11.106—Confidentiality of information—requires that "[a] practitioner shall disclose to the Office information necessary to comply with applicable duty of disclosure provisions." 37 C.F.R. § 11.106(c).

Rule 11.303—Candor toward the tribunal—similarly requires that "a practitioner shall disclose to the Office information necessary to comply with applicable duty of disclosure provisions." *Id.* § 11.303(e).

Rule 1.56, also addressing the duty of candor and good faith, similarly sets forth that "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." 37 C.F.R. § 1.56(a). Rule 1.56 further states that "information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and . . . (2) [i]t refutes, or is inconsistent with, a position the applicant takes in: . . . (ii) [a]sserting an argument of patentability." *Id.* § 1.56(b).

Our rules also provide for routine discovery, that is, an obligation to disclose certain information and materials to other parties (and the Board). 37 C.F.R. § 42.51(b)(1). Routine discovery includes the service of "any exhibit cited in a paper or in testimony" together with "the citing paper or testimony." *Id.* § 42.51(b)(1)(i). It also includes "[c]ross examination of affidavit testimony prepared for the proceeding." *Id.* § 42.51(b)(1)(ii). Finally, it requires the service of

> 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. This requirement does not make discoverable

> anything otherwise protected by legally recognized privileges such as attorney-client or attorney work product.

Id. § 42.51(b)(1)(iii).

Furthermore, with respect to complying with its duties before this tribunal, "Fairness to opposing party and counsel" under our Rule 304 requires that "[a] practitioner shall not: . . . Knowingly disobey an obligation under the rules of a tribunal except for an open refusal based on an assertion that no valid obligation exists." 37 C.F.R. § 11.304(c).

AUTHORITY FOR SANCTIONS

> The Board has the authority to
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> impose a sanction against a party for misconduct, including:
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> (1) Failure to comply with an applicable rule or order in the proceeding;
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> . . .
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> (3) Misrepresentation of a fact;
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> . . .
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> (7) Any other improper use of the proceeding, including actions that . . . cause unnecessary delay or an unnecessary increase in the cost of the proceeding.

37 C.F.R. § 42.12(a); *cf. PQA* at 3 ("Failure to comply with an order is sanctionable." (citing 37 C.F.R. § 42.12(a)(1)), *id.* at 4 ("Each aspect of PQA's conduct—discovery misconduct, violation of an express order, abuse of the IPR process, advancing a misleading argument, and a misrepresenting of fact—taken alone, constitutes sanctionable conduct." (citing 37 C.F.R. § 42.12(a)(1)–(3), (6)); *OpenSky* at 2–3 ("Failure to comply with an order is sanctionable." (citing 37 C.F.R. § 42.12(a)(1)); *id.* at 3 ("Each aspect of

OpenSky's conduct—discovery misconduct, violation of an express order, abuse of the IPR process, and unethical conduct—taken alone, constitutes sanctionable conduct.") (citing 37 C.F.R. § 42.12(a)(6)).

> Sanctions include entry of one or more of the following:
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> (1) An order holding facts to have been established in the proceeding;
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> (2) An order expunging or precluding a party from filing a paper;
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> (3) An order precluding a party from presenting or contesting a particular issue;
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> (4) An order precluding a party from requesting, obtaining, or opposing discovery;
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> (5) An order excluding evidence;
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> (6) An order providing for compensatory expenses, including attorney fees;
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> (7) An order requiring terminal disclaimer of patent term; or
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> (8) Judgment in the trial or dismissal of the petition.

37 C.F.R. § 42.12(b).

Imposition of sanctions is discretionary, and sanctions are subject to review for an abuse of discretion by the Federal Circuit; "[a]n abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." *Abrutyn v. Giovanniello*, 15 F.3d 1048, 1050–51 (Fed. Cir. 1994) (citing *Heat & Control, Inc. v. Hester Indus., Inc.*, 785 F.2d 1017, 1022 (Fed. Cir. 1986)).

In *Abrutyn*, the court affirmed the Board entering default judgment against a party to an interference for failing to file preliminary papers by deadlines set by rule. *Id.* at 1052–53. The court found that "[t]he Board could have reasonably concluded that [the party's] deliberate inaction was egregious behavior which made appropriate imposition of a default judgment . . . because lesser sanctions would not have effectively protected the PTO's interests. Those interests include creating sufficient deterrence for like cases in the future." *Id.* at 1053; *see also PQA* at 4 (determining the sanctions imposed "necessary to deter such conduct by PQA and others in the future") (citing 37 C.F.R. § 42.11(d)(4)); *OpenSky* at 4 (determining the sanctions imposed "necessary to deter such conduct by OpenSky or others in the future") (citing 37 C.F.R. § 42.11(d)(4)).

ATTORNEY WORK-PRODUCT DOCTRINE

The work-product doctrine "can protect 'documents and tangible things' prepared in anticipation of litigation that are both non-privileged and relevant." *In re EchoStar Comms. Corp.*, 448 F.3d 1294, 1301 (Fed. Cir. 2006) (citing Fed. R. Civ. P. 26(b)(3)). However, the work-product doctrine is not absolute and generally allows for "a party to discover certain types of work product if they have 'substantial need of the materials in the preparation of the party's case and that party is unable without undue hardship to obtain the substantial equivalent . . . by other means.'" *Id.* at 1302 (citing Fed. R. Civ. P. 26(b)(3)) (alteration in original). "This rule . . . allows discovery of 'factual' or 'non-opinion' work product and requires a court to 'protect against the disclosure of the mental impressions,

conclusions, opinions, or legal theories of an attorney or other representative.'" *Id.*

Work product protection may be extended to documents prepared in anticipation of proceedings before the Board. *In re Natta*, 410 F.2d 187, 192 (3rd Cir. 1969) (*cert. denied*) (involving a patent interference).

The scope of attorney work product protection before the Office is limited. *Cf. Natta v. Hogan*, 392 F.2d 686, 693 (10th Cir. 1968) ("Phillips has a duty to disclose to the Patent Office all facts relating to the possible equities of the patent application. It cannot hide behind the work product doctrine the research, tests, and experiments which are pertinent to the patent application." (footnote omitted)). The doctrine does not excuse the failure to disclose such material information subject to the duty of candor and good faith. *Cf. Knogo Corp. v. U.S.*, 1980 WL 39083, *4 (Ct. C. 1980) (holding "[attorney-client] privilege only applies to the communication that takes place between the attorney and the client" and that "[i]t does not apply to the technical information itself, so long as that technical information is sought by other techniques outside of the context of the attorney-client communication."). "The expectation of confidentiality applies to the communication, but not to the information contained in the communication." *Id.* (citing *In re Ampicillin Antitrust Litigation*, 81 F.R.D. 377, 389, n.23 (D. D.C. 1978)). In this regard, *Knogo* explains that "[t]he attorney 'has no duty to transmit information which is not material to the examination of the application'" (*id.* at *5 (quoting 37 C.F.R. § 1.56(b) (1979))), demonstrating a duty to transmit, that is, to disclose, information to the Office that is material.

A high degree of candor and good faith is required of attorneys appearing before the Patent Office, including any proceeding seeking patent claims. *See Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949) (agreeing with the statement, "[b]y reason of the nature of an application for patent, the relationship of attorneys to the Patent Office requires the highest degree of candor and good faith."); *see also* 37 C.F.R. § 1.56 (a) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that information to be material to patentability."). In addressing whether client communications with non-attorney patent agents are privileged, Judge Reyna (in dissent) similarly highlighted that "[u]nder Patent Office regulations, patent lawyers, patent agents, inventors, and assignees, . . . have 'a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability' of an application" and that, if properly informed of their duty, "the client will know that she has a duty to reveal . . . [pertinent] information to her attorney or agent, and that he must reveal it to the Patent Office if he believes it is material to patentability." *In re Queens University at Kingston*, 820 F.3d 1287, 1304 (Fed. Cir. 2016) (Reyna, dissenting) (citing *Kingsland v. Dorsey*, 338 U.S. at 319; 37 C.F.R. § 1.56). Judge Reyna further explains that the patent agent-client privilege found by the majority "can be effective only to encourage the disclosure of information that the client does not believe is material to whether the invention is patentable" because "patent agents and clients are subject to a duty of candor before the USPTO." *Id.*

Although privilege may be asserted to prevent disclosure of attorney-client communications and attorney work product, these doctrines cannot be used to shield *factual information* from discovery that is inconsistent with positions taken by a party before the Board. *See* 37 C.F.R. § 42.51(b)(1)(iii) ("This requirement [to serve relevant information that is inconsistent with a party's position] does not make discoverable anything otherwise protected by legally recognized privileges such as attorney-client or attorney work product."); *cf. Upjohn Co. v. United States*, 449 U.S. 383, 395 (1981) ("The [attorney-client privilege] only protects disclosure of communications; it does not protect disclosure of the underlying facts by those who communicated with the attorney."); *In re Unilin Décor N.V.*, 153 F. App'x 726, 728 (Fed. Cir. 2005) (non-precedential) (quoting *Resolution Trust Corp. v. Dabney*, 73 F.3d 262, 266 (10th Cir. 1995) ("Because the work product doctrine is intended only to guard against divulging the attorney's strategies and legal impressions, it does not protect facts concerning the creation of work product or facts contained within the work product."). "Parties and individuals involved in a proceeding before the Board have a duty of candor and good faith to the Office during the course of the proceeding." 37 C.F.R. § 42.11(a); *OpenSky* at 17. A party should not take a position that is contrary to any fact known to the party, without disclosing that fact, even if it could otherwise withhold the information as not being material to patentability, or being privileged, because taking such a position while shielding the factual information from the Board violates the duty of candor and good faith to the Office.

As noted above, Rules 11.106 (Confidentiality of information) and 11.303 (Candor toward the tribunal) require that "[a] practitioner shall disclose to the Office information necessary to comply with applicable duty of disclosure provisions" (37 C.F.R. §§ 11.106(c), 11.303(e)), and Rule 11.304 (Fairness to opposing party and counsel) requires, at the very least, that refusal to comply with any disclosure rule must be done openly, with an assertion that there is no valid obligation to comply (*id.* §11.304(c)).

Cases cited by Patent Owner throughout these proceedings are not contrary to the duty of candor and good faith to the Office. *See, e.g.*, IPR2021-00847, Paper 32. *Pevarello v. Lan*, 2007 WL 594728 at *12 (BPAI 2007), cited by Patent Owner for "protecting draft report[s] from discovery" (IPR2021-00847, Paper 32, 1) stands for protecting draft reports and communications between experts and counsel, not to excuse the duty of Patent Owner to disclose factual information contrary to positions it takes in a proceeding before the Office, including any factual information material to patentability when seeking issuance of claims.

Employees Committed for Justice v. Eastman Kodak, Company, 251 F.R.D. 101, 104 (W.D.N.Y. 2008), cited by Patent Owner (IPR2021-00847, Paper 32, 1–2), and not involving any proceeding before the Patent Office, similarly does not excuse the duties of parties before the Patent Office. Rather, *Employees Committed* simply stands for the proposition that "[w]hen an expert serves as a testifying witness, Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure requires disclosure of materials considered, reviewed or generated by the expert in forming the opinion, irrespective of

whether the materials were actually relied on by the expert." *Employees Committed*, 251 F.R.D. at 104.

Positive Technologies, Inc. v. Sony Electronics, 2013 WL 1402337 at *2, *5 (N.D. Cal. 2013), cited by Patent Owner (IPR2021-00847, Paper 32, 2), likewise does not excuse the duties of parties before the Patent Office, as it involves a Federal District Court proceeding, not a proceeding before the Patent Office.

As to *Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00044, Paper 25 (PTAB June 21, 2013) ("*Corning*"), cited by Patent Owner (IPR2021-00847, Paper 76, 6–7), this case does not stand for the proposition set forth by Patent Owner—that Board rules "exclud[ing] from mandatory 'routine discovery' anything 'otherwise protected by legally recognized privileges such as attorney-client or attorney work product'" exclude factual information material to patentability from mandatory routine discovery (*id.* at 6 (citing 37 C.F.R. § 42.51(b)(1)(iii))).[8] As expressly set forth in *Corning*, there were three discovery requests, but none of the materials at issue were "routine discovery" and, as such, do not fall under Rule 42.51(b)(1). *Corning*, 3 (determining the first discovery request "a request for additional discovery under 37 C.F.R. § 42.51(b)(2)"), 5 (determining the second discovery request "a request for additional discovery"), 6–7

[8] Rule 42.51 requires the service of "relevant information that is inconsistent with a position advanced by the party during the proceeding concurrent with the filing of the documents . . . that contain[] the inconsistency" but that "[t]his requirement does not make discoverable anything otherwise protected by legally recognized privileges." 37 C.F.R. § 42.51(b)(1)(iii).

(determining the third request fulfilled as to "routine discovery"—relating to information and results inconsistent with arguments— and then denying the request for "a privilege log" under the standards for "additional discovery").

Attorney work product doctrine does not negate the duty of candor due the Office to, at the very least, communicate factual information that is material to patentability of claims during examination or is inconsistent with any argument or position taken during a proceeding before the Office.

Furthermore, as noted above, our Rules specifically require that when information is withheld because it is confidential, that "[a] practitioner shall disclose to the Office information necessary to comply with applicable duty of disclosure provisions." 37 C.F.R. §§ 11.106(c) & 11.303(e). And disobeying an obligation, including the obligation to disclose information contrary to a position taken by a party, including information material to patentability, further requires a party or practitioner to make "an open refusal based on an assertion that no valid obligation exists" (*id.* § 11.304(c)), and not simply to decline to make the required disclosure to the Board and/or any opposing party.

PATENT OWNER'S ACTIONS

In our Decisions instituting *inter partes* review, we determined that "Patent Owner implicitly relies on narrow constructions of 'kill pathogens' and 'not degrade nucleic acids.'" '847 Dec. 9 n.13. As to "kill pathogens," we further determined that "[o]n their face, . . . the claims do not require killing every potential pathogen in a sample." *Id.* at 17. We also expressly stated that "we do not read the challenged claims as requiring the claimed

composition to clear every sample of every type of pathogenic agent" (*id.* at 17–18), and that "we decline" to modify the plain meaning of the claims to reflect Patent Owner's contentions grounded on "render[ing] the sample sufficiently or entirely non-pathogenic to allow safe handling and transport of the sample" (*id.* at 18).

As to "not degrad[ing] nucleic acids," we further determined Petitioner had "met its burden in showing that Birnboim discloses 'not degrad[ing] nucleic acid of a sample' under the term's plain and ordinary meaning." *Id.* at 22 (alteration in original). That is, we determined the phrase "not degrade nucleic acids" has its plain and ordinary meaning. *Id.*

Following institution, in each proceeding, Patent Owner filed a Response in which, as discussed in detail below, Patent Owner repeats many of its claim construction arguments we rejected in the institution decisions. IPR2021-00847, Paper 22 ("Original PO Resp."). Patent Owner contends that "the claim phrase 'kill pathogens' should be construed to mean: 'rendering the sample substantially non-pathogenic'" (*id.* at 3) and that to "not degrade nucleic acid," must be read in context of "inactivate nucleases"—contended to require inactivation of both DNA and RNA nucleases—such that both RNA and DNA must be preserved (*id.* at 14, 16). Applying its preferred constructions, Patent Owner then argues that Birnboim—the primary reference relied on for each ground in each of the IPR proceedings—sets forth an exemplary formulation, in its Example 3, and that the exemplary formulation fails both to "kill pathogens" and to "not degrade nucleic acid." *Id.* at 17–18, 22–25.

Further applying its preferred constructions, Patent Owner also contends that

> [N]othing in Birnboim teaches that its compound [sic] . . . is bactericidal, let alone kills pathogens (including viruses and fungi) sufficient to render a sample substantially non-pathogenic. Even if Petitioner could show that Birnboim teaches a compound that would lyse some small subset of individual pathogen cells from a sample, that is a far cry from, and nothing in Birnboim teaches, rendering a sample substantially non-pathogenic.
>
> Moreover, unlike Petitioner's reliance on generalizations, assumptions, and conjecture about what effect Birnboim's composition may have on pathogens, Patent Owner has undertaken testing of a sample composition prepared according to Birnboim Example 3. Testing showed that Birnboim's composition failed to kill the vast majority of both viral and bacterial pathogen organisms in a sample. Birnboim's compound did not render a sample substantially non-pathogenic.

Id. at 17–18 (citing Ex. 2015 ¶¶ 24–26; Ex. 2018).

In making these arguments, Patent Owner and its declarant, Dr. DeFilippi, rely only on tests using MS2 virus and *B. subtilis* bacterial spores. *Id.* at 18; Ex. 2015; Ex. 2019. Patent Owner relies on this testing using this virus and these bacterial spores to show that a composition disclosed in Birnboim's Example 3, failed to kill the vast majority of both viral and bacterial pathogen organisms in a sample. Original PO Resp. 18; Ex. 2015 ¶¶ 24–26; Ex. 2019, 2. Patent Owner sets forth, specifically, that it "has undertaken testing of a sample composition prepared according to Birnboim Example 3. Birnboim's compound did not render a sample

substantially non-pathogenic." Original PO Resp. 18 (citing Ex. 2015 ¶¶ 24–26; Ex. 2018; Ex. 2001). Patent Owner contends that "[a]s such, under an appropriate claim construction, Birnboim cannot anticipate claim 1 or its dependent claims." *Id.* Patent Owner also relies on the testing as to "not degrad[ing] nucleic acid," contending that "Birnboim Example 3 does not preserve RNA at all, and discloses preserving 50% of the DNA in a sample, but discloses nothing about preserving any more than 50% of the DNA in the sample, let alone nearly all of it" and, thus, falls "far short of 'does not degrade nucleic acid of a sample' under the proper claim construction." *Id.* at 22 (citing Ex. 2015 ¶ 18).

In addition, Patent Owner filed a Contingent Motion to Amend under 37 C.F.R. § 42.121 in each proceeding. The originally proposed substitute claims included further limitations, including those directed to: a composition biologically inactivating a sample suspected of containing pathogens (IPR2021-00847, Original MTA, App'x A, claim 52); a method for denaturing proteins, inactivating nucleases and killing pathogens without degrading nucleic acids of a biological sample suspected to contain pathogens wherein a portion of cells are lysed (IPR2021-00850, Paper 21, App'x A, claim 43); a composition that, when contacted with a sample, renders the sample substantially non-pathogenic (IPR2021-00854, Paper 20, App'x A, claim 36); a stock solution that kills pathogens that may be present in a sample thereby rendering the sample substantially non-pathogenic (IPR2021-00857, Paper 20, App'x A, claim 36); and a stock solution that, when combined with a biological sample suspected of containing a

pathogen, kills pathogens and renders the biological sample substantially non-pathogenic (IPR2021-00860, Paper 20, App'x A, claim 21).

In each Contingent Motion to Amend, Patent Owner contended that the substitute claims cited above, and others, are patentable over every instituted ground for the same reasons as the original claims, including those grounded on the requirement of the claims to kill pathogens and to not degrade nucleic acid of the sample contacted with the composition (or stock solution). *See, e.g.*, IPR2021-00847, Paper 21, 13–24.

In each proceeding, Patent Owner took the position that the original claims, and the substitute claims, should be construed to require that "kill pathogens" means not only killing pathogens, and not only killing all pathogens that are present, but still further to meet standards for safe transportation and handling of treated specimens without additional safety protocols. *See, e.g.*, Original PO Resp., Paper 22, 3–10 (arguing patentability of original claims); IPR2021-00847, Paper 21, 13–24 (arguing patentability of proposed substitute claims for the same reasons as original claims). Patent Owner also took the position that to "not degrade nucleic acids," means that no significant portion of nucleic acid is degraded, whether that nucleic acid is DNA or RNA, and also that an inability to preserve both DNA and RNA, whether both are present or not, constitutes a failure to "not degrade nucleic acids." *See, e.g.*, Original PO Resp., 10–17 (including discussion of inactivating nucleases); IPR2021-00847, Paper 54, 1–4.

Patent Owner then relies on these claim construction positions in determining what it is obligated to disclose in these proceedings. But in ignoring the alternative constructions discussed in the institution decisions,

Patent Owner unduly limits the scope of its obligatory disclosures to the Office and Petitioner, omitting data and information it should have disclosed under the duty of candor and fair dealing. Even though our claim construction in the institution decisions was preliminary, it clearly indicates the scope of what the Board deemed relevant to the issue of patentability in these proceedings. As discussed above, in the institution decisions, we expressly rejected the notion that "killing pathogens" required anything more than killing a subset of pathogens present—or potentially present—in a sample. *See, e.g.*, '847 Dec. 18–19. Also, with respect to preserving nucleic acids (or inactivating nucleases), as discussed above, we similarly determined that it was enough to preserve a significant amount of a nucleic acid present in a sample; that is, it was neither necessary that there was a capability to preserve nucleic acids that were not present nor was it necessary that the methods or solutions had to preserve both DNA and RNA. *See, e.g.*, *id.* at 21–22 (determining that preservation of some significant fraction of *DNA* sufficient to meet the plain and ordinary meaning of the term "not degrade nucleic acid").

The proposed substitute claims submitted with the Original Motions to Amend likewise oblige Patent Owner to disclose the same such omitted data and information. Specifically, the added limitations, on their face, do not require what Patent Owner contends is required by the original claims, which is Patent Owner's apparent basis for withholding the data and information at issue. In IPR2021-00847, substitute claim 52, for example, adds that "the sample is biologically inactivated when contacted by the composition," but the recited sample is merely "a sample *suspected of*

containing pathogens." IPR2021-00847, Paper 21, App'x A (emphasis added). The additional claim language does not bridge the gap between inactivating what is *actually* present, in accordance with our preliminary claim construction, and being capable of inactivating any further pathogen that could *potentially* be present in the sample, in accordance with Patent Owner's contended construction for the original claims. *Id.*

Likewise, in IPR2021-00850, substitute claim 66 adds to "killing pathogens" "thereby rendering a biological sample substantially non-pathogenic" (IPR2021-00850, Paper 21, App'x A); in IPR2021-00854, substitute claim 36 adds that "the sample [suspected of containing nucleic acids] is rendered substantially non-pathogenic when contacted by the composition" and deletes "one or more" as a modifier for "pathogens" (IPR2021-00854, Paper 20, App'x A); in IPR2021-00857, substitute claim 36 adds to "kills pathogens that may be present in the sample" "thereby rendering the sample substantially non-pathogenic" (IPR2021-00857, Paper 20, App'x A); and in IPR2021-00860, substitute claim 21 adds "thereby rendering the biological sample [suspected of containing a pathogen] substantially non-pathogenic" (IPR2021-00860, Paper 20, App'x A). Accordingly, we declined to adopt Patent Owner's proposed claim construction for the substitute claims in our Preliminary Guidance on the Motions to Amend. *See, e.g.*, IPR2021-00847, Paper 49, 9–10 (addressing enablement).

Patent Owner's positions as to "killing pathogens" and preserving nucleic acids (or inactivating nucleases) are also contrary to the express language of both original and proposed substitute dependent claims. That is,

there are dependent claims that cannot reasonably be construed to require killing broad categories of pathogens or to preserve both DNA and RNA. Although Patent Owner is free to maintain its arguments for, and arguments grounded on, its construction of these claims throughout this proceeding, doing so does not excuse Patent Owner's duty of candor and good faith dealing, including to disclose material information relating to our preliminary construction of the claims. Specifically, in IPR2021-00847, original claims 11, 34, and 51 of the '443 patent recite that "the pathogens" are one of several enumerated pathogens or categories of pathogen and claim 13 recites that the composition is "free of RNase *or* DNAse activity" (emphasis added). In IPR2021-00850, original claims 12 and 27 of the '467 patent are analogous to claim 11 of the '443 patent, reciting that the "pathogens are" one of several enumerated pathogens. In IPR2021-00854, original claim 14 of the '240 patent recites that the composition is "substantially free of RNase *or* DNase activity" (emphasis added) and claim 16 recites "isolated polynucleotides that comprise RNA, DNA, or a combination thereof." In IPR2021-00857, original claim 14 of the '399 patent recites "free of RNAse *or* DNAse activity" (emphasis added). In IPR2021-00860, original claim 11 of the '256 patent recites that "*the pathogen* [that claim 1 sets forth is killed by the stock solution] *is* hepatitis virus, papillomavirus, HIV, biological agent of SARS, corona virus, rotavirus, Influenza virus, Ebola virus, methicillin-resistant *Staphylococcus*, or *M. tuberculosis*" (emphasis added).

The corresponding substitute claims originally proposed for the claims cited above include the same language that makes plain that "killing

pathogens" does not require killing any and all pathogens that might be present, as the amendment from the original claims simply corrects the base claim from which they depend. *See, e.g.*, IPR2021-00847, Paper 21, App'x A, claims 62, 85, 102. Similarly, the corresponding originally proposed substitute claims that recite compositions substantially free of RNase or DNase activity and where the isolated polynucleotides can comprise RNA, DNA, or a combination, also plainly do not require that the claimed compositions are free of both RNase *and* DNase activity. *See, e.g.*, *id.*, claim 64. Patent Owner's positions as to "killing pathogens" and preserving nucleic acids (or inactivating nucleases) that it contends excuses its failure to disclose relevant material information are also contrary to the express language of the proposed substitute dependent claims in the same manner its positions are contrary to the original claims.[9] Accordingly, there is no reasonable basis for Patent Owner to withhold data and information that would be relevant when applying our preliminary claim construction as set forth in the institution decisions.

After Patent Owner filed its Original Patent Owner Response and Contingent Motion to Amend in each case, Patent Owner objected to questions during Petitioner's deposition of the ABL witnesses associated with the MS2 virus, *B. subtilis* bacterial spore, and nuclease inactivation

[9] The Revised Patent Owner Contingent Motions to Amend (and Corrected Revised Contingent Motion to Amend) maintained the same language as in the original claims, adding further limitations to the base claims, but only after Patent Owner's obfuscation of material test results was found out during these proceedings. *See, e.g.*, IPR2021-00847, Paper 55, App'x A, claims 62, 64, 85, 102; Paper 90, App'x A, claims 62, 64, 85, 102.

testing results. *See, e.g.*, IPR2021-00847, Ex. 1046, 22:18–23:5, 26:23–28:18. Patent Owner further instructed the witnesses not to answer these questions on the basis that information responsive to the questions would violate attorney work product privilege. *Id.*; Paper 28, 1. Petitioner contacted the Board with concerns that Patent Owner was improperly seeking to withhold relevant information relating to the testing Patent Owner had disclosed and relied on in its Response. Ex. 3006. The Board authorized Petitioner to file a motion seeking relief from the Board to overrule Patent Owner's attorney work product objections. Following briefing from both Petitioner (*e.g.*, IPR2021-00847, Paper 28) and Patent Owner (*e.g.*, *id.* Paper 32), we granted Petitioner's request for relief, overruling Patent Owner's objections, and granted additional time for deposing witnesses related to the testing. Specifically, we issued an Order (1) authorizing limited additional deposition of the relevant witnesses and (2) requiring that Patent Owner serve on Petitioner any relevant inconsistent information as required by 37 C.F.R. § 42.51(b)(1)(iii). *See, e.g.*, IPR2021-00847, Paper 34.

Patent Owner then subsequently complied with the Order, but maintains that the Order (*e.g.*, IPR2021-00847, Paper 34) is improper and that the testimony and test results should be limited to MS2 virus, *B. subtilis* spores, and RNase on the basis that the testing conducted on its behalf [redacted] is privileged as attorney work product (*see, e.g.*, IPR2021-00847, Paper 82, 11–15 (seeking to exclude Exhibits 1201–1211 that include testing and test results [redacted]

[redacted]).[10] Patent Owner further maintains that the withheld data was not "inconsistent with any statement in the Assured Bio witnesses' testimony, Exhibit 2019," and was not "inconsistent with anything that the patent owner has said." Paper 104, 63:12–18.

In complying with the Order, witnesses involved in conducting the testing provided additional testimony and Patent Owner served additional documents [redacted] (IPR2021-00847, Ex. 1071 ¶¶ 15–23; Exs. 1201, 1202, 1206, 2019), and [redacted] (IPR2021-00847, Ex. 1071 ¶¶ 24–30; Exs. 1206–1207).[11]

The additional documents that Patent Owner served on Petitioner, and which Petitioner then filed as Exhibits, describe testing conducted at or about the same time as the testing Patent Owner originally disclosed. These additional documents include the "Standard Operating Procedure" for "Remenick Solution Efficacy Testing" (Ex. 1206), which is analogous on its

[10] Patent Owner lists Exhibits 1200–1211, however, there is no Exhibit 1200.

[11] Unreported validation testing on *E. coli* by ABL, working on behalf of Patent Owner, showed Birnboim's composition also inactivated *E. coli*. *See* Ex. 1069, 236:11–237:15. This validation testing was not entered into the record as an exhibit or otherwise reported by Patent Owner. Rather, the testing came to light during the deposition of Dr. Birkebak. *See id*.

face with pages 4–7 of Exhibit 2019, and is similarly set forth within the document filed as Exhibit 2019 as the "Standard Operating Procedure" for "Remenick Solution Efficacy Testing." *Compare* Ex. 1206, *with* Ex. 2019, 4–7. Each of these documents includes an "Effective Date" of "1/7/2022." Ex. 1206, 1; Ex. 2019, 4. These "Standard Operating Procedure[s]" have overlapping "Experimental Start/End Date[s]," with that from Exhibit 1206 of "1/10/2022–Current" and from Exhibit 2019 of "1/10-2022–2/7/2022" that differ as to end dates.[12] Other differences between these two documents setting forth the "Standard Operating Procedure" for "Remenick Efficacy Testing" include that Exhibit 1206 also provides [redacted]. These "Standard Operating Procedure[s]" also differ in that Exhibit 1206 notes a "Testing Modification" in how the [redacted] experiments were conducted (Ex. 1206, § 8), while Exhibit 2019 does not identify any "Testing Modification," stating that there was "[n]one" (Ex. 2019, 7 (§ 8)).

As discussed above, Patent Owner argues in its Response that "kill pathogens" has a special limited meaning, that is, not only killing all pathogens that are present, but also that it meet standards for safe transportation and handling of treated specimens without additional safety

[12] The relevant time period for the Standard Operating Procedure set forth in Exhibit 1206—"1/10/2022–Current"—must reasonably be the same or similar to that set forth in Exhibit 2019—"1/10/2022–2/7/2022"—because the withheld testing data according to Exhibit 1206 was generated prior to filing Exhibit 2019, which was filed February 11, 2022. *See, e.g.*, IPR2021-00847, Ex. 1069 (269:15–270:8).

protocols. *See, e.g.*, Original PO Resp. 3–10. As also discussed above, Patent Owner takes the position that to "not degrade nucleic acids," means that no significant portion of nucleic acid is degraded, whether that nucleic acid is DNA or RNA, and that an inability to preserve both DNA and RNA, whether both are present or not, constitutes a failure to "not degrade nucleic acids." *See, e.g.*, *id.* at 14 ("a [person of ordinary skill in the art's] understanding of 'does not degrade nucleic acid aligns with . . . a high level of stability such that very little, e.g., 1–2%, of the polynucleotides are degraded"), 14–15 (arguing that "the use of the plural term 'nucleases' in the claims and consistent pairing of RNA/DNA in the Specification" would lead a person of ordinary skill in the art to "understand that 'inactivate nucleases' in the claims of the '443 patent [to] require[] inactivation of both RNA and DNA nucleases (DNase and RNase)").

Patent Owner relies on these same claim construction positions in arguing for the patentability of its proposed substitute claims over the instituted grounds for the same reasons as the original claims; contending substitute claims are "patentable over every Ground . . . for the same reasons as the original claim[s]." *See, e.g.*, IPR2021-00847, Paper 21, 13 (for substitute claim 52 to replace claim 1), 21 (for substitute claim 99 to replace claim 48). Moreover, as discussed above, the additional limitations added by amendment to the original proposed substitute claims do not, on their face, require killing all such potential pathogens so as to meet standards for safe transportation and handling of treated specimens without additional safety protocols and preserving both DNA and RNA of a pathogen that may be present.

In sum, the relevant limitations in both the original claims and the substitute claims in the Original Motions to Amend require, as to killing pathogens, nothing more than killing, or being able to kill, pathogens that are present in the sample set forth in the claims, such as a sample suspected of containing a pathogen, and, as to preserving either DNA *or* RNA, as is accomplished by inactivating DNAse and/*or* RNAse.

The testing data that Patent Owner initially withheld [redacted], and related information, is relevant to the patentability of the claims as we construed them in the institution decisions, as this data demonstrated "killing pathogens" under our preliminary construction. Moreover, the testing data that Patent Owner withheld is also relevant to the patentability of the claims as Patent Owner seeks to construe them. Particularly as set forth during the Merits Hearing, as Patent Owner attempted to clarify its position, Patent Owner's construction would not require that the recited solutions be capable of killing any potential pathogen:

> JUDGE DERRICK: [D]oes your claim construction require the composition to kill any and all potential pathogens?
>
> MR. WILLIAMS: I don't believe that that has been our position. So my understanding is that when the sample is contacted with the composition, the claims that recite kill pathogens, so in four of the five patents, require that the sample be rendered substantially nonpathogenic and safe for human handling.
>
> JUDGE DERRICK: Okay.
>
> MR. WILLIAMS: Are there some nonhuman pathogens? Sure. Are there some pathogens that would not be present in the

> sample? Possibly. So I don't think it necessarily reaches every single pathogen.

IPR2021-00847, Paper 108, 104:10–22. Patent Owner's counsel here seemingly disavows nonhuman pathogens, as well as, potentially, pathogens that would not be present in a sample. *Id.* Patent Owner's counsel was further questioned:

> JUDGE POLLOCK: Mr. Williams, . . . I think I heard you say that this limitation required killing any human pathogen. So would that extend to prions? Bacterial spores that cause human disease? I'm really not getting a solid idea of how far your claim construction extends. So if you could address that [on sur-rebuttal], that would be great.

Id. at 106:7–13. Patent Owner's counsel then, on sur-rebuttal, concedes that the claims do not extend to spores and prions if these are not in the Specification:

> JUDGE BRADEN: So if spores is not in there, . . . we're not getting it out there to prions and spores, . . . ?
>
> MR. WILLIAMS: That's correct, Your Honor.
>
> . . .
>
> It's within the scope of what's disclosed.

Id. at 124:21–125:5. Patent Owner's counsel argues, however, that under Patent Owner's construction the compositions or methods do not have to kill all pathogens, but all pathogens within the categories recited:

> JUDGE BRADEN: We're not saying that it has to kill all pathogens that are recited within the specification?
>
> MR. WILLIAMS: Within the categories recited, Your Honor, yes.

Id. at 134:11–15. As discussed above, however, these proceedings include both original and proposed substitute claims that expressly do not require killing (or the ability to kill) all pathogens within the categories recited in the Specification. In IPR2021-00847, for example, original claims 11, 34, and 51 of the '443 patent recite that "the pathogens" are one of several enumerated pathogens or categories of pathogen; in IPR2021-00850, original claims 12 and 27 of the '467 patent recite that the "pathogens are" one of several enumerated pathogens; and in IPR2021-00860, original claim 11 of the '256 patent recites that "*the pathogen* [that claim 1 sets forth is killed by the stock solution] *is* hepatitis virus, papillomavirus, HIV, biological agent of SARS, corona virus, rotavirus, Influenza virus, Ebola virus, methicillin-resistant *Staphylococcus*, or *M. tuberculosis*" (emphasis added).

Accordingly, for these reasons, the ability of Birnboim Example 3 to kill a pathogen as defined by the Specification is itself highly material. We note that it is undisputed that [redacted] fall within that category of pathogens set forth in the Specification. Also, *Staphylococcus aureus* is specifically identified as a pathogen according to the Specification. *See, e.g.*, IPR2021-00847, Ex. 1001, 25:47–48 ("microbes like . . . *staphylococcus* . . . and other pathogens"), 26:62–65 ("This example illustrates . . . killing a potential bacterial contaminant . . . . Methicillin-resistant *Staphyloccus aureus*."). Thus, given the materiality of the test results [redacted] within the meaning of the

claims, as interpreted in light of the specification, withholding the test results was inexcusable.

The duty of candor due the Office, as set forth above, is not limited to the examination of a patent application prior to issuance as a patent. On its face, as set forth in Rule 42.11, the duty of candor applies to any proceeding before the Board. 37 C.F.R. § 42.11. That would include, necessarily, these proceedings as to the patentability of both the original and proposed substitute claims. Patent Owner presents no cogent argument to the contrary, but rather contends in effect that the duty of candor and good faith was not violated because the withheld data was not "inconsistent with any statement in the Assured Bio witnesses' testimony, Exhibit 2019" and was not "inconsistent with anything that the patent owner has said." *See, e.g.*, IPR2021-00847, Paper 104, 63:12–18.

Patent Owner's position it has complied with its duty of candor and good faith is not supported by the record. The ABL Report, Exhibit 2019, includes on the first page, in the first two sentences of the "project notes," that, "Assured Bio has been tasked by Remenick PLLC *with testing nuclease inactivation and antimicrobial activity* . . . . The tests will look to *determine if either solution* [according to Birnboim Example 3] *kills bacterial and viral agents and if standard nucleases are inactivated* upon addition to solution" (emphasis added). Ex. 2019, 1. As detailed above, the withheld testing [redacted]. The withheld results were directly relevant to the stated purposes

of the testing, as set forth in Exhibit 2019, as the results showed the very effects that the testing was purported to seek.[13]

The ABL Report, Exhibit 2019, also includes on page 3, in regard to microbial viability, that, "[t]his assay *uses standard testing organisms*, methodologies, and analytical frameworks comparable to those used by accepted procedures *with minimal modifications made to accommodate the specific testing requirements of the solutions and their intended application*." *Id.* at 3 (emphasis added). As discussed above, the purpose set forth for the testing was to determine if the tested solutions "kill[] bacterial and viral agents and if standard nucleases are inactivated upon addition to solution" (*id.* at 1), yet the "minimal modifications" in this instance were to omit [redacted] (*compare* Ex. 1206, *with* Ex. 2019, 4–7). Moreover, it is apparent based on the effective dates set forth for the "Standard Operating Procedure" for Patent Owner's originally submitted "Remenick Solution Efficacy Testing" (Ex. 2016, 4) and that later provided to Petitioner (Ex. 1206, 1) that ABL contemplated a standard testing

[13] Patent Owner represented to the Board that "no other testing exists relating to the conclusions or results presented in Ex. 2019." IPR2021-00847, Paper 32, 2 (relying on testimony controlled and influenced by instructions from Patent Owner's counsel). This statement appears wholly untrue on its face where the stated purpose of the testing was to determine if the solutions killed bacterial or viral agents and inactivated nucleases, and the withheld testing results [redacted]

protocol [redacted] in addition to MS2 virus and *B. subtilis* spores (Ex. 1206, 2 (Section 6.1)), and [redacted] in addition to RNase (*id.*, 1 (Sections 7.2.1, 5.11)).

The failure of ABL to include the results [redacted] despite the asserted purpose of the testing "to determine if either solution [according to Birnboim Example 3] kills bacterial and viral agents and if standard nucleases are inactivated" (IPR2021-00847, Ex. 2019, 1), is explained by the intervention of Patent Owner's counsel (*see, e.g.*, IPR2021-00847, Ex. 1069 (Birkebak Deposition) 269:15–270:8). Witness testimony states that ABL was originally instructed to perform tests on [redacted] MS2 virus, and *B. subtilis* spores, but then instructed to omit the data [redacted] once the results were known:

> [Mr. Anger] Okay. So you were instructed by [counsel] to perform tests on [redacted] MS2 virus, and *Bacillus subtilis*]; right?
>
> [Dr. Birkebak] Yes.
>
> [Mr. Anger] And then it's your testimony that [counsel] instructed you to omit data [redacted] from the final project report, is that right?
>
> . . .
>
> [Dr. Birkebak] Remenick requested that we only include data regarding the B. subtilis and the MS2 in the final report.
>
> [Mr. Anger] And why is that?

. . .

[Dr. Birkebak] I don't know.

Id.

Patent Owner's assertion that the withheld data is not "inconsistent with anything that the patent owner has said" (Paper 104, 63:17–18) is also contrary to the record. As noted above, Patent Owner's representation to the Board that "no other testing exists relating to the conclusions or results presented in Ex. 2019" (Paper 32, 2) appears wholly untrue on its face where the stated purpose of the withheld testing was to determine if the solutions killed bacterial or viral agents, not merely MS2 virus and *B. subtilis* spores, and inactivated standard nucleases, [redacted], not merely RNase (*see supra*).

Furthermore, Patent Owner affirmatively acted to limit the "test results" provided to its testifying declarant, Dr. DeFilippi, to those results showing that the Birnboim Example 3 compositions failed "to inactivate or kill MS2 viruses or *B. subtilis* bacteria." Ex. 2015 ¶ 24. Dr. DeFilippi testified that "[t]hese two microorganisms are standard microorganisms used for testing antimicrobial activity of a solution against EPA standards . . . [and that] [a] solution that fails to kill or inactivate these two microorganisms cannot be expected to kill or inactivate bacteria or viruses more generally." *Id.* Dr. DeFilippi's testimony, however, is based on a selected subset of ABL's test results provided to him by Patent Owner ([redacted]), while also explaining that the purpose of the tests was "to determine

if either solution kills bacterial and viral agents." Ex. 2015, App'x, 1 (reproducing Ex. 2019).

As explained above, the test results, and related documentation, provided to Dr. DeFilippi were misleading at best and omitted information that a declarant reasonably would have considered relevant to the conclusion he reached as to the compositions of Birnboim Example 3 being considered effective antimicrobial compositions. Furthermore, while Dr. DeFilippi notes in his supplemental report—filed with the Patent Owner Responses and Original Motions to Amend—that "[k]illing only two individual pathogen organisms out of a sample is entirely inconsistent with how 'kills pathogens' is used" (Ex. 2033 ¶ 11), it does not follow that the omitted test results [redacted] were irrelevant. Rather, [redacted] the results reasonably support that [redacted] pathogens would be killed.

We note also that MS2 virus is in fact a bacteriophage rather than a human pathogen (*see, e.g.*, Ex. 2019, 2; Paper 104 (Motions Hearing) 12:16–18), raising the issue of whether it is a pathogen within the meaning of the patents,[14] and Patent Owner's testing of *B. subtilis* included *B. subtilis*

[14] As to MS2 bacteriophage, during the Hearing, Judge Derrick asked "does your claim construction require the composition to kill any and all potential pathogens?" (IPR2021-00847, Paper 108, 104:10–11) and Patent Owner's counsel responded that "I don't believe that has been our position. . . . the claims that recite kill pathogens, . . . require that the sample be rendered substantially nonpathogenic and safe for human handling. . . . Are there

spores (*see* Patent Owner Sur-Reply 5–6, n.3), where spores are determined to be pre-pathogens and not pathogens within the meaning of the patents subject to review (*see, e.g.*, Paper 112, 15–16).[15] Accordingly, [redacted] Patent Owner presented the two—MS2 virus and *B. subtilis* that included *B. subtilis* spores—that appear may not fall within the scope of the claims [redacted]. Here it appears that Dr. DeFilippi was not informed sufficiently of the bounds of "pathogen" where the test results provided him were based on a bacteriophage and samples including a pre-pathogen, heightening the relevance of the test results [redacted]

some nonhuman pathogens? Sure. . . . So I don't think it necessarily reaches every single pathogen" (*id.* 104:12–17, 19–22).

[15] As to spores, Patent Owner's counsel clarified that "kills pathogens" only applies to those classes of pathogen disclosed in the Specification. Paper 108 (Merits Hearing) 104:8–105:11, 134:11–15. But contrary to counsel's belief that the Specification disclosed spores, we do not identify any disclosure of bacterial spores in the challenged patents. Consistent with our determination, Dr. DeFilippi, Patent Owner's technical expert, testified that he "do[es] not believe spores were addressed in the specifications." Ex. 1064, 185:1–186:5. Patent Owner's counsel was also unable to point to such evidence at oral argument and conceded that, to the extent the Specification does not disclose spores, the claims do not encompass killing or inactivating spores. *See* Paper 108, 123:19–125:5, 136:1–137:8. Also pertinent to our understanding of "kills pathogens," Dr. DeFilippi testified that "a spore in the form of a spore is not pathogenic" but a "pre-pathogen." Ex. 1064, 186:19–187:10.

[redacted] that Patent Owner withheld from even its own expert.

Dr. DeFilippi's later testimony confirms the relevance of the withheld testing results to his opinion. Dr. DeFilippi was deposed for a second time on April 12, 2022 (Ex. 1064), following Patent Owner filing its Response and Motion to Amend in each case, as well as the parties' briefing as to Patent Owner's counsel's objections to questions about additional testing, but prior to the issuance of the Order (*see, e.g.*, IPR2021-00847, Paper 34, issued April 13, 2022) requiring Patent Owner to serve any relevant inconsistent information as required by 37 C.F.R. § 42.51(b)(1)(iii). It appears that Dr. DeFilippi had not been provided with the withheld testing data and, in response to questioning, testified as follows:

> [Mr. Anger] So let's consider if a composition as recited in Claim 1 of the '443 Patent, if that composition kills influenza and E. coli, but does not kill MS2, does that composition kill pathogens within the meaning of the claim term "kill pathogens"?
>
> . . .
>
> [Dr. DeFilippi] It simply states "pathogens," and there's no information here to have me exclude anything. There is no information. There is no data.
>
> [Mr. Anger] . . . your position as to whether if the composition kills two pathogens but not another pathogen, does that meet the claim limitation of "kills pathogens"?
>
> . . .

> [Dr. DeFilippi] It's talking about killing pathogens. It does not limit that. It doesn't say "all," it doesn't say "four out of five." It says what it says. It just kills pathogens.

Ex. 1064, 209:7–210:8.

> [Mr. Anger] So the composition recited in Claim 1, if that kills influenza and is also shown to separately kill E. coli, but then is also separately shown that it does not kill MS2, does that composition meet the claim term "kill pathogens"?
>
> . . .
>
> [Dr. DeFilippi] I see no reason not to do that. In other words, I see no reason to say, oh, it's not performing the function as described.
>
> [Mr. Anger] Okay.
>
> [Dr. DeFilippi] It is within the scope when you say "kill pathogens," that it's killing pathogens. Not all, every single pathogen, it's just killing pathogens.

Id. at 211:13–212:8. Where Dr. DeFilippi testifies, as above, that killing a subset of pathogens meets the claim term "kill pathogens," it follows that the [redacted] to formation of his original opinion as to the testing results. *See* IPR2021-00847, Ex. 2015 ¶ 24.

Following our Order, service of the withheld testing results, and Petitioner serving its motion for sanctions (prior to requesting authorization to move for sanctions), Patent Owner filed an amended supplemental report of Dr. DeFilippi. *See, e.g.*, IPR2021-00847, Ex. 2033. The amended supplemental report adds only a footnote Patent Owner contends clarifies Dr. DeFilippi's conclusion "that neither of the two compositions described in Birnboim Example 3 can be considered to act as effective antimicrobial

compositions."[16] *Id.* ¶ 24, n.1. With regard to the amended supplemental report, Dr. Filippi was asked "[s]o you didn't consider correcting mistakes in your prior report that result from data being kept . . . from you?" (Ex. 1096, 846:17–19) and he responded "that question was not raised. So I did not address a question that was not raised" (*id.* at 846:22–847:2) and "I didn't have the question presented to me and, thus, I did not reformulate an updated response or opinion" (*id.* at 847:12–14). As to being able to correct his earlier opinion, and whether his attorneys suggested he could correct his

[16] Dr. DeFilippi's amended supplemental report repeats the last sentence of paragraph 24 from the original supplemental report that states "[t]hus, the conclusion drawn from these studies is that neither of the two compositions described in Birnboim Example 3 can be considered to act as effective antimicrobial compositions," but adds a footnote stating:

> In making this observation, I apply the construction of "kill pathogens" as rendering the sample (that may contain pathogens) safe for shipment and handling (non-pathogenic) as discussed above. Similarly, my observations below about the failure of the tested sample to preserve RNA or inactivate RNases applies Patent Owner's constructions of not degrade nucleic acids and inactivate nucleases. Whether other microorganisms may or may not be killed (or other nucleic acids not degraded, or other nucleases inactivated) misses the point. The failure of Birnboim's formulation (1) to render substantially non-pathogenic the tested samples (one containing a virus and another a bacterium, both commonly used to test disinfection claims), (2) to inactivate RNases and (3) to not degrade RNA, establishes that Birnboim does not perform the claimed functional limitations of the patented invention according to the proper constructions discussed above.

Ex. 2033, 18 n.1.

opinion, Dr. Filippi testifies that "[n]o suggestion came my way." *Id.* at 847:16–848:1.

Patent Owner's position that the initially withheld data was not "inconsistent with anything that the patent owner has said" (Paper 104 (Motions Hearing) 63:17–18) is also untenable because Patent Owner has taken an overly strict view of what is material to patentability of the claims while simultaneously taking a lax view as to the duty of candor and fair dealing. Even under Patent Owner's proposed construction that to "kill pathogens" is to meet standards for safe transportation and handling of treated specimens without additional safety protocols, the omitted data is highly relevant, as examples, to whether the solutions generally kill pathogens.

The fact that Patent Owner surmises that the solutions do not "kill" certain pathogens it deems are within the scope of the claims does not negate the relevance of the fact [redacted]. Indeed, if the testing for the ability to kill pathogens is intended to account for pathogens generally, but the claims do not require the ability to kill all potential pathogens, then data relating to [redacted] appears highly relevant. At the very least, even assuming that MS2 virus and *B. subtilis* spores were properly considered "pathogens" within the meaning of the claims, data [redacted] including those that Patent Owner omitted from the testing report, are highly relevant [redacted]. Moreover, as

discussed above, it was improper for Patent Owner to withhold information on the basis of its own claim construction positions where the Board, in expressly considering and then provisionally rejecting Patent Owner's construction, made it plain that the information it considered relevant to patentability would encompass [redacted].

The dependent claims of the various patents that limit the pathogen to pathogens other than MS2 virus and *B. subtilis*, discussed above, independently make clear that testing results [redacted] are highly relevant and material to patentability even under Patent Owner's proposed claim constructions. In the '860 IPR, the '256 patent's original claim 11 recites that "the pathogen [that claim 1 sets forth is killed by the stock solution]" is selected from a list that includes "methicillin-resistant *Staphylococcus*," and the Specification discloses testing with methicillin-resistant *Staphylococcus aureus* (IPR2021-00860, Ex. 1001, 26:59–29:30).[17] The plain meaning of claim 11 is that "methicillin-resistant *Staphylococcus*" by itself, without any other pathogen, can be the suspected pathogen that might be present in a sample. *Cf. Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339 (1961) ("the claims made in the patent are the sole measure of the grant").

[17] We note that the methicillin response of the *S. aureus* strain used in the originally withheld testing results is not reported in the protocol, nor is there evidence that antibiotic sensitivity would have any effect on the test results. *See, e.g.*, IPR2021-00860, Ex. 1206.

Nonetheless, Patent Owner omitted the test results [redacted], which demonstrated [redacted], until compelled to do so by the Order. IPR2021-00847, Paper 34. Likewise, Patent Owner also withheld the test results for DNase I, relying on its argument that inhibiting both DNase and RNase was required such that both DNA and RNA would be preserved.[18] As also detailed above, however, some of the subject patents' original claims on their face expressly require only preserving DNA, not both DNA and RNA (or inhibiting DNase, not both DNase and RNase), e.g., in IPR2021-00847 (claim 13), IPR2021-00854 (claim 14), and IPR2021-00857 (claim 14). Accordingly, the withheld [redacted] was highly relevant to the patentability of original claims in these IPR proceedings, regardless of Patent Owner's arguments directed to independent claims requiring preservation of both RNA and DNA (or inhibiting both DNase and RNase).

As Patent Owner maintains that dependent claims [redacted] are patentable, the

[18] Patent Owner's argument is that "inactivate nucleases" recited in the base independent claim requires inactivation of both RNase and DNase, however, Patent Owner's counsel concedes during the Merits Hearing that the limitation "inactivate nucleases" is not present in the base independent claim 1 in the '240 patent (IPR2021-00854)—which recites "one or more nucleases"—and that, accordingly, a "dependent claim reciting RNase, DNase, . . . wouldn't have a relationship to the earlier limitation of inactivate nucleases in the independent claim because it's not there." Paper 108 (Merits Hearing) 97:9–98:1. The '240 patent, claim 14, depending from claim 1 further requires that "[t]he composition . . . [is] at least substantially free of RNAse *or* DNAse activity" (emphasis added).

withheld information was subject to routine discovery. 37 C.F.R. § 42.51(b)(1)(iii). As set forth above, [redacted] and Patent Owner, having asserted the patentability of these claims, was obligated to serve the "relevant information that is inconsistent" with its position that the claims were patentable; [redacted] *Id.*

Furthermore, Patent Owner's position that this information was privileged as attorney work product falls short because, as set forth above, there is no sound basis for the withheld *factual information* being privileged as work product. Contrary to even potentially conveying the opinions or thoughts of its attorney, the withheld data appears on its face to be the very type of factual information—research, tests, and experiments pertinent to patentability—that cannot be hidden behind the work product doctrine. *Cf. Natta*, 392 F.2d at 693 ("Phillips has a duty to disclose to the Patent Office all facts relating to the possible equities of the patent application. It cannot hide behind the work product doctrine the research, tests, and experiments which are pertinent to the patent application.").

Even if Patent Owner had misunderstood that the report was privileged as attorney work product and thus that Patent Owner was not obligated to serve Petitioner, this does not explain its failure to file the material with the Board, as a party may file an exhibit under seal as "Filing Party and Board Only" in the Board's electronic filing system. Doing so would have allowed Patent Owner to comply with its duty of candor and

good faith to the Office and shielded the information while the Board determined what was material to patentability and what was otherwise privileged. In failing to do so, Patent Owner failed to comply with Rules 11.106(c) and 11.303(e) that mandate "[a] practitioner shall disclose to the Office information necessary to comply with applicable duty of disclosure provisions." 37 C.F.R. § 11.106(c). Moreover, on this record, where there is no reasonably plausible argument that the withheld information was not material to patentability, or contrary to Patent Owner's positions, as explained above and below, Patent Owner's counsel could only properly disobey its obligation to disclose the information it withheld by "an open refusal based on an assertion that no valid obligation exists."[19] *Id.* § 11.304(c). Thus, Patent Owner's reliance on the material being privileged as attorney work product does not excuse its failure to properly assert the privilege when filing (and serving) the respective Patent Owner's Responses and its Original Motions to Amend as required by rule. *Id.*

Also, to the extent Patent Owner takes the position that the duty of candor is somehow lessened in *inter partes* review as compared to patent examination, and is seeking to distinguish its willful withholding of material information until compelled to do so by our Order, these proceedings also include Patent Owner seeking allowance (if required) of proposed substitute claims. Seeking allowance of substitute claims invokes the duty of candor

[19] The required service of information that can only be properly disobeyed upon "an open refusal based on an assertion that no valid obligation exists" is a duty owed, according to the section title, in "Fairness to opposing party and counsel." 37 C.F.R. § 11.304 (section title), § 11.304(e).

and fair dealing, as that duty "includes a patent owner's duty to disclose to the Board information of which the patent owner is aware that is material to the patentability of substitute claims, if such information is not already of record in the case." *Lectrosonics, Inc. v. Zaxcom, Inc.*, Case IPR2018-01129, -01130, Paper 15 at 9–10 (PTAB Feb. 25, 2019) (precedential) ("Under 37 C.F.R. § 42.11, all parties have a duty of candor, which includes a patent owner's duty to disclose to the Board information of which the patent owner is aware that is material to the patentability of substitute claims, if such information is not already of record in the case."); *see also* TPG 72 (quoting same).

Patent Owner also relies on its claim construction position as a means to avoid its obligation to disclose the withheld testing results [redacted], and related documents. *See, e.g.*, IPR2021-00847, Paper 76, 8 ("[D]iscovery of ABL's work product information does not prevent injustice in this case because the work product materials are ***consistent*** with Longhorn's claim construction position."). Paper Owner, however, offers no meaningful argument that the withheld data is not relevant absent its claim construction argument having any import.

Patent Owner's reliance on its claim construction positions fails for multiple reasons. As highlighted above, the Board set forth an interpretation of the claims under which these test results were highly material to the issue of patentability, namely, that "killed pathogens" would be met by killing the pathogens that are present, that is, a subset of those that might be present, and preserving nucleic acid would be met by inactivating DNAses or

RNAses, or both, such that a nucleic acid of interest was preserved. *See, e.g.*, '847 Dec. Also, the test results [redacted] purposefully withheld by Patent Owner appear on their face to meet the requirements of claims in each IPR, including proposed substitute claims in some of the IPRs, as detailed above. Furthermore, having been fully apprised of the Board's understanding of the claim terms in the institution decisions, Patent Owner could not reasonably rely on its own contrary constructions to limit its disclosure as it improperly did. Even if only preliminary, the Board's claim constructions, set forth in the institution decisions, convey the measure of what is reasonably material to patentability. To the extent Patent Owner disagrees with the Board's constructions, it was free to contest them at trial, but it was not free to simply withhold information that the Office (including the Board) would find material to patentability, here, for both original and proposed substitute claims.

In ignoring the claim construction set forth in the institution decisions, and arguing its preferred claim construction without disclosing at least the underlying facts of the test results, to at least the Board,[20] Patent Owner put itself in an untenable position as to meeting its duty of candor and fair dealing.

[20] Patent Owner could have, for example, requested authorization for *en camera* review of the withheld information and briefing on its privilege claim before its existence was revealed at deposition. Patent Owner chose to remain silent.

Patent Owner's behavior also raises significant concerns as to what it would have done had it not been discovered that it had withheld information material to the patentability of claims. Had Petitioner's counsel not pressed for answers during the deposition of the ABL employees who conducted the testing, and had we not ordered Patent Owner to serve relevant inconsistent information on Petitioner (IPR2021-00847, Paper 34, 11), it seems likely that Patent Owner would have withheld the test results indefinitely. On this record, it is reasonably foreseeable that a final written decision in each of these cases would have issued under which the withheld test results would be material to patentability.

Furthermore, even assuming that Patent Owner would have otherwise concluded that the relevant information it withheld earlier should be disclosed, particularly on issuance of final written decisions, Patent Owner would be unable to fully mitigate the harm to these proceedings that its lack of candor would reasonably cause. In addition to the cost and effort that has been needlessly expended, withholding the information throughout the course of the proceedings would have undercut the ability of this tribunal to reach a sound decision in a timely manner. Thus, despite possible actions that might be taken to mitigate the harm, such as requesting rehearing, the ultimate decisions would be both less timely and grounded on a less complete record than properly should have been developed.

SANCTIONS

As discussed above, Patent Owner, through its intentional actions, has failed to fulfill its duty of candor and fair dealing throughout these

proceedings until it was compelled to do so by the Board. This misconduct begins with the intentional failure of Patent Owner to serve or inform the Board of relevant information that is inconsistent with a position advanced by Patent Owner, which applies to its Response in all of the proceedings. Patent Owner now relies on (1) its contentions that the withheld information was not contrary to how it argued the case due to its proposed claim construction, and (2) privileged as attorney work product. But, as explained above, this information is both highly relevant regardless of the parties proposed claim construction and not privileged as factual information rather than attorney opinion.

Furthermore, as explained above, Patent Owner proffered evidence, Exhibit 2019, that was intentionally misleading both because it omits results contrary to Patent Owner's general position and it omits standard testing protocols. Moreover, as explained above, it is apparent that Patent Owner intentionally intervened with the evidence of the ABL witness(es) in order to "tailor" the test results and omit relevant results. Patent Owner then supplied the report (Ex. 2019) omitting these relevant results to its declarant Dr. DeFilippi as support for his testimony (e.g., Ex. 2015 ¶¶ 24–26 (citing report at pages 44–56 also filed as Ex. 2019)), which Patent Owner then also relied on in its Response. Still further, Patent Owner withheld these test results as to its proposed substitute claims submitted during the course of these proceedings by way of its Original Motions to Amend.

Until it was found out, as described above, Patent Owner failed to take any action necessary to meet its duty of candor and good faith dealing with the Office. For example, as described above, Patent Owner could have filed

any necessary exhibit to inform the Board of the relevant facts under seal as "Filing Party and Board" in the Board's electronic filing system. Doing so would have allowed any privileged information to be shielded, as appropriate, while attempting to comply with the duty of candor and good faith. Rather than taking any such action, Patent Owner simply ignored the import of the Board's preliminary claim construction to the contrary, as well as the plain meaning of the express language of a number of claims, which it argued were patentable. As explained above, under these circumstances, Patent Owner's actions not only failed to meet its duty of candor and good faith at the time, but also were not reasonable for meeting its duty of candor and good faith in a timely manner.[21]

Patent Owner contends that its conduct does not warrant sanctions. IPR2021-00847, Paper 76. Patent Owner contends that it argued in good faith its proposed claim construction and that its attorney work product objections are supported by legal authority. *Id.* at 1, 5–9. Patent Owner also contends that its briefing and Dr. DeFilippi's Declaration reflect Patent Owner's claim construction arguments and are not false or misleading. *Id.* at 9–13. Patent Owner also contends that the sanction of terminating the

[21] Although there are mechanisms by which a party can seek to disclose information contrary to its positions throughout any proceeding, the proper use of those outside standard briefing should be to address late-arising issues. *See, e.g.*, 37 C.F.R. § 42.51(b)(1)(iii) (requiring service of relevant inconsistent information "concurrent with the filing of the documents or things that contains the inconsistency"). Other than as compelled by our Order, however, Patent Owner did not avail itself of this or any other method of disclosing its inconsistent information.

proceedings in Petitioner's favor is disproportionate and improper. *Id.* at 13–15.

As discussed above, Patent Owner's arguments based on its proposed claim constructions fall far short. Similarly, as also discussed above, there is no sound basis for privilege as attorney work product for the factual information withheld, especially as to the proposed substitute claims. Patent Owner's reliance on *Corning* as support for privilege excusing disclosure of information contrary to arguments or assertions, as required by Rule 42.51(b)(1)(iii) (IPR2021-00847, Paper 76, 6–7), is entirely without foundation because, as discussed above, the denied discovery was "additional discovery" and not "routine discovery." *Corning* 3, 6–7. Patent Owner's arguments "that even a weak objection is not frivolous," and the cases cited in support (IPR2021-00847, Paper 76, 5–6), fail because it is well-established that factual information material to patentability or contrary to argument or contentions must be disclosed as a matter of course (see above).

None of the cases cited by Patent Owner in support of weak objections not being frivolous relate to objections relating to information arguably material to patentability or contrary to argument or contentions in any proceeding before the Board. *See, e.g.*, IPR2021-00847, Paper 76, 5–6 (citing *Atlanta Gas Light Co. v. Bennett Regulator Guards*, Inc., IPR2013-00453, Paper 88 (PTAB Jan 6, 2015), at 16–17 (relates to alleged collusion between court reporter and videographer); *Cont'l Cas. Co. v. St. Paul Surplus Lines Ins. Co.*, 265 F.R.D. 510, 531 (E.D. Cal. 2010) (relates to an insurance case in Federal district court, finding assertion of privilege and

work product substantially justified where "issues presented novel facts and new legal questions on which there has been little published authority for guidance"); *Cobell v. Norton*, 213 F.R.D. 1, 1415 (D.D.C. 2003) (relates to an action alleging breach of fiduciary duties by Secretaries of the Interior and Treasury in Federal district court, finding objection asserting documents and things privileged as work product substantially justified prior to a ruling by the court ruling on the applicability of the doctrine to the case).

Furthermore, in contrast to the cited cases, as applied to the factual information of the withheld test results, there is no lack of guidance that Patent Owner was obligated to fulfill its duty of candor and fair dealing, and that this duty applied to the proceedings before the Board. Likewise, Patent Owner's reliance on the applicability of the Federal Rules of Evidence, particularly FRE 502, fails because the factual information itself is not protected as attorney work product.

Additionally, Patent Owner chose to argue for the patentability of claims for which the withheld test results were on their face material. Having done so, it was obligated to disclose that information. Patent Owner's arguments and proffered testimony that run contrary to the withheld test results, likewise, were within Patent Owner's rights to make, but, having made those arguments and relied on that testimony, Patent Owner was obligated to disclose the test results it withheld, [redacted].

Patent Owner's argument that its briefing and Dr. DeFilippi's testimony merely reflect Patent Owner's claim construction arguments and

are not false or misleading falls short. IPR2021-00847, Paper 76, 9–13. As discussed above, Patent Owner failed to fulfill its duty of candor and fair dealing. Patent Owner further argues that Petitioner "must show that the amended response and declaration remain misleading." *Id.* at 9–13 (citing 37 C.F.R. § 42.11(d)(2)); *cf. Gray v. Staley*, 310 F.R.D. 32, 40 (D.D.C. 2015)) (with parenthetical "no sanctions merited where misstatement in pleading was corrected by amendment under Rule 11 safe harbor")). Patent Owner's argument again falls short. Both 37 C.F.R. § 42.11(d)(2) and *Gray* allow for the correction of a challenged paper to suffice,[22] but Patent Owner's repeated intentional failures to comply with its duty of candor and good faith in these proceedings amount to much more than misstatements that may be excused when corrected.[23]

Patent Owner contends that the sanction of terminating the proceedings in Petitioner's favor is disproportionate and improper. *Id.* at 13–15. Patent Owner cites the Federal Circuit as "holding that 'harsh sanction' of termination requires clear and convincing evidence of bad faith,

[22] The court in *Gray* found that there was no merit to plaintiff's argument that defendant's statements violated Rule 11 and expressly stated that "[t]he court does not view them as efforts to mislead it." *Gray*, 310 F.R.D. at 39–40.

[23] While our decision focuses on Patent Owner's violation of its duties to the Board, as detailed above, Patent Owner also failed in its obligations of fairness to opposing party and counsel (*see* 37 C.F.R. § 11.304), including "disobey[ing] an obligation under the rules" without doing so by "open refusal" with "an assertion that no valid obligation exists" (*id.* § 11.304(c)). We do not, however, separately impose sanctions on that basis, as it is unnecessary and largely redundant to Patent Owner's violation of its duties to the Board.

resulting prejudice, and why lesser sanctions are insufficient." *Id.* at 13 (citing *Micron Tech., Inc. v. Rambus Inc.*, 645 F.3d 1311, 1327–29 (Fed. Cir. 2011)). Patent Owner offers no explanation how *Rambus*, reviewing a district court's dismissal of the case as a sanction and declaring Rambus' asserted patents unenforceable against Micron, based largely on spoliation of documents, informs what sanctions are appropriate for Patent Owner's misconduct before the Board. Moreover, as set forth above, the Board has authority to impose a sanction against a party for misconduct, and we determine that Patent Owner's actions constituted misconduct. 37 C.F.R. § 42.12(a).

Patent Owner also argues that sanctions are not warranted because Petitioner never asserts and cannot establish that Patent Owner's attorney work product objections were frivolous and that the statements in Patent Owner's Response and Dr. DeFilippi's declaration, as amended, were made in bad faith to mislead the Board. IPR2021-00847, Paper 76, 2–3, 4–9.

The strength of Petitioner's pleadings in its motion for sanctions is largely immaterial to our decision to impose sanctions. We have been made aware of Patent Owner's actions and we can judge them for ourselves, having the authority to issue sanctions *sua sponte* when and where appropriate. 37 C.F.R. § 42.12(a) ("The Board may impose a sanction against a party for misconduct.").

As set forth above, Patent Owner's failure to disclose factual information that was clearly contrary to the patentability of original claims and original proposed substitute claims establishes that Patent Owner willfully failed to meet its duty of disclosure and fair dealing. The

seriousness of this failure is heightened by Patent Owner affirmatively acting to obfuscate that there was additional relevant testing, for example, in directing revision of the test reports and withholding particular test results from its declarant Dr. DeFilippi. Also, as set forth above, the withheld factual information was not reasonably considered to be privileged as attorney work product in these proceedings under these circumstances, particularly where Patent Owner affirmatively chose to make arguments and prosecute claims contrary to the withheld facts. The argument that Patent Owner took reasonable care due its duty of candor and good faith in dealing with the Office is unsupported on this record, as detailed above. The duty of candor and good faith dealing requires reasonable inquiry at the very least. There is no evidence that a reasonable inquiry in these cases would fail to establish an obligation to disclose evidence withheld by Patent Owner. Rather, the most reasonable conclusion is that Patent Owner's actions were contrary to those of any reasonable person seeking to fulfill their duty to act in good faith.

Accordingly, weighing Patent Owner's actions in these proceedings, we exercise our authority to impose sanctions against Patent Owner for both its willful failures to comply with applicable rules in these proceedings and for its unwarranted disregard relating to its duty of disclosure and fair dealing before this tribunal. Although not necessary to our determination that sanctions are justified, we further find that Patent Owner's disregard as to meeting its duty of disclosure and fair dealing is, in itself, misconduct. *Cf. Hydril Co. LP v. GrantPrideco LP*, 474 F.3d 1344, 1349 (Fed. Cir. 2007) ("This court has consistently explained that *Walker Process* fraud is a

variant of common law fraud, and that the elements of common law fraud include: (1) a representation of a material fact, (2) the falsity of that representation, and (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter)." (internal quotations omitted) (cited with approval in *Inline Packaging, LLC v. Graphic Packaging Int'l, LLC*, 962 F.3d 1015, 1025 (8th Cir. 2020).[24]

As set forth in Rule 42.12(a), we have the authority to impose sanctions for such misconduct, including the "[f]ailure to comply with an applicable rule or order in the proceeding" (§ 42.12(a)(1)) and the "[m]isrepresentation of a fact" (§ 42.12(a)(3)). *See supra*; Ex. 2019, 1, 3; Paper 32, 2.

Furthermore, based on misrepresentations to its declarant, Dr. DeFilippi's testimony relied on by Patent Owner (e.g., Ex. 2015 ¶ 24 (testifying that "[a] solution that fails to kill or inactivate [MS2 or *B. subtilis*] cannot be expected to kill or inactivate bacteria more generally")) is at odds with Dr. DeFilippi's candid testimony relating to withheld testing data (*see supra*; Ex. 1064 209:7–210:8 (testifying [redacted]), 211:13–212:8 (testifying [redacted])).

[24] We need not reach whether actions taken by Patent Owner or its counsel would support a *Walker Process* fraud claim or otherwise render the patents unenforceable and, accordingly, decline to do so.

As discussed above, it is well established that parties and individuals involved in any proceeding before the Board "have a *duty of candor and good faith* to the Office during the course of a proceeding" (emphasis added). 37 C.F.R. § 42.11(a); *see also PQA* at 23 (quoting same); *OpenSky* at 17 (quoting same). As in *Abrutyn*, in which the Federal Circuit upheld the Board entering default judgment against a party for deliberately failing to comply with a filing deadline, here we have determined that Patent Owner acted deliberately in failing to comply with its duty of candor and good faith before the Board, that Patent Owner's behavior was egregious, and that protecting the PTO's interests, and those of the public, properly includes judgment against Patent Owner. *See Abrutyn*, 15 F.3d at 1053. Here, as in *Abrutyn*, the Office's interests include "creating sufficient deterrence for like cases in the future." *Id.*; *see also PQA* at 4 (determining the sanctions imposed "necessary to deter such conduct by PQA and others in the future"); *OpenSky* at 4 (determining the sanctions imposed "necessary to deter such conduct by OpenSky or others in the future"). Moreover, we also determine that the sanctions imposed are proportionate to the harm, including the harm to Petitioner, the public, and to trust in our process, where Patent Owner's actions risked an unjust result in this proceeding, required additional resources, and delayed a decision. *See PQA* at 36–37 (citing *R.J. Reynolds Vapor Co. v. Fontem Holdings 1 B.V.*, IPR2017-01318, Paper 16 at 5, 8 (PTAB Aug. 6, 2018) (considering "whether the potential sanctions are proportionate to the harm").

Accordingly, we impose the sanction of "[j]udgment in the trial" as to all challenged claims in IPR2021-00847 (claims 1–51), IPR2021-00850

(claims 1–42), IPR2021-00854 (claims 1–35), IPR2021-00857 (claims 1–35), and IPR2021-00860 (claims 1–20).[25] 37 C.F.R. § 42.12(b)(8). We likewise enter judgment against Patent Owner's Revised Motions to Amend as a sanction in each of the pending cases. *Id.*

As to Petitioner's requested sanction of "holding that Birnboim meets the 'kills pathogens' and 'not degrade nucleic acid limitations' and precluding [Patent Owner] from contesting otherwise" (IPR2021-00847, Paper 56, 1–2). We decline to impose this sanction because the issue is moot as we determine the same on the merits in the Final Written Decisions in each case (*see, e.g.*, *id.*, Paper 112, 142–43).[26]

The majority agrees with our colleague that Patent Owner has committed "an egregious abuse of the PTAB process." *Infra* (Braden, concurring).[27] But as to the further requested sanction of "providing Petitioner compensatory expenses, including attorney fees" (Paper 56, 2), we decline because it is neither sufficient, nor necessary to protect the interests of the PTO and the public. *Abrutyn*, 15 F.3d at 1053. First, we determine

[25] We also find claims unpatentable on the merits of the challenges set forth by Petitioner: in IPR2021-00847, claims 1–51; in IPR2021-00850, claims 1–17 and 24–42; in IPR2021-00854, claims 1–35; in IPR2021-00857, claims 1–35; and in IPR2021-00860, claims 1–13 and 15–20.
[26] Although a number of claims are not determined to be unpatentable on the merits, based on the grounds set forth by Petitioner (e.g., IPR2021-00857, Paper 107; IPR2021-00860, Paper 108), we do determine that the general proposition that Birnboim "kills pathogens" and does "not degrade nucleic acids" is met, as reflected in the Final Written Decision in each case.
[27] The concurrence, as noted in its caption, only applies to IPR2021-00847, -00850, and -00857, as Lead Administrative Patent Judge Braden is not a panel member in IPR2021-00854 and -00860.

compensatory fees, including attorney fees, would not be a sufficient deterrent to parties (and their attorneys) who decline to meet their duty of candor and fair dealing, but are willing to pay compensatory fees if they are caught as a cost of doing business. Second, having imposed the sanction of judgment in the trial against Patent Owner as to all challenged claims and the Revised Motions to Amend, we determine the sanction of judgment creates sufficient deterrence, such that no further sanction is required.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner, through its counsel, has failed to meet its duty of candor and fair dealing in its actions before the Board under 37 C.F.R. § 1.56, § 11.106(c), § 11.303, § 42.11(a), and § 42.51(b)(1)(iii) in IPR2021-00847, IPR2021-00850, IPR2021-00854, IPR2021-00857, and IPR2021-00860;

FURTHER ORDERED that Adverse Judgment against Patent Owner under 37 C.F.R. § 42.12 shall be entered in the Final Written Decisions in each of IPR2021-00847 (claims 1–51), IPR2021-00850 (claims 1–42), IPR2021-00854 (claims 1–35), IPR2021-00857 (claims 1–35), and IPR2021-00860 (claims 1–20);

FURTHER ORDERED that Patent Owner's Revised Contingent Motion to Amend in each of IPR2021-00847, IPR2021-00850, IPR2021-00854, IPR2021-00857, and IPR2021-00860 shall be denied with Adverse Judgment being entered in each of the Final Written Decisions;

FURTHER ORDERED that this Order is sealed pending the expiration of any appeal before the Federal Circuit; within 10 business days of this Order, the parties shall jointly provide a minimally redacted version for public dissemination; and

FURTHER ORDERED that parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS LLC,
Petitioner,

v.

LONGHORN VACCINES & DIAGNOSTICS, LLC,
Patent Owner.

IPR2021-00847 (Patent 8,084,443 B2)
IPR2021-00850 (Patent 8,293,467 B2)
IPR2021-00857 (Patent 9,212,399 B2)

BRADEN, Lead Administrative Patent Judge, CONCURRING.

I respectfully concur with the majority's opinion regarding its finding that Patent Owner has failed to meet its duty of candor and fair dealing in its actions before the Board under 37 C.F.R. § 1.56, § 11.106(c), § 42.11(a), and § 42.51(b)(1)(iii) in IPR2021-00847, IPR2021-00850, and IPR2021-00857. I further concur with the majority's opinion in ordering Adverse Judgment against Patent Owner under 37 C.F.R. § 42.12 and in denying Patent Owner's Revised Contingent Motion to Amend in each proceeding.

I do not, however, concur with the majority's opinion in declining to provide Petitioner with compensatory expenses, including attorney fees. The majority specifically states:

> [a]s to the further requested sanction of "providing Petitioner compensatory expenses, including attorney fees" (*id.*, 2), we decline because it is neither sufficient, nor necessary to protect the interests of the PTO and the public. *Abrutyn*, 15 F.3d at 1053. First, we determine compensatory fees, including attorney fees, would not be a sufficient deterrent to parties (and their attorneys) who decline to meet their duty of candor and fair dealing, but are willing to pay compensatory fees if they are caught as a cost of doing business. Second, having imposed the sanction of judgment in the trial against Patent Owner as to all challenged claims and the Revised Motions to Amend, we determine the sanction of judgment creates sufficient deterrence, such that no further sanction is required.

Supra at 58–59.

Whether the imposition of compensatory damages alone is sufficient to protect the interests of the USPTO and the public is irrelevant in the present case. As is a determination of whether compensatory damages alone is a sufficient deterrent to future parties (and their attorneys). The imposition of adverse judgment and a denial of Patent Owner's motions to amend in each proceeding may well act to protect the agency and public's interest as well as to stand as a deterrent to other similarly situated parties.

Under the circumstances of the present case, however, ordering Patent Owner to pay Petitioner's attorney fees and laboratory costs associated with countering Patent Owner's egregious and willful actions would serve, first, as a compounding sanction hand-in-hand with adverse judgment against Patent Owner in order to prevent a gross injustice to Petitioner. And, second, would compensate and make Petitioner whole for the time and money it spent addressing incomplete laboratory data and test results, incorrect deposition testimony, and knowingly false attorney arguments. *See*

PPG Indus., Inc. v. Celanese Polymer Specialties Co., Inc., 840 F.2d 1565, 1568–69 (Fed. Cir. 1988) (prevailing defendant entitled to fees for participation in PTO proceedings undertaken after defendant discovered invalidating prior art known to patentee, as PTO proceedings substituted for district court litigation).

Nothing in our rules impede or preclude the Board from exercising our discretion to make whole a party injured by an egregious abuse of the PTAB process. *See* 37 C.F.R. 42.12. Rather, Rule 42.12(b)(6) specifically allows for compensatory expenses, including attorney fees. Therefore, analyzing the facts as a whole, I would impose multiple sanctions, including Adverse Judgment against Patent Owner, denial of Patent Owner's Revised Contingent Motion to Amend, and payment of Petitioner's attorney fees and laboratory costs that arose due to Patent Owner's failure to comply with its duty of candor and fair dealing in order to (1) protect the interests of the USPTO and the public, (2) serve as a deterrent to future parties (and their attorneys) who decline to meet their duty of candor and fair dealing, and (3) to remunerate Petitioner and make them whole again.

IPR2021-00847 (Patent 8,084,443 B2)
IPR2021-00850 (Patent 8,293,467 B2)
IPR2021-00854 (Patent 8,669,240 B2)
IPR2021-00857 (Patent 9,212,399 B2)
IPR2021-00860 (Patent 9,683,256 B2)

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