

NOTE: This disposition is nonprecedential.

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

CAROLYNNE OLSON,
Petitioner-Appellant

v.

**SECRETARY OF HEALTH AND HUMAN
SERVICES,**
Respondent-Appellee

2018-1467

Appeal from the United States Court of Federal
Claims in No. 1:13-vv-00439-EJD, Senior Judge Edward
J. Damich.

Decided: December 21, 2018

MITCHEL OLSON, Law Office of Mitchel J. Olson, J.D.,
M.D., Encinitas, CA, for petitioner-appellant.

JENNIFER LEIGH REYNAUD, Vaccine/Torts Branch,
Civil Division, United States Department of Justice,
Washington, DC, for respondent-appellee. Also repre-
sented by ALEXIS B. BABCOCK, C. SALVATORE D'ALESSIO,
CATHARINE E. REEVES, JOSEPH H. HUNT.

Before WALLACH, TARANTO, and HUGHES, *Circuit Judges*.

PER CURIAM.

Appellant Carolynne Olson sued Appellee Secretary of Health and Human Services (“the Government”) for compensation under the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”). *See* Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-2–33 (2012)). Ms. Olson alleges that she developed rheumatoid arthritis (“RA”)¹ as a result of receiving the Gardasil®² vaccine for HPV. A Special Master of the U.S. Court of Federal Claims found that, inter alia, Ms. Olson “failed to carry her burden in establishing causation,” such that Ms. Olson was not entitled to compensation. *Olson I*, 2017 WL 3624085, at *1. Ms. Olson filed a motion for review in the Court of Federal Claims, which was denied. *See Olson v. Sec’y of Health & Human Servs. (Olson II)*, 135 Fed. Cl. 670, 672 (Fed. Cl. 2017); *see also* J.A. 1 (Judgment).

Ms. Olson appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(3) (2012). We affirm.

¹ “RA is a long-term autoimmune condition mainly affecting the joints.” *Olson v. Sec’y of Health & Human Servs. (Olson I)*, No. 13-439V, 2017 WL 3624085, at *5 (Fed. Cl. July 14, 2017). RA “involves an autoimmune attack on the synovial membranes of the joints, causing inflammation and later erosion and destruction of joint surfaces, along with deformity of affected joints, fingers, or toes. It can also cause complications in the lungs, kidneys, and other organs.” *Id.* (citing, inter alia, J.A. 654–59 (providing a scientific article on RA)).

² Gardasil is the tradename of a vaccine that inoculates individuals against human papillomavirus (“HPV”). *See* J.A. 420.

BACKGROUND

On July 1, 2010, Ms. Olson received the HPV vaccination from her gynecologist. *Olson II*, 135 Fed. Cl. at 672.³ Ms. Olson sought the vaccine “to treat warts after learning from her daughter’s dermatologist” that the vaccine “could be effective” in this regard. *Id.* At the time of the vaccination, she was fifty-two years old, and therefore not within the target age group for the vaccine. *Id.* She was also being treated for the following medical conditions: hypothyroidism, vitamin D deficiency, osteochondroma, an Achilles tendon rupture, anemia, asthma, sinus pressure, facial pain, lung congestion, and chronic sinusitis. *Id.*

Within two weeks of being administered the vaccine, Ms. Olson began experiencing a burning sensation in both of her hands. *Id.* The first medical documentation of her symptoms was made by her gynecologist on December 13, 2010, almost five and a half months post-vaccination. *Id.* Ms. Olson recounted to her gynecologist that she had been experiencing persistent “knuckle enlargement with pain” since receiving the HPV vaccine, and her gynecologist referred Ms. Olson to a rheumatologist for further treatment. *Id.* (internal quotation marks, brackets, and citation omitted).

On February 22, 2011, the rheumatologist documented that Ms. Olson’s “clinical presentation was highly suspicious for *reactive* arthritis^[4].” *Id.* (internal quotation

³ Because the parties do not dispute the Court of Federal Claims’ recitation of the facts, we cite to the Court of Federal Claims’ opinion for the background. *See Olson II*, 135 Fed. Cl. at 672–73. *See generally* Appellant’s Br.; Appellee’s Br.

⁴ “Reactive arthritis is not [RA]. Reactive arthritis is joint pain and swelling triggered by an infection in

marks, brackets, and citation omitted). He, therefore, ordered laboratory testing, the results of which revealed biological indicators “of a prior resolved infection consistent with reactive arthritis.” *Id.* The results were negative, however, for two indicators “that are strongly associated with RA.” *Id.* (citation omitted). Ms. Olson continued seeing the rheumatologist until late 2013. *Id.*

For most of the time Ms. Olson saw the rheumatologist, she continued experiencing the symptoms noted above, though she would occasionally experience “only minor joint pain.” *Id.* When the symptoms worsened, however, Ms. Olson began treatment with a second rheumatologist, Dr. Gregory Middleton, beginning in September 2013. *Id.* Dr. Middleton diagnosed Ms. Olson with seronegative RA,⁵ and “attributed the RA to [Ms. Olson’s] immune system over-reaction from her 2010 HPV vaccine.” *Id.* (internal quotation marks and citation omitted).

DISCUSSION

I. Standard of Review and Legal Standard

“We review an appeal from the Court of Federal Claims in a Vaccine Act case de novo, applying the same standard of review as the Court of Federal Claims applied in reviewing the special master’s decision.” *Oliver v. Sec’y of Health & Human Servs.*, 900 F.3d 1357, 1360 (Fed. Cir. 2018) (internal quotation marks, brackets, and citation omitted). “Although we review legal determinations without deference, we review the special master’s factual findings under the arbitrary and capricious standard.” *Id.*

another part of the body.” *Olson II*, 135 Fed. Cl. at 672 n.5 (internal quotation marks and citation omitted).

⁵ “Seronegative RA is a diagnosis of RA despite the absence in the blood of the two . . . markers . . . that are strongly associated with RA.” *Olson II*, 135 Fed. Cl. at 672 (internal quotation marks omitted).

(internal quotation marks and citation omitted). “This standard is uniquely deferential and difficult for an appellant to satisfy with respect to any issue, but particularly with respect to an issue that turns on the weighing of evidence by the trier of fact.” *Id.* (internal quotation marks and citation omitted). If “the special master’s conclusion is based on evidence in the record that is not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.” *Id.* at 1360–61 (internal quotation marks and citation omitted); see *Hines ex rel. Sevier v. Sec’y of the Dep’t of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991) (“If the special master has considered the relevant evidence of record, drawn plausible inferences[,] and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate.”).

“The Vaccine Act distinguishes between . . . ‘Table injuries,’ for which causation is presumed when a designated condition follows the administration of a designated vaccine within a designated period of time, and all other injuries alleged to be caused by a vaccine, [i.e.,] ‘off-Table injuries,’ for which causation must be proved . . .” *Moberly ex rel. Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010) (citations omitted); see 42 U.S.C. § 300aa-14 (Vaccine Injury Table). Where, as here, a petitioner alleges an off-Table injury, “the petitioner’s ‘burden is to show by preponderant evidence’ each of the requirements set forth in *Althen v. Secretary of Health and Human Services* (‘the *Althen* prongs’)” for causation. *Oliver*, 900 F.3d at 1361 (quoting 418 F.3d 1274, 1278 (Fed. Cir. 2005)). The *Althen* prongs are: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen*, 418 F.3d at 1278. “If the petitioner satisfies this burden, she

is entitled to recover unless the Government shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.” *Oliver*, 900 F.3d at 1361 (internal quotation marks, brackets, and citation omitted).

We have specified that, with respect to *Althen* prong one, “a paucity of medical literature supporting a particular theory of causation cannot serve as a bar to recovery.” *Andreu ex rel. Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (internal quotation marks, brackets, and citations omitted). Accordingly, even a possible link between a vaccine and an injury, “hitherto unproven in medicine,” can be sufficient for a finding of causation. *Althen*, 418 F.3d at 1280. In this regard, we require “a reputable medical theory,” *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006) (emphasis added) (citation omitted), providing that the vaccine in question “can cause” the injury suffered, *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006) (citation omitted); see *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (providing the explanation simply must be “legally probable, not medically or scientifically certain” (internal quotation marks and citation omitted)).

II. Ms. Olson Has Not Demonstrated Causation Because She Did Not Meet Her Burden of Providing a Medical Theory Causally Connecting the HPV Vaccination and Her RA

The Special Master concluded that, inter alia, Ms. Olson failed to meet her burden to show “the HPV vaccine *could* cause RA.” *Olson I*, 2017 WL 3624085, at *19. Specifically, the Special Master determined that Ms. Olson’s “causation theory is wholly dependent on the

vaccine's adjuvant^[6] causing her RA, but reliable science does not corroborate its alleged potential to initiate a pathogenic^[7] sequence. Moreover, [Ms. Olson's] medical history does not demonstrate her theory in action." *Id.* at *1. Ms. Olson argues, inter alia, the Special Master acted arbitrarily and capriciously by making unsupported findings under *Althen* prong one. See Appellant's Br. 25–30, 33–41, 44–45. We disagree with Ms. Olson.

The Special Master made plausible findings based on the record under *Althen* prong one. Ms. Olson's theory of how the HPV vaccine caused her RA involved (1) her history of inflammatory lung conditions, *see id.* at 19, and (2) an adjuvant in the vaccine called "alum," *see id.* at 21–22. Essentially, Ms. Olson claims that her inflammatory lung conditions predisposed her to developing RA, *see id.* at 19–20; *see also* J.A. 100–15 (testimony of Dr. Middleton), 354–56 (declaration of Dr. Middleton), and the introduction of alum into her body via the HPV vaccine stimulated the condition's onset, *see* Appellant's Br. 21–22; *see also* J.A. 115–21 (testimony of Dr. Middleton), 358–62 (declaration of Dr. Middleton). Following a thorough recitation of record evidence, *see Olson I*, 2017 WL 3624085, at *1–14, the Special Master found "[a] few overarching aspects of [Ms. Olson's] theory [to be] medi-

⁶ "An adjuvant is a substance that aids another, such as an auxiliary remedy. In this case, the adjuvant boosts the immune system to make more antibodies with the result that the vaccine is more effective and long-lasting." *Olson II*, 135 Fed. Cl. at 673 n.6 (internal quotation marks and citation omitted).

⁷ "Pathogenic means 'causing disease or morbid symptoms.'" *Sumner v. Sec'y of Health & Human Servs.*, No. 99-946V, 2015 WL 5173644, at *11 n.28 (Fed. Cl. Aug. 13, 2015) (quoting *Pathogenic*, Dorland's Illustrated Medical Dictionary (32d ed. 2012)).

cally or scientifically sound,” *id.* at *20. For example, the Special Master noted that “[Ms. Olson] has offered persuasive evidence in support of her contention that persistent lung inflammation is often associated with RA,” and her explanation for why was “logical and scientifically reliable.” *Id.* The Special Master also remarked that Ms. Olson “offer[ed] trustworthy articles exploring the not-fully-understood processes by which adjuvants like alum help stimulate the innate immune system,” and established that certain immune system protein complexes and cell secretions “play *some* role in the process of encouraging the unchecked inflammation that is so integral to RA’s development.” *Id.*

However, the Special Master found that Ms. Olson’s specific theory of causation failed to reputably show that the HPV vaccine *can* cause RA. *See id.* at *19–22. With regard to the first facet of Ms. Olson’s theory, the Special Master found that Ms. Olson “relie[d] on science that is ultimately inapposite to the present context.” *Id.* at *21. Specifically, Ms. Olson adduced evidence that specific antibodies result from the process by which inflammatory lung conditions increase an individual’s risk of RA. *See id.*; *see also* J.A. 111 (stating, by Dr. Middleton, that “anti-citrullinated protein antibod[ies]” (“ACPAs”) are indicative of inflammatory lung conditions that increase an individual’s risk of RA, and are “present in 70 percent of patients with [RA]”). Yet, test results showed that ACPAs were not present in Ms. Olson, *see* J.A. 351 (stating, in Dr. Middleton’s supplemental expert report, that Ms. Olson’s ACPA levels “have been negative”), and the Special Master concluded that, “therefore[,] she cannot credibly propose a theory involving a process that she cannot also establish occurred to her,” *Olson I*, 2017 WL 3624085, at *21. The Special Master additionally determined that this finding “impacts [Ms. Olson]’s argument that an individual with chronic lung infections, due to asthma or other respiratory ailments, is susceptible to a vaccine

trigger, since the literature discussing the lung as an initiatory situs for RA largely depends on [the process by which ACPAs are produced] occurring there first.” *Id.*; see J.A. 575–76 (discussing the process that produces an ACPA response).

With regard to the second facet of Ms. Olson’s theory, the Special Master discerned that alum was “the *sole* HPV [vaccine] component implicated,” and “[i]t was therefore critically important that [Ms. Olson] marshal reliable scientific or medical evidence suggesting that alum could precipitate RA or some other comparable autoimmune disease.” *Id.* at *20. However, the Special Master found that “the literature [Ms. Olson] offered—the most scientifically-reliable items of which were studies aimed at understanding *how* alum performs as a stimulatory actor in the immune process—[did] not do this.” *Id.* (citing, inter alia, J.A. 491–502 (investigating, in a scientific article on adjuvant activity, how alum stimulates the immune system), 503–10 (similar)). Ms. Olson’s evidence that alum stimulates protein complexes associated with RA was deemed inadequate by the Special Master to show a possible causal relationship between alum and RA, see J.A. 496 (concluding, in a scientific article, that alum functions as an adjuvant by stimulating specific protein complexes that were claimed by Dr. Middleton to play a role in RA); see also J.A. 360–62 (discussing, in Dr. Middleton’s supplemental expert report, these protein complexes’ role in RA), particularly given “[t]he fact that many vaccines also contain alum but have not been implicated in RA or other autoimmune conditions,” *Olson I*, 2017 WL 3624085, at *21. The Special Master, therefore, determined that the relevant record evidence merely “explore[d] in detail [the] known fact[] that alum is an effective adjuvant,” and “d[id] not permit the broader conclusion that [Ms. Olson] urges: that alum can be pathogenic—and indeed *none* of [Ms. Olson]’s offered literature so proposes.” *Id.* (footnote omitted).

Ms. Olson's counterarguments are unavailing. First, Ms. Olson asserts that the Special Master applied an incorrect legal standard under *Althen* prong one. See Appellant's Br. 16–17. Specifically, Ms. Olson argues that the Special Master “erred in requiring prong one proof of *probability* rather than *plausibility*.” *Id.* at 16 (emphases added) (formatting modified). Throughout the Special Master's analysis of the evidence, he correctly applied the law of *Althen* prong one. The Special Master surveyed the record to determine whether Ms. Olson's theory was medically reputable, see *Olson I*, 2017 WL 3624085, at *19–22; see also *Pafford*, 451 F.3d at 1355–56 (holding that a special master correctly applied *Althen* prong one in requiring a petitioner to “provide a *reputable* medical theory causally connecting the vaccination and the injury” (emphasis added) (citation omitted)), and at no point demanded anything but a showing that Ms. Olson's theory was *possibly* true in light of the marshaled evidence, see *Olson I*, 2017 WL 3624085, at *19–22; see also *Capizzano*, 440 F.3d at 1326 (concluding that “the first prong of the *Althen* . . . test was satisfied by the finding that the . . . vaccine *can cause* [the injury]” (emphasis added) (citation omitted)). For example, in his determinations that Ms. Olson's assertions were inadequately supported, the Special Master stated that, inter alia, the assertions were “speculative” and that “[r]eliable scientific support [wa]s lacking.” *Olson I*, 2017 WL 3624085, at *20.

Second, Ms. Olson contends that the Special Master improperly increased her evidentiary burden “by requiring the testimony of an immunologist.” Appellant's Br. 13. In assessing the evidence provided by Dr. Middleton, the Special Master observed that, “though qualified to testify about RA generally and its possible etiology, [Dr. Middleton] lacked the specialized immunologic grounding necessary to explain and defend in a persuasive manner the theory articulated in this case, given that theory's

dependency on complex immune system processes.” *Olson I*, 2017 WL 3624085, at *21; *see id.* at *6 (stating Dr. Middleton’s qualifications), *8 n.13 (noting “Dr. Middleton’s lack of particularized expertise on the topic of immunology”). Special masters “are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” *Moberly*, 592 F.3d at 1326. While special masters may not “cloak the application of an erroneous legal standard in the guise of a credibility determination,” *Andreu*, 569 F.3d at 1379, here, the Special Master did no such thing. The Special Master’s assessment of Dr. Middleton’s credibility was appropriate given the former’s role as fact finder, and tracks with Dr. Middleton’s express acknowledgement of the limitations to his expertise when discussing alum and its potential immune system effects, *see* J.A. 165 (“I am testifying here as a clinical rheumatologist, not as a vaccine expert.”), and the fact that “Dr. Middleton did not even *begin* to see [Ms.] Olson until three years from [the] date of her . . . vaccination,” *Olson I*, 2017 WL 3624085, at *21. The Special Master did not require evidence from an immunologist, but rather properly evaluated Dr. Middleton’s individual competence to opine on the matters at issue. *See Moberly*, 592 F.3d at 1325–26 (“Assessments as to the reliability of expert testimony often turn on credibility determinations, particularly in cases . . . where there is little supporting evidence for the expert’s opinion.”). Thus, Ms. Olson failed to meet her burden to demonstrate causation under *Althen* prong one.⁸

⁸ We need not address the Special Master’s findings with respect the remaining two *Althen* prongs because we affirm the Court of Federal Claims’ primary holding that Ms. Olson did not carry her burden under *Althen* prong

CONCLUSION

We have considered Ms. Olson's remaining arguments and find them unpersuasive. Accordingly, the Judgment of the U.S. Court of Federal Claims is

AFFIRMED

one. *See W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1358 (Fed. Cir. 2013) (“[A] petitioner must establish all three prongs of the *Althen* test” (internal quotation marks and citation omitted)).