

# United States Court of Appeals for the Federal Circuit

2006-5056

PATRICIA ANN WALTHER,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

Richard Gage, Richard Gage, P.C., of Cheyenne, Wyoming, argued for petitioner-appellant.

Mark Curtis Raby, Senior Trial Counsel, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With him on the brief were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Vincent J. Matanoski, Acting Deputy Director, and Gabrielle M. Fielding, Assistant Director.

Appealed from: United States Court of Federal Claims

Judge Nancy B. Firestone

# United States Court of Appeals for the Federal Circuit

2006-5056

PATRICIA ANN WALTHER,

Petitioner-Appellant,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee.

---

DECIDED: May 1, 2007

---

Before DYK and PROST, Circuit Judges, and McKINNEY, Chief Judge.<sup>\*</sup>

DYK, Circuit Judge.

Appellant Patricia Ann Walther (“Walther”) appeals a decision of the Court of Federal Claims sustaining the decision of a special master denying compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 et seq. (2000) (“Vaccine Act”). Because we conclude that the special master appears to have applied an incorrect legal standard—requiring Walther to eliminate other possible causes of her injury—we vacate the decision and remand for a determination under the correct standard.

---

<sup>\*</sup> Honorable Larry J. McKinney, Chief Judge of the United States District Court for the Southern District of Indiana, sitting by designation.

## BACKGROUND

Walther was a captain in the United States Army at the time of the events in question. On July 31, 1997, she received tetanus-diphtheria (“Td”),<sup>1</sup> yellow fever, typhoid, and meningitis vaccinations. On August 6 she also received a rabies vaccination. On August 7 and 8 she experienced trembling in her left hand, weakness, and fatigue. When Walther continued to experience problems with her hands and her left leg, she sought medical treatment, which revealed progressive weakness in both hands and a mild partial paralysis of the left side of her body. On December 12, 1997, Dr. Seth Stankus, a military neurologist, diagnosed her with post-vaccinal acute disseminated encephalomyelitis (“ADEM”). ADEM is a neurological disorder caused by damage to the myelin sheath (fatty covering) insulating the nerve cells in the brain.

Two other neurologists and the Army’s Physical Evaluation Board agreed with this diagnosis. Walther was placed on the Army’s temporary disability retired list on May 22, 1998. She claims to continue to experience muscular weakness on her left side, fatigue, head tremors, and migraines resulting from ADEM. On July 20, 2000, Walther filed a petition under the Vaccine Act claiming that the Td vaccine caused her ADEM.

The special master held a hearing on May 20, 2005. The government’s primary contention was that Walther did not suffer from ADEM. Walther presented the testimony of two experts to establish that she suffered from ADEM. The government

---

<sup>1</sup> There are two forms of the vaccine. The appellant and the special master stated that Walther received the DT form of the vaccination, but the government and the Court of Federal Claims stated that she received the Td form. We presume that Walther, an adult, received the Td vaccine, rather than the pediatric DT version; there has been no suggestion that any difference between the two would affect the outcome.

introduced contrary testimony from two other experts. The government also contended that, even if Walther suffered from ADEM, it was not caused by the Td vaccine. On the causation question, Walther's expert, Dr. Vera Byers, opined that "it is more likely than not that [Walther's] diagnosed ADEM was produced by the tetanus toxoid-diphtheria vaccination she received" because: (1) the medical literature confirmed that it was biologically plausible for Td vaccine to cause ADEM; (2) Walther developed her symptoms during the medically accepted timeframe—within six days of receiving the vaccine; (3) the other vaccines Walther received were unlikely to have caused her illness for reasons specific to each vaccine. J.A. at 73.

On the question of causation Walther also relied on her medical records, which reflected the opinions of her treating physicians that her condition was caused by a vaccination, and the report of another expert (Dr. Kinsbourne) in which he opined that "to a reasonable degree of medical certainty . . . Dr. Walter's ADEM . . . w[as] caused by the tetanus toxoid vaccination that she received." J.A. at 63. Petitioner also relied on two other special master decisions that held that the tetanus vaccine caused ADEM. See Kuperus v. Sec'y of Health & Human Servs., 2003 WL 22912885 at \*1 (Fed. Cl. 2003) (special master) (DTaP); Johnson v. Sec'y of Health & Human Servs., 2000 WL 1141582 at \*10 (Fed. Cl. 2000) (special master) (Td).

In an opinion issued on July 29, 2005, the special master dismissed Walther's petition. He did not reach the question that had been the focus of the hearing—whether Walther suffered from ADEM. Instead, he concluded that Walther had failed to carry her burden to prove that her illness was caused by the Td vaccine. He used a three-part test that required "proof of biologic plausibility between a vaccine and an injury;

proof that an injury occurred within a medically-acceptable time period following vaccination; and proof eliminating other potential causes for the injury.” Walther v. Sec’y of Health & Human Servs., No. 00-0426V, slip op. at 3-4 (Fed. Cl. July 29, 2005) (special master) (emphasis added) [“Special Master’s Decision”].

The government conceded that the Td vaccine was a biologically plausible cause of Walther’s ADEM and that her symptoms appeared within a medically-acceptable time period. Special Master Hearing Tr. 26; 35 (May 20, 2005). The government concluded that the petitioner had not adequately established causation for a number of reasons including that “Walther has not adequately eliminated the other vaccines that she received in Summer 1997 as causative agents for her condition.” Special Master’s Decision at 2 (internal quotation marks omitted). Viewing Dr. Byers’s opinion as the only evidence on causation, the special master addressed her testimony directly and found that she was not credible on the causation issue. He “reject[ed] Dr. Byers’s opinion” because he “harbor[ed] significant concerns regarding the quality and the substance of Dr. Byers’s testimony.” Id. at 4. In particular, the special master concluded that Dr. Byers had not stated “a viable proposition that Dr. Walther’s [Td] vaccination, rather than one of Dr. Walther’s other vaccinations, caused more likely than not [her] condition.” Id. at 5 (emphasis added). Additionally, the special master distinguished the two other special master decisions that found that forms of the tetanus vaccine caused ADEM, both of which involved only one vaccine, based on Walther’s failure to eliminate the other vaccines as potential causes. Id. at 6.

In seeking review in the Court of Federal Claims, Walther argued that “the special master applied the wrong legal standard for causation.” Walther v. Sec’y of

Health & Human Servs., 69 Fed. Cl. 123, 124 (2005). The Court of Federal Claims affirmed the special master's decision, finding that it was not arbitrary and capricious. Id. The Court of Federal Claims stated "that the special master denied the petitioner relief because he rejected Dr. Byers' opinion testimony and not because he applied the wrong legal standard," finding that "Dr. Byers failed to persuade the special master that the tetanus component of the Td vaccine was any more likely to have caused the petitioner's ADEM than were any of the other vaccines that she received at or around the same time." Id. at 127-28.

Walther timely appealed the Court of Federal Claims' decision to this court. We have jurisdiction pursuant to 42 U.S.C. § 300aa-12(f). We review the Court of Federal Claims review of the special master's decision without deference. See Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). We review the special master's legal determinations under a non-deferential "not in accordance with law" standard. See id., 451 F.3d at 1355. By contrast, given the special master's role "to perform the fact finding function for the Program," Munn v. Sec'y of Health & Human Servs., 970 F.2d 863, 868 (Fed. Cir. 1992), we review factual determinations under the deferential "arbitrary and capricious standard," Pafford, 451 F.3d at 1355.

## DISCUSSION

On appeal, the petitioner's primary contention is that the special master applied an incorrect standard requiring her to eliminate other potential causes in order to establish a prima facie case of causation. The special master appeared to require that the petitioner eliminate alternative causes to carry her burden to establish a prima facie case. Not only was the elimination of alternative causes one of the prongs of his three-

part causation test, but he also concluded that “the evidence does not demonstrate affirmatively that [Td] vaccine caused actually Dr. Walther’s condition” at least in part because he did not believe that Dr. Byers had stated “a viable proposition that Dr. Walther’s [Td] vaccination, rather than one of Dr. Walther’s other vaccinations, caused more likely than not Dr. Walther’s conditions.” Special Master’s Decision at 5 (emphasis added). Moreover, he distinguished the two other special master’s decisions that found that forms of the tetanus vaccine caused ADEM on the grounds that those cases involved only one vaccine whereas “Dr. Walther received concurrently one Table vaccine and many non-Table vaccines, every one of which represented a biologically-plausible explanation for her condition.” Id. at 6 (emphasis added).

We conclude that the special master’s decision, to the extent that it did place a requirement on the petitioner to establish a lack of alternative causation, was erroneous.

I

In order “to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines,” as well as to insure the production of necessary vaccines, Congress enacted the Vaccine Act in 1986. 42 U.S.C. §§ 300aa-1, 300aa-2(a)(5) (2000). The Vaccine Act created the National Vaccine Injury Compensation Program (“Program”), which is administered by the Secretary of Health and Human Services, “under which compensation may be paid for a vaccine-related injury or death.” 42 U.S.C. § 300aa-10(a). Petitions seeking compensation under the Vaccine Act are referred in the first instance to the Office of Special Masters of the Court of Federal Claims. 42 U.S.C. § 300aa-12(d). The special master’s decision on compensation is binding unless a

party seeks review in the Court of Federal Claims. 42 U.S.C. § 300aa-12(e)(3). In the event a party does seek review, the Court of Federal Claims can set aside the special master's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2).

The statute provides two ways for a petitioner to satisfy his or her prima facie case of causation. In a "Table case," a petitioner who shows that he or she received a vaccination listed in the Vaccine Injury Table ("Table"), 42 U.S.C. § 300aa-14, and suffered an injury listed in the Table within the time period prescribed by the Table gains a presumption of causation. 42 U.S.C. § 300aa-11(c)(1)(C)(i); see also Pafford, 451 F.3d at 1355. In an "off-Table case," in which the injury either occurred outside of the Table's time period or was not listed in the Table, the petitioner must prove that he or she received a vaccine listed in the Table and that he or she suffered an injury that was actually caused by the vaccine.<sup>2</sup> 42 U.S.C. § 300aa-11(c)(1)(C)(ii); see also Pafford, 451 F.3d at 1355. Of the vaccines Walther received, Td is the only one listed in the Table and therefore the only one for which Walther can recover under the Vaccine Act. ADEM is not an injury listed in the Table for the Td vaccine, 42 U.S.C. § 300aa-14(a), and therefore Walther acknowledges that she must prove actual causation.

---

<sup>2</sup> Additionally, in both Table and off-Table cases, the petitioner must prove that he or she: (1) received the vaccination in the United States; (2) either suffered effects of her injury for six months, died, or was hospitalized and underwent surgery; and (3) has not received other damages for the injury. 42 U.S.C. § 300aa-11(c)(1)(B), (D), & (E).



## II

### A

While our recent decision in Pafford held that a petitioner as a practical matter may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient, 451 F.3d at 1359, we conclude that the Vaccine Act does not require the petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case.

The statutory text itself makes clear that the petitioner does not bear the burden of eliminating alternative causes. Under 42 U.S.C. § 300aa-13(a)(1), compensation is awarded if the special master finds:

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title [including in an off-Table case that the illness "was caused by a vaccine" covered by the Vaccine Act], and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

Subsection (A) thus explicitly places the burden on the petitioner to establish the elements of § 300aa-11(c)(1), including causation. This court has adopted the actual causation standard of the Restatement (Second) of Torts, which requires the petitioner to show that the vaccine is a "but for" cause of the illness—i.e., that the harm would not have occurred but for the vaccine. See Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999); see also Pafford, 451 F.3d at 1355; Restatement (Second) of Torts, §§ 430-432 (1965). Our precedent has established that a petitioner

satisfies this standard by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect; and (3) a proximate temporal relationship between the vaccination and the injury. Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); see also Pafford, 451 F.3d at 1355. Under our case law, “close calls regarding causation are resolved in favor of injured claimants.” Althen, 418 F.3d at 1280.

The alternative causation issue is addressed in subsection (B). That provision does not specifically place the burden on the petitioner with respect to alternative causation. When juxtaposed with subsection (A)'s clear statement as to the burden of proof under that prong, the absence of any such language in subsection (B) suggests that the petitioner does not bear the burden as to alternative causation under the second prong. Moreover, it would be unusual to require a party to prove that “there is not a preponderance of the evidence,” as our legal system rarely requires a party to prove a negative. A plain reading of the statutory text more naturally places the burden on the government to establish that there is an alternative cause by a preponderance of the evidence.

Indeed, placing the alternative causation burden on the petitioner would essentially write § 300aa-13(a)(1)(B) out of the statute. On the one hand, if the petitioner did not successfully eliminate other causes, then the petition would fail and the second prong would not be reached. On the other hand, if the petitioner did eliminate alternative causes, the second prong would not be reached because the question of alternative causation would already have been resolved. Thus, construing the statute in such a way would make § 300aa-13(a)(1)(B) “redundant or largely

superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative.” Colautti v. Franklin, 439 U.S. 379, 392 (1979).

Moreover, under the Restatement (Second) of Torts, which is controlling in off-Table cases, see Shyface, 165 F.3d at 1351-52, for purposes of the causation analysis the petitioner is treated as the equivalent of the tort plaintiff and the government is treated as the equivalent of the tort defendant. Under the Restatement, “the burden of proof that the tortious conduct of the defendant has caused the harm to the plaintiff is [normally] upon the plaintiff.” Restatement (Second) of Torts § 433B(1). Under the Restatement, in cases involving multiple independent potential causes, if it is clear “that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.”<sup>3</sup> Restatement (Second) of Torts § 433B(3). Thus, applying the Restatement to the Vaccine Act context, the petitioner generally has the burden on causation, but when there are multiple independent potential causes, the government has the burden to prove that the covered vaccine did not cause the harm. On the other hand, a petitioner is certainly permitted to use evidence eliminating other potential causes to help carry the burden on causation and may find it necessary to do so when the other evidence on causation is insufficient to make out a prima facie case, as was

---

<sup>3</sup> Restatement (Second) of Torts § 433B(3) states in full:

Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm.

true in Pafford.<sup>4</sup> In such instances, clearly the special master must evaluate what evidence a claimant presents as part of determining whether the claimant makes a prima facie case.

Consistent with the statutory language and the Restatement, the cases have recognized that in both Table and off-Table cases the government bears the burden of establishing alternative causation by a preponderance of the evidence once the petitioner has established a prima facie case. As we have previously noted, the text and structure of “[t]he Vaccine Act separates the inquiry for alternative etiologies from the inquiry for causation. These are two separate inquiries under the statute.” Grant v. Sec’y of Health & Human Servs., 956 F.2d 1144, 1149 (Fed. Cir. 1992). Thus in Whitecotton v. Secretary of Health & Human Services., 17 F.3d 374 (Fed. Cir. 1994), rev’d on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995), we stated:

Once petitioners satisfy their burden of proving presumptive or actual causation by a preponderance of evidence, they are entitled to recover unless the Secretary shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.

Id. at 376 (emphasis added); see also Knudsen v. Sec’y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994) (same). Although reversing the Whitecotton decision on

---

<sup>4</sup> The Restatement distinguishes between forces that combine to produce a harm, and forces that independently caused a harm. When a case involves multiple causes acting in concert (not the situation involved here), we recognized in Shyface that a petitioner need not show the asserted vaccine was the predominant cause, but must show that it was substantial. Shyface, 165 F.3d at 1352-53. Where multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine. We need not address here whether and when the petitioner may be required to make such a showing.

other grounds,<sup>5</sup> the Supreme Court explicitly endorsed our recitation of the government's burden on alternative causation. See Shalala, 514 U.S. at 270. The Supreme Court confirmed:

While a claimant may establish prima facie entitlement to compensation by introducing proof of actual causation, § 300aa-11(c)(1)(C)(ii), she can reach the same result by meeting the requirements of what the Act calls the Vaccine Injury Table. . . . The Secretary of Health and Human Services may rebut a prima facie case by proving that the injury or death was in fact caused by "factors unrelated to the administration of the vaccine."

Id. at 270-71 (emphases added). In other cases we have specifically recognized that the government bears the burden on alternative causation when, as here, the petitioner attempts to establish a prima facie case through the off-Table path of proving actual causation. We have described the question as "whether an alternative causation has been proved by HHS," Jay v. Sec'y of Health & Human Servs., 998 F.2d 979, 984 (Fed. Cir. 1993) (emphasis added), and referred to "the Secretary's proof of alternative causation," Shyface, 165 F.3d at 1350 (emphasis added).

We conclude that the petitioner does not bear the burden of eliminating alternative independent potential causes, and, to the extent the special master assigned that burden to the claimant, we conclude that he erred.

---

<sup>5</sup> Whitecotton involved a child who showed some symptoms of her condition before vaccination (as well as symptoms within the appropriate Table period after vaccination). The Supreme Court reversed this court's conclusion that Whitecotton could recover, holding that a petitioner must show that no symptoms of the illness appeared before the vaccination and that symptoms appeared within the required Table period after vaccination in order to gain the Table's presumption of causation. Shalala, 514 U.S. at 274.

## B

The government argues that, even if the special master applied an erroneous legal standard in this case, the evidence clearly shows that Walther failed to carry her burden to establish a prima facie case of causation. We think this issue is best considered by the special master in the first instance.

Since we conclude that the special master appeared to apply an erroneous legal standard, we must set aside the decision and remand for further proceedings. “Insofar as a finding is derived from the application of an improper legal standard to the facts, it cannot be allowed to stand.” Charles Alan Wright et al., Federal Practice & Procedure § 2585 at 574 (2d ed. 1994); see also United States v. Singer Mfg. Co., 374 U.S. 174, 194 n.9 (1963); FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1417 (Fed. Cir. 1987). In such a circumstance, this court must remand for new factual findings in light of the correct legal standard. For example, in Panduit Corp. v. Denninson Manufacturing Co., 810 F.2d 1561, 1576 (Fed. Cir. 1987), we concluded that a district court’s legal error in construing patent claims necessarily affects its factual findings as to differences between the prior art and the claims and noted that the factual findings “will necessarily be clearly erroneous” and “a remand . . . is required.” Id. at 1576. In this case, since the special master appeared to apply an incorrect legal standard, we think the special master should make a new causation determination under the correct standard in the first instance.

We therefore vacate the special master’s decision and remand for a new causation determination that applies the correct legal standard to the record as a whole. In doing so, we do not dictate a particular causation finding, nor do we address the main

contention of the government, that Walther did not suffer from ADEM, an issue not reached by the special master.

#### CONCLUSION

We remand the case to the special master to reconsider the causation issue under the correct legal standard and for other proceedings not inconsistent with this opinion.

#### VACATED AND REMANDED

#### COSTS

No costs.