

United States Court of Appeals for the Federal Circuit

**TODD SIMANSKI AND JULIA SIMANSKI,
AS PARENTS AND NEXT FRIENDS OF OLIVIA ANN
SIMANSKI,**
Petitioners-Appellants,

v.

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

2011-5050

Appeal from the United States Court of Federal Claims in Case No. 03-VV-103, Judge Christine O.C. Miller.

Decided: March 6, 2012

Sylvia Chin-Caplan, Conway, Homer & Chin-Caplan, P.C. of Boston, Massachusetts, argued for petitioners-appellants. On the brief was RONALD C. HOMER

TRACI R. PATTON, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With her on

the brief were TONY WEST, Assistant Attorney General, MARK W. ROGERS, Acting Director, VINCENT J. MATANOSKI, Acting Deputy Director, and CATHARINE E. REEVES, Assistant Director.

Before BRYSON, MOORE, and REYNA, *Circuit Judges.*
BRYSON, *Circuit Judge.*

This case requires us to examine the procedures employed by a special master in adjudicating a petition for compensation stemming from a vaccine-related injury. The procedural history of this case is quite complex, and to conduct a fair assessment of the issues raised on appeal requires that we review it in some detail.

I

A

Olivia Simanski was born on November 2, 2000. Aside from having a low birth weight, she appeared to be healthy. She was scheduled to receive her first set of vaccines at a pediatric visit two months later, but because she was suffering from some gastrointestinal problems at that time, her pediatrician decided to postpone the inoculations. Two days later, on January 26, 2001, Olivia returned to the pediatrician's office and received the following five vaccines: diphtheria, acellular pertussis, and tetanus; haemophilus influenzae type B; inactivated polio vaccine; pneumococcal conjugate; and a hepatitis B vaccine.

Three days after receiving the shots, Olivia experienced a change in her overall well-being. Her mother described Olivia as being lethargic, mildly irritated,

lacking in appetite, and having labored breathing. The next day, Olivia suffered acute respiratory failure and was rushed to a nearby hospital. There she was intubated and placed on a ventilator. Her treating physicians thought that she might have been infected with respiratory syncytial virus (“RSV”). They took cultures for the presence of that virus, which came back positive.

Olivia’s condition required extensive hospitalization and treatment. She was initially treated at the admitting hospital but was subsequently transferred to other institutions for diagnosis and treatment. Throughout the course of her treatment, several of Olivia’s treating physicians concluded that she was suffering from either Guillain-Barré Syndrome (“GBS”), an acute neurologic disorder of the peripheral nervous system, or a GBS-like syndrome. Although Olivia’s condition subsequently stabilized, she still requires the use of a ventilator and a wheelchair, and she faces many physical and developmental challenges.

B

Olivia’s parents filed a petition with the National Vaccine Injury Compensation Program on January 17, 2003. Congress created that program in 1986 when it enacted the National Childhood Vaccine Injury Act (“the Vaccine Act”), 42 U.S.C. §§ 300aa-1 to 300aa-34, to provide compensation for vaccine-related injuries and deaths. The Vaccine Act identifies two categories of compensable vaccine injuries: “Table injuries” and “off-Table injuries.”

“Table injuries” are those covered by the Vaccine Injury Table. The Table consists of a list of conditions that have been determined to be significantly associated with particular vaccines when the symptoms or manifestations

of those conditions arise within a specified period after the administration of the vaccine. 42 U.S.C. § 300aa-14; 42 C.F.R. § 100.3. For an injury covered by the Vaccine Injury Table, the statute creates a presumption that the vaccine caused the injury in question. *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1307 (Fed. Cir. 1999).

“Off-Table injuries” are injuries that are not covered by the Vaccine Injury Table. Petitioners with off-Table injuries cannot rely on the statutory presumption of causation but instead must demonstrate actual causation by a preponderance of competent evidence. *See Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321-22 (Fed. Cir. 2010). Because it is undisputed that the injury in this case is not covered by the Table, the parties have treated this as an off-Table case. In order to establish entitlement to compensation, the Simanskis are therefore required to show, by a preponderance of the evidence, that one or more of the vaccines that were administered to Olivia caused or significantly aggravated her condition. 42 U.S.C. §§ 300aa-11(c)(1)(C)(ii), 300aa-13(a)(1)(A).

Congress vested jurisdiction over Vaccine Act cases in the Court of Federal Claims and authorized the creation of the Office of Special Masters to adjudicate the petitions for compensation. *See* 42 U.S.C. § 300aa-12. Congress envisioned that the special masters would become specialists in vaccine-related injuries and would use “their accumulated expertise in the field [to] judg[e] the merits of the individual claims.” *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000), quoting *Hodges v. Sec'y of the Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993).

The Vaccine Act directs the Court of Federal Claims, with input from the special masters, to promulgate rules of procedure for Vaccine Act cases. 42 U.S.C. § 300aa-12(d)(2). The statute directs that the rules shall, *inter alia*, “provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions, . . . include flexible and informal standards of admissibility of evidence, [and] include the opportunity for summary judgment.” *Id.*

In accordance with that mandate, the Court of Federal Claims has promulgated a set of rules known as the Vaccine Rules. *See* Vaccine Rules of the U.S. Court of Federal Claims, Rules of Ct. of Fed. Claims app. B. Those rules are designed to ensure that claims for compensation under the Vaccine Act are resolved in a manner that is both speedy and fair. *See* 42 U.S.C. § 300aa-12(d); *see also* Vaccine R. 3(b)(2).

The statute and the Vaccine Rules give the special masters broad authority in conducting proceedings under the Act, including full control over discovery and the power to require the production of evidence and information. 42 U.S.C. § 300aa-12(d)(3); *see also* Vaccine R. 3(a), 7(a), 8(c). The Vaccine Rules also provide that a special master may “dismiss a petition . . . for failure of the petitioner to . . . comply with these rules or any order of the special master.” Vaccine R. 21(b)(1).

While allowing for flexibility, the Vaccine Rules contain certain procedural requirements to guarantee fairness in the adjudicatory process. For instance, parties retain the ability to ask for formal discovery if they believe, in a particular case, that informal production is insufficient. *See* Vaccine R. 7(b). Moreover, the Vaccine Rules provide that the special masters can decide

cases on written submissions, including, in appropriate cases, by summary judgment. *See Vaccine R. 8(d); see also 42 U.S.C. § 300aa-12(d)(2)(C)* (requiring that the Vaccine Rules include the opportunity for summary judgment).

C

Pursuant to the statutory scheme, when the Simanskis filed their petition for compensation due to Olivia's injuries, the petition was assigned to a special master. After several periods of delay, the Simanskis ultimately perfected their petition by submitting medical records, an affidavit from Olivia's mother, and reports from two medical experts in support of their claim.

The Simanskis' first expert report was one prepared by Dr. Paul Maertens, who stated that in his opinion Olivia's respiratory failure was due to RSV. Dr. Maertens noted, however, that the vaccines she received "could have played a role" in her condition. The report proposed a theory by which the vaccines could have had such an effect, but stated that the determination of whether the immunizations were a factor in the onset of symptoms was one "best made by an immunologist."

The special master concluded that Dr. Maertens' report alone was insufficient to establish a *prima facie* claim of causation. The Simanskis then explained that they were consulting with an immunologist to obtain an additional expert report. In 2009, an immunologist, Dr. Yehuda Shoenfeld, examined materials the Simanskis provided to him and submitted an expert report and supporting documentation, including a large number of references to medical literature.

In his report, Dr. Shoenfeld cited articles supporting the theory that several of the vaccines Olivia received could cause GBS or its chronic variant, chronic inflammatory demyelinating polyneuropathy (“CIPD”). He proposed several potential mechanisms by which the vaccines could have caused Olivia’s condition. He explained that autoimmune diseases such as GBS and CIPD can be triggered in susceptible persons by environmental agents such as infections and vaccinations, and that the contents of the vaccines such as diluents, adjuvants, preservatives, and stabilizers, could lead to the development of autoimmunity. He cited literature for the proposition that “molecular mimicry” is the most likely mechanism by which vaccines cause autoimmune conditions. At the end of his report, Dr. Shoenfeld stated, “Therefore with great confidence and certain[t]ly I can say that the vaccines with all their immunological aspects were the cause of the GBS/CIPD leading to phrenic nerve paralysis and failure to extubate Olivia Simanski from artificial respiration.”

D

After the Simanskis submitted Dr. Shoenfeld’s report, the special master held a status conference at which he discussed the report with the parties. *See Simanski v. Sec’y of Health & Human Servs.*, No. 03-vv-103, Dkt. No. 85 (Fed. Cl. Spec. Mstr. Apr. 13, 2009) (April 13, 2009, Order). The Simanskis asserted that the Shoenfeld report sufficed to meet their burden under *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005), to establish causation. The respondent disagreed and contended that the report was deficient in several respects. The respondent claimed that rather than obtaining and submitting its own expert report to refute Dr.

Shoenfeld's conclusions, it intended to file a motion for summary judgment. April 13, 2009, Order at 2.

The special master concluded that Dr. Shoenfeld's report raised questions about Dr. Shoenfeld's position regarding the issue of causation. In particular, the special master identified the following questions as left unresolved by the report: (1) which vaccine Dr. Shoenfeld believes was responsible for causing Olivia's adverse reaction; (2) if Dr. Shoenfeld believes that the acellular pertussis vaccine caused Olivia's adverse reaction, whether the acellular nature of the vaccine would affect his opinion in light of recent changes in the make-up of the pertussis vaccine; (3) whether Dr. Shoenfeld has a theory that would explain, to the level of more probable than not, how one or more of the vaccines caused Olivia's adverse reaction; (4) how Dr. Shoenfeld would account for the treating doctors' suggestions that Olivia's problems were caused by an RSV infection; and (5) whether Dr. Shoenfeld had presented "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Althen*, 418 F.3d at 1278, particularly with respect to the timing of the onset of symptoms. Dr. Shoenfeld's report indicated that GBS resulting from a vaccination typically manifests itself no sooner than five days after the vaccination, whereas Olivia's respiratory failure occurred only four days after she received the vaccines.

Although the Simanskis stated that they were comfortable resting on Dr. Shoenfeld's report and did not wish to obtain a supplemental report, the special master stated that he would afford the Simanskis an opportunity to review the record and supplement it if they so desired. The special master added that if the Simanskis "believe that the existing record supports a finding that they have

met their burden, then respondent has indicated that he [sic] will file a motion for summary judgment and seek a ruling before obtaining an expert report.” April 13, 2009, Order at 2.

E

In response to the special master’s order, the Simanskis submitted a supplemental report in the form of a two-page letter from Dr. Shoenfeld. The letter addressed the timing issue raised by the special master but did not otherwise address the special master’s questions. As to the issue of timing, Dr. Shoenfeld wrote that the early onset of Olivia’s symptoms could be attributable to her very young age and immature immune system, which can produce “great variability in the onset of timing between one individual and another,” or to a condition known as “congenital autoimmunity.” That condition, he explained, results from prior sensitization of an infant’s mother to a vaccine or to bacteria that can result in “passive transfers of antibodies,” which in turn can “enhance and accelerate the eventual reaction” or result in “enhanced autoimmunity.”

The special master found Dr. Shoenfeld’s supplemental report to be lacking, in that it failed to address four of the five questions he had raised. Stating that the supplemental report “requires additional clarification and/or explanation,” the special master issued an order giving the Simanskis an opportunity to file a second supplemental report. The special master added several other points that he said needed clarification in light of Dr. Shoenfeld’s supplemental report.

With respect to the timing issue, the special master asked that Dr. Shoenfeld explain which of Olivia’s initial

symptoms were indications of an autoimmune reaction and whether those symptoms were manifestations of GBS or some other autoimmune disease. The special master also asked Dr. Shoenfeld to explain how the immune system of a three-month-old child differs from that of an adult, and whether the literature discussing the development of neurologic conditions in adults who have received different types of vaccines is relevant to the way Olivia reacted. In light of Dr. Shoenfeld's reference to "congenital autoimmunity," the special master asked whether Dr. Shoenfeld believed it was reasonably probable that congenital autoimmunity contributed to Olivia's development of GBS and whether Dr. Shoenfeld believed it was reasonably probable that Olivia's mother had a prior sensitization to bacteria that contributed to Olivia's condition.

In requesting that additional information, the special master again noted that "[m]ore information from Dr. Shoenfeld is especially advantageous in this case" because the respondent had stated that it intended to file a motion for summary judgment arguing that the Simanskis had not met their burden of proof under *Althen*. In addition, the special master stated that "a written disclosure of all of Dr. Shoenfeld's opinions will allow respondent and [the special master] to prepare for the hearing" and "eliminate any surprise testimony and thereby increase the likelihood that the hearing can be completed in one session." *Simanski v. Sec'y of Health & Human Servs.*, No. 03-vv-103, Dkt. No. 89 (Fed. Cl. Spec. Mstr. June 26, 2009) (June 26, 2009, Order).

F

The Simanskis responded to the June 26, 2009, Order by stating that they would not produce a second supplemental report from Dr. Shoenfeld. They took the position

that it was unreasonable for the special master to require such detail at the pre-hearing stage of the proceeding when, in their view, the evidence they had submitted at that point had established a *prima facie* case that Olivia's vaccines caused her GBS. They argued that the respondent should be required to address the reasons, if any, why compensation should be denied. They added that the questions propounded by the special master in his two previous orders "not only serve as a disincentive for the respondent to resolve the case, but inappropriately provide the respondent, and the respondent's expert, with a road map as to how to attack the opinions of Dr. Shoenfeld." In any event, they noted, the respondent's expert might agree with much of what Dr. Shoenfeld had stated and might answer some of the special master's questions.

In the alternative, the Simanskis argued, the special master could invite the respondent to move for summary judgment. In that event, the Simanskis said, they would respond and the special master could then issue a ruling based on the state of the record at that time.

G

Several months later, the special master issued an order to show cause why the Simanskis' petition should not be dismissed. *See Simanski v. Sec'y of Health & Human Servs.*, No. 03-vv-103, Dkt. No. 94 (Fed. Cl. Spec. Mstr. Nov. 20, 2009) (Order to Show Cause). That order consisted of a lengthy opinion that summarized the facts of the case and addressed the special master's authority to direct the submission of a supplemental report. Besides discussing the consequences of failing to comply with such an order, the special master addressed whether dismissal

of the petition would be a permissible sanction in these circumstances.

Apart from the discussion of the propriety of ordering the production of additional evidence and dismissing the petition as a sanction for failure to comply with such an order, the special master devoted a considerable portion of the Order to Show Cause to addressing the merits of the case. After analyzing the evidence submitted by the Simanskis, the special master concluded that the Simanskis had not established causation and that, without more evidence, dismissal was appropriate.

To begin with, the special master noted that Dr. Shoenfeld had not identified the vaccine that caused Olivia's GBS. Dr. Shoenfeld reported that the principal vaccine associated with GBS is the influenza vaccine, which Olivia did not receive. With respect to other vaccines, including ones Olivia did receive, the special master noted that Dr. Shoenfeld simply stated that those vaccines "are involved with" GBS. As to the pertussis vaccine, which Dr. Shoenfeld discussed in his report, the special master identified "several gaps" in Dr. Shoenfeld's discussion. First, Olivia did not receive the whole cell version of the pertussis vaccine, and many of the articles cited by Dr. Shoenfeld in support of his opinion were directed to the whole cell version of that vaccine. The special master stated that "Dr. Shoenfeld may believe that the acellular pertussis vaccine [that Olivia received] can cause the same problems as the whole cell pertussis vaccine," but that "[i]f Dr. Shoenfeld holds this belief, then he should clearly state his opinion and provide the basis for his opinion." Second, the special master noted that Dr. Shoenfeld had stated that the pertussis vaccine "can aggravate other infections" but added that Dr. Shoenfeld did not state that he believed, to a level of

medical probability, that the acellular pertussis vaccine aggravated Olivia’s RSV infection. If Dr. Shoenfeld did hold such a belief, the special master added, he “should propose that theory explicitly.”

As to Dr. Shoenfeld’s discussion of the mechanism by which vaccines can induce autoimmunity, the special master found “multiple problems” with the report. First, although the report discussed autoimmunity generally, it did not “connect autoimmunity to Olivia.” Second, Dr. Shoenfeld expressed his views in terms of what conditions “may” trigger autoimmunity, which the special master viewed as not constituting “probative evidence that it was more likely than not that a vaccine did cause a problem.” The special master concluded that Dr. Shoenfeld needed to “articulate his opinion that ‘it is more probable than not’ that something happened (or did not happen),” and that his statement that a vaccine “may induce autoimmunity” was not sufficient to “discharge the Simanskis’ obligation to present a preponderance of evidence.” Third, the special master complained that Dr. Shoenfeld had failed to identify which vaccine may have triggered an autoimmune response.

With respect to Dr. Shoenfeld’s discussion of the theory of “molecular mimicry” as an explanation relating vaccine exposure to an autoimmune response, the special master first noted that Dr. Shoenfeld did not state that he believed it was more likely than not that molecular mimicry resulting from vaccine exposure explained Olivia’s GBS. Moreover, Dr. Shoenfeld did not “provide a basis for finding that molecular mimicry is a reliable theory in Olivia’s case.” According to the special master, in the absence of an explanation of how molecular mimicry could have been responsible for Olivia’s condition, Dr. Shoenfeld’s “simple assertion of molecular mimicry” did

not constitute a reliable medical theory causally connecting Olivia’s vaccination and her injury, as required by the *Althen* test.¹

Turning to the issue of the temporal relationship between Olivia’s vaccination and the onset of her injury, the special master noted that although Dr. Shoenfeld acknowledged that the appropriate interval between vaccination and the onset of a condition such as GBS is 5 to 21 days, and that Olivia’s respiratory failure occurred four days after she received the vaccines, Dr. Shoenfeld did not provide an adequate explanation for why he believed the vaccines had caused Olivia’s GBS despite the fact that her symptoms did not manifest themselves within the medically appropriate time period. In particular, the special master criticized Dr. Shoenfeld’s report for providing several possible explanations for the timing disparity, but not saying how those explanations applied to Olivia’s case. The special master noted that in a different case, a neonatal immunologist had testified that children younger than six months of age are *less* likely, not *more* likely, to develop autoimmune reactions because their immune systems are not strong enough to attack the host. As for Dr. Shoenfeld’s theory of “congenital autoimmunity,” the special master observed that Dr. Shoenfeld had not identified GBS as a disease caused by congenital autoimmunity. And as for Dr. Shoenfeld’s comment that Olivia’s mother may have had a prior sensitization to bacteria that accelerated Olivia’s autoimmune reaction,

¹ The special master briefly alluded to the discussion of adjuvants in Dr. Shoenfeld’s report, noting that Dr. Shoenfeld had failed to identify the particular adjuvant that he believed may have affected Olivia and that a portion of his discussion of adjuvants related to a vaccine that Olivia did not receive.

the special master pointed out that Dr. Shoenfeld had not identified any evidence of such sensitization on the part of Olivia's mother.

Speaking more generally about the flaws in Dr. Shoenfeld's reports, the special master pointed to "the lack of a clearly articulated theory" of causation: If Dr. Shoenfeld's theory was based upon a toxic response to the vaccine (which may happen in the case of the pertussis vaccine), the onset of symptoms would likely be rapid, for example within 72 hours. On the other hand, if Dr. Shoenfeld's theory was based on an autoimmune response, the onset of symptoms would occur after a greater lapse of time, as the body would require time to develop an autoimmune reaction. The special master explained that if Dr. Shoenfeld clarified his opinion with regard to the theory of causation, "his opinion with regard to the time that medical science expects to a vaccine reaction would also become more clear." Finally, the special master noted that Dr. Shoenfeld did not identify which of Olivia's symptoms were manifestations of GBS. The special master observed that a neurologist examined Olivia 13 days after her vaccination and 9 days after the date on which she began to develop symptoms of illness, yet the results of that neurologist's examination seemed to be inconsistent with a dysfunction in the peripheral nervous system. In view of that report, the special master concluded, Dr. Shoenfeld needed to explain when Olivia first began to manifest signs of GBS.

In light of the failure of Dr. Shoenfeld's reports to show a theory of causation and a temporal connection between the vaccine and the injury (the first and third prongs of the *Althen* test), the special master stated that it was "not surprising that Dr. Shoenfeld failed to articulate a logical sequence of cause and effect showing that

the vaccination was the reason for Olivia’s injury” (the second prong of the *Althen* test). In summary, the special master observed that “Dr. Shoenfeld’s report is more like a general discourse about various topics instead of presenting a theory for explaining how a vaccine that Olivia received caused her GBS.”

As for Dr. Shoenfeld’s ultimate conclusion that he could say with “great confidence and certain[t]y” that “the vaccines with all of their immunological aspects were the cause of” Olivia’s condition, the special master found that assertion unsupported by “any reliable theory to explain why a vaccine that Olivia received caused her to develop GBS.” Without an “explicit presentation of Dr. Shoenfeld’s opinions that fit Olivia’s case,” the special master concluded, “there appears to be too great an analytic gap to support Dr. Shoenfeld’s conclusion.” The special master added that the Simanskis would be given an opportunity to “cure these deficiencies by obtaining a supplemental report from Dr. Shoenfeld.”

H

In response to the Order to Show Cause, the Simanskis again declined to submit a supplemental report from Dr. Shoenfeld or offer any other evidence to support their claim. Rather, they stated that they believed the special master lacked authority to dismiss the petition for failure to comply with the special master’s “personal order for discovery” without considering “the remaining evidence contained in the record as a whole.” They argued that the special master had “ignore[d] the evidence in the record” and threatened to dismiss the case “for refusing to comply with his discovery order . . . without ever addressing the merits.” They contended that they had presented sufficient evidence to establish causation and that in light

of their showing, the burden should have shifted to the respondent to refute their showing with its own expert report. Because they claimed that they had made out a *prima facie* case for compensation and the respondent “has chosen to remain silent,” they asked that an award be entered in their favor.

In reply to the Simanskis’ response, the respondent argued that dismissal was an appropriate sanction for the Simanskis’ failure to comply with the special master’s discovery order to produce supplemental reports. The respondent added that the special master is authorized “to require the submission of information that is reasonable and necessary to support a finding in petitioners’ favor,” and that the Simanskis’ failure to comply with the special master’s directives to produce additional information “leaves the special master with insufficient evidence to support a finding in their favor.”

I

The special master subsequently dismissed the Simanskis’ petition. *Simanski v. Sec’y of Health & Human Servs.*, No. 03-vv-103, 2010 WL 2292200 (Fed. Cl. Spec. Mstr. May 13, 2010). In his opinion directing the entry of judgment for the respondent, the special master stated that the Simanskis had not met their burden of establishing the elements that are required by the *Althen* test to entitle them to compensation. In particular, he stated, Dr. Shoenfeld’s reports did not present a medical theory causally connecting a vaccine that Olivia received with the onset of her GBS; they did not establish a logical sequence of cause and effect showing that the vaccination was the reason for Olivia’s injury; and they did not establish that there was a medically appropriate time period between Olivia’s vaccinations and the onset of her GBS.

Their failure to satisfy the *Althen* test, he stated, “means that the Simanskis cannot prevail.”

The special master stated that Dr. Shoenfeld’s reports referred to what a vaccine “may” do, but did not demonstrate that it was more likely than not that any vaccine had caused Olivia’s condition, and that despite positing many possibilities, Dr. Shoenfeld did not “explain what he believes happened to Olivia.” Accordingly, the special master dismissed the petition “for failing to comply with the show cause order, which required the Simanskis to produce sufficient evidence to meet the *Althen* prongs.”

J

The Simanskis appealed the dismissal order to the Court of Federal Claims, arguing that the special master had abused his discretion in dismissing the case before requiring the respondent to submit an expert report to counter the Simanskis’ evidence. The Court of Federal Claims affirmed in a lengthy opinion. *Simanski v. Sec’y of Health & Human Servs.*, 96 Fed. Cl. 588 (2010). After reviewing the background of the case and the applicable legal principles in detail, the court concluded that “the special master did not abuse his discretion in failing to require evidence from respondent.”

The court ruled that after a Vaccine Act petitioner has perfected his petition, the special master may proceed in one of three ways: (1) on written submissions; (2) by calling for a motion for summary judgment; or (3) by holding an evidentiary hearing. The court rejected the Simanskis’ argument that Vaccine Rule 4(c) requires the respondent to file a report in every case. Although normally the petitioner files an expert report, the respondent files a report, and the case then proceeds to a hearing, the

court explained that in appropriate cases a petition could be disposed of without a hearing, either on written submissions or pursuant to a motion for summary judgment. *See* Vaccine R. 8(a).

In this case, the court found that the special master had decided the case on “written submissions,” not on summary judgment, and that he had done so upon concluding that the Simanskis’ evidence was “unpersuasive in [meeting] the elements of causation-in-fact articulated in *Althen*.” Thus, the court held that the special master’s dismissal order “was not entered solely as a sanction for failure to comply” with the special master’s orders to supplement Dr. Shoenfeld’s report, but instead “was a de facto analysis of the merits.” Although acknowledging that the special master had “stepped outside the boundaries of an adversarial proceeding,” the court concluded that the Vaccine Act, which encourages the use of more informal proceedings than ordinary civil litigation, allowed the special master to do just that.

The court further concluded that the Simanskis were not prejudiced by the manner in which the special master proceeded. Reviewing the special master’s conduct of the proceedings, the court ruled that the special master had carefully considered the material facts in the record, and that the Simanskis had failed “to pinpoint deficiencies in the special master’s findings.” Because the Simanskis had not shown the special master’s decision to be arbitrary and capricious, the court determined that it could not disturb the special master’s findings.

In the end, the court concluded, “[w]hat is presented in the instant case is a ruling on a procedural issue, and the ruling calls for review of an underlying detailed factual analysis made by the special master.” The court

may do that, it explained, if the petitioner “points to deficiencies in the special master’s analysis.” For the petitioners to mount an adequate challenge to the special master’s factual findings, “they must point to particular missteps made by the special master,” and raise “specific objections to the special master’s findings.” In this case, because the petitioners failed to set forth their “particular objections to the special master’s findings,” the court sustained the special master’s ruling denying their claim.

The Simanskis then appealed to this court.

II

The Simanskis’ appeal is addressed in part to procedure and in part to the merits. With regard to procedure, the Simanskis argue that the special master should have required the respondent to file a report under Vaccine Rule 4(c) setting forth its position as to whether an award should be granted. With regard to the merits, they argue that they have satisfied their burden to show entitlement to compensation, that it was error for the special master to find that they failed to establish a *prima facie* case, and that this court should rule as a matter of law that they are entitled to compensation.

A

Vaccine Rule 4(c)(1) provides as follows:

Within 90 days after the filing of a petition, or in accordance with any schedule set by the special master after petitioner has satisfied all required documentary submissions, respondent must file a report setting forth a full and complete statement

of its position as to why an award should or should not be granted.

The Simanskis argue that they perfected their petition by filing Olivia's medical records and their experts' reports. Once they had completed that step, they argue, the respondent was required to file a Rule 4(c) report. The respondent's failure to file such a report was prejudicial to them, the Simanskis argue, because the report might have conceded their claim or at least narrowed the dispute between the parties.

The Court of Federal Claims rejected the Simanskis' interpretation of Rule 4(c). The court ruled that under Rule 4(c)(1) the intended course of action in most cases is for the respondent to file a report after the perfection of the petition, but that the special master is authorized by the statute and the Vaccine Rules "to pretermit the need for respondent to set forth its statement of position" in appropriate cases. Besides the broad authority granted to special masters to conduct proceedings in Vaccine Act cases, the court explained, Rule 4(c)(1) itself provides that the filing of the respondent's report is subject to the scheduling discretion of the special master.

In this case, the respondent indicated at several points that it intended to file a motion for summary judgment. In such a case, the Court of Federal Claims held, the respondent can move for summary judgment before filing a report if the respondent believes that the evidence submitted by the petitioner would be insufficient to support a compensation award. As directed by the Vaccine Act, 42 U.S.C. § 300aa-12(d)(2)(C), Rule 8(d) of the Vaccine Rules provides that the special master may decide a case on the basis of written submissions, including a motion for summary judgment. Rule 8(d) states

that such motions are governed by the procedures of Rule 56 of the Rules of the Court of Federal Claims, which is substantively similar to Rule 56 of the Federal Rules of Civil Procedure.

A party moving for summary judgment under Rule 56 of the Federal Rules of Civil Procedure or the Rules of the Court of Federal Claims is not necessarily required to submit evidence in support of its motion. Instead, when the non-moving party bears the burden of proof on an issue, the moving party can simply point out the absence of evidence creating a disputed issue of material fact. The burden then falls on the non-moving party to produce evidence showing that there is such a disputed factual issue in the case. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986); *Dairyland Power Coop. v. United States*, 16 F.3d 1197, 1202 (Fed. Cir. 1994). Applying those principles in the context of a Vaccine Act case means that the respondent may move for summary judgment without having filed evidence, in the form of a report or otherwise, contesting the petition.

Because the Vaccine Rules contemplate the use of summary judgment procedures based on the practice under Rule 56, we agree with the Court of Federal Claims that Vaccine Rule 4(c) does not require the respondent to file a report in every case after the petitioner has perfected his or her petition. For the same reason, we reject the Simanskis' related argument that they were entitled to refuse to comply with the special master's order to produce a supplemental report from Dr. Shoenfeld because the special master "lacked the authority [to] suspend respondent's Rule 4(c) report" once the Simanskis had perfected their petition.

B

On the merits, the Simanskis argue that the evidence of record required the special master to award compensation in this case and that this court should direct the entry of judgment in their favor on remand. They contend that their evidence satisfies each of the *Althen* factors and that, in the absence of evidence from the respondent showing a different cause for Olivia's condition, they have met their burden of proving causation by a preponderance of the evidence.

The Simanskis' request for a ruling on the merits is premature. It was within the authority of the special master to suspend the respondent's time for complying with Vaccine Rule 4(c). As a result, the respondent has not waived its right to file a responsive report setting forth its evidence and presenting its arguments in response to the petition and the evidence the Simanskis have introduced into the record. In light of the fact that, despite its lengthy pendency, this case is still at an early procedural stage and the respondent has not been called upon to present its position with respect to the petition and the supporting evidence, it would be inappropriate for us to hold at this point that the Simanskis are entitled to compensation under the Act.

C

To conclude that the Simanskis are not entitled to the entry of a compensation award at this time does not, of course, answer the question whether it was error for the special master to dismiss the petition without a hearing. To answer that question, we must address the scope of a special master's authority to dismiss a petition when the petitioner fails to respond to the special master's requests

for additional information. As indicated below, we believe that notwithstanding the broad statutory grant of discretion to the special masters in conducting Vaccine Act proceedings, there is a limit to their power to dismiss petitions for failure to comply with orders to produce additional information. We hold that in this case the special master exceeded that limit.

1

The Court of Federal Claims correctly noted that by statute special masters are entrusted with considerable authority over discovery and the production of evidence in Vaccine Act cases. The Act provides that in conducting a proceeding on a compensation petition, a special master may require “such evidence as may be reasonable and necessary,” may require “the submission of such information as may be reasonable and necessary,” and may require “the testimony of any person and the production of any documents as may be reasonable and necessary.” 42 U.S.C. § 300aa-12(d)(3)(B). Moreover, the statute provides that there may be “no discovery in a proceeding on a petition other than the discovery required by the special master.” *Id.*; see *Whitecotton v. Sec'y of Health & Human Servs.*, 81 F.3d 1099, 1108 (Fed. Cir. 1996) (noting that “the permissible scope of the special master’s inquiry is virtually unlimited”). Accordingly, orders to produce supplemental information of the sort issued by the special master in this case are well within the special master’s authority.

In appropriate circumstances, an unjustified failure to comply with a lawful order of a special master can result in dismissal of the petition, just as dismissal can be ordered for failure to prosecute a petition. See Vaccine R. 21(b)(1) (authorizing dismissal of a petition for failure to

comply with an order of the special master or the court). Similarly, in ordinary civil litigation dismissal is one of the sanctions that can be used in cases of discovery violations, *see Nat'l Hockey League v. Metro. Hockey Club, Inc.*, 427 U.S. 639, 643 (1976) (per curiam), although the ultimate sanction of dismissal of a claim with prejudice has been reserved for extreme cases, whether in the context of discovery or litigation misconduct, *see Micron Tech., Inc. v. Rambus Inc.*, 645 F.3d 1311, 1328 (Fed. Cir. 2011); *Univ. of Pittsburgh v. Varian Med. Sys., Inc.*, 569 F.3d 1328, 1334 (Fed. Cir. 2009).

We do not believe the sanction of dismissal with prejudice was warranted on the facts of this case. The special master regarded both Dr. Shoenfeld's initial report and his supplemental report as raising questions about whether the Simanskis had met their burden to show causation. In his first order, the special master related that the Simanskis were "comfortable resting on Dr. Shoenfeld's [first] report, and did not want to obtain a supplemental report." Nonetheless, the special master "afforded [them] an opportunity to review the record" and then to advise the special master "how they would like the case to proceed." The special master added the following:

If the Simanski[s] believe that the existing record supports a finding that they have met their burden, the respondent has indicated that he will file a motion for summary judgment and seek a ruling before obtaining an expert report. Alternatively, the Simanskis may wish to obtain a supplemental report from Dr. Shoenfeld.

That order was not couched as a directive to supplement Dr. Shoenfeld's report, but rather as offering the Si-

manskis a choice whether to file additional evidence or to proceed on the record they had made to that point.

When the Simanskis submitted their supplemental report from Dr. Shoenfeld, the special master found that report to be insufficient and stated that the Simanskis “are given another opportunity to present an additional report from Dr. Shoenfeld.” The special master noted that “[b]efore respondent assesses the petitioners’ case, petitioners and Dr. Shoenfeld should make as complete [a] disclosure as possible. More information from Dr. Shoenfeld is especially advantageous . . . because during the April 13, 2009 status conference, respondent stated that it intended to file a motion for summary judgment.” The special master added that “if the case proceeds to a hearing, a written disclosure of all of Dr. Shoenfeld’s opinions will allow respondent and [the special master] to prepare for the hearing. A written disclosure will also eliminate any surprise testimony and thereby increase the likelihood that the hearing can be completed in one session.” Again, the special master’s order was couched as providing the Simanskis with an opportunity to supplement the record, not as a directive insisting that they do so.²

² That order included a sentence reading, “As previously stated, the petitioners are ordered to file a second supplemental report from Dr. Shoenfeld by Friday, July 24, 2009.” That sentence alludes to the prior provision of the order giving the petitioners “another opportunity to present an additional report from Dr. Shoenfeld” and setting forth the deadline for filing that report. We do not interpret the quoted sentence as requiring the Simanskis to file such a report, but rather as setting the deadline by which any such report must be filed.

In the subsequent Order to Show Cause, the special master characterized the two previous orders differently. He stated that the Simanskis had “failed to comply with the April 13, 2009 order and the June 26, 2009 order, which required the Simanskis to obtain a supplemental expert report.” The special master alluded to “several unrecorded status conferences” at which the special master had “discussed the reasons the Simanskis should obtain a supplemental expert report,” but he relied on the Simanskis’ “refus[al] to comply” with the April 13, 2009, and June 26, 2009, orders as the basis for issuing the Order to Show Cause. In response to the Order to Show Cause, the Simanskis argued that the respondent should be required to file a report in response to their petition, and they requested that the special master proceed to rule on the compensation issue.

While the Order to Show Cause contained more directory language than the special master’s two prior orders, even the Order to Show Cause invited the Simanskis to supplement Dr. Shoenfeld’s report in order to avoid dismissal on the merits. It explained that “this order presently gives the Simanskis an opportunity to cure any gaps in Dr. Shoenfeld’s opinion,” and added that if the Simanskis “present a supplemental response from Dr. Shoenfeld that addresses the concerns in this show cause order, their case will be improved and the case will continue.”

Under these circumstances, we hold that the special master should not have dismissed the petition as a sanction for the Simanskis’ failure to comply with the orders to supplement Dr. Shoenfeld’s report. To be sure, it was entirely reasonable for the special master to suggest that the Simanskis supplement Dr. Shoenfeld’s report, both to provide better support for their claim and to allow the

respondent and the special master to prepare for the hearing. However, having given the Simanskis the option to supplement the report or face a summary judgment motion or a dismissal on the merits based on the record as it stood, the special master should not have dismissed the petition for noncompliance with the prior orders when they elected to stand on Dr. Shoenfeld's original report and his supplemental letter.

Apart from the particular circumstances of this case, if a Vaccine Act petitioner has produced what the petitioner believes is enough evidence to prevail, or at least to proceed to a hearing, the petitioner is normally entitled to a ruling on that question. If the petitioner cannot produce additional evidence in response to a special master's order—or chooses not to do so—the petitioner may be at risk of an adverse ruling on the merits, but that ruling should be based on the merits and not on the petitioner's failure to come forward with additional evidence.

In such a case, if the respondent believes the petitioner's evidence is insufficient to set forth facts that could justify a compensation award, the proper course is for the respondent to move for summary judgment, as the respondent indicated it was prepared to do in this case. In ruling on that motion, the special master can decide whether the petitioner's evidence is sufficient to allow the matter to proceed to a hearing. If the special master denies summary judgment and orders the case to proceed to a hearing, and the special master is concerned that the petitioner's expert may seek to testify to matters beyond the scope of his expert report, there are several measures the special master can employ to minimize that risk. First, the special master can order the experts to confine their testimony to the issues addressed in their reports. Second, the special master can insist on a proffer of the

experts' testimony well in advance of the hearing. Third, the special master can order some form of discovery from the experts prior to the hearing. However, in a case such as this one, where the question is whether the petitioners' evidence is sufficient to survive a summary judgment motion by the respondent, it is ordinarily not appropriate for the special master to dismiss the petition as a sanction for the petitioners' failure to comply with a directive to produce additional evidence in support of their claim.

2

As the Court of Federal Claims pointed out, the special master's Order to Show Cause contained a detailed assessment of the merits of the case, which the special master included as part of his analysis of whether any less severe sanction would be appropriate for the Simanskis' failure to comply with his invitations to supplement Dr. Shoenfeld's report. Based on his analysis of the merits, the special master concluded that Dr. Shoenfeld's two reports "fail to meet the petitioners' burden of producing persuasive evidence" on each of the three parts of the *Althen* test for proving causation in an off-Table case.

Besides arguing that the special master was authorized to dismiss the petition for failure to comply with the special master's orders, the respondent contends that the special master addressed the merits of the Simanskis' claim and correctly held their evidence insufficient to satisfy the three parts of the *Althen* test. The Court of Federal Claims agreed that the special master addressed the merits of the case and concluded that the "petitioners' information [was] unpersuasive in [meeting] the elements of causation-in-fact articulated in *Althen*." The court noted, however, that in reaching that conclusion, the special master "did not afford petitioners review under

the summary judgment standard that would give them the benefit of all inferences,” and that the special master “directly analyz[ed] the merits of the case without calling for a statement of position from respondent or without calling for a motion for summary judgment.” In so doing, the Court of Federal Claims stated, “the special master in the instant case stepped outside the boundaries of an adversarial proceeding.” However, in view of the broad authority granted to special masters in conducting vaccine compensation proceedings, the court concluded that “the Vaccine Act allows him to do just that.”

On this point, we disagree with the Court of Federal Claims. The manner in which the special master addressed the merits amounted to making a decision in the case on written submissions, but not applying summary judgment standards and not conducting a hearing on the claim. As a result, the issues of the sufficiency of the evidence and the Simanskis’ failure to comply with the special master’s directives became intertwined in this case in a way that obscured the question whether the Simanskis had proffered sufficient evidence to survive summary judgment and entitle them to a hearing on the merits of their claim.

The special master focused on the perceived inadequacies in Dr. Shoenfeld’s theory of causation, but his analysis was not couched as an inquiry into whether the Simanskis had made a sufficient showing of causation to withstand summary judgment. In particular, in discussing the *Althen* factors the special master appears to have demanded more from the petitioners than would be required in a conventional summary judgment proceeding. For example, in addressing whether the Simanskis had provided “a medical theory causally connecting the vaccination and the injury,” *Althen*, 418 F.3d at 1278, the

special master objected to Dr. Shoenfeld’s report on various grounds. One ground was that Dr. Shoenfeld had stated that a vaccine “may induce autoimmunity.” That statement was insufficient to satisfy the “medical theory” requirement, the special master ruled, because it was not sufficient to establish, by a preponderance of the evidence, that the vaccine *did* cause autoimmunity in Olivia.

The special master also criticized Dr. Shoenfeld for failing to present a “clearly articulated theory” of how the vaccines in question caused Olivia’s GBS, including “identification and proof of specific biological mechanisms.” That was too demanding a standard. Although a finding of causation “must be supported by a sound and reliable medical or scientific explanation,” causation “can be found in vaccine cases . . . without detailed medical and scientific exposition on the biological mechanisms.” *Knudsen v. Sec’y of the Dep’t of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). It is not necessary for a petitioner to point to conclusive evidence in the medical literature linking a vaccine to the petitioner’s injury, as long as the petitioner can show by a preponderance of the evidence that there is a causal relationship between the vaccine and the injury, whatever the details of the mechanism may be. *Moberly*, 592 F.3d at 1325; *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009).

Likewise, in addressing whether the Simanskis had shown “a proximate temporal relationship between vaccination and injury,” *Althen*, 418 F.3d at 1278, the special master noted that Olivia’s respiratory failure had occurred one day earlier than would be expected according to the medical literature. Dr. Shoenfeld sought to explain why in Olivia’s case an earlier date of onset was not inconsistent with a vaccine-related injury, but the special

master found his explanation insufficient to satisfy that prong of the *Althen* test. This court has explained that requiring a “temporal relationship” between the vaccination and the injury is designed to ensure that it is “medically acceptable to conclude that the vaccination and the injury are causally linked.” *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). While the special master’s critique of Dr. Shoenfeld’s explanations for the early onset is thorough and may ultimately be convincing, we think Dr. Shoenfeld’s explanations were sufficient at least to present a factual dispute as to that issue from which a trier of fact could conclude that the one-day variance in the time of onset of Olivia’s symptoms is not inconsistent with a vaccine-related injury.

As a final point regarding the special master’s analysis of Dr. Shoenfeld’s report, the special master observed that while Dr. Shoenfeld had stated that a vaccine “may induce autoimmunity,” he did not state that a vaccine received by Olivia “did induce autoimmunity in Olivia,” and that if he “holds that opinion, then the Simanskis should file a supplemental report from Dr. Shoenfeld” to that effect. To the extent that the special master was concerned that Dr. Shoenfeld had failed to state his opinion as to whether a vaccine had induced autoimmunity in Olivia, a fair reading of his initial report makes it clear that he holds that opinion. In the report, he stated that “GBS is a clinical autoimmune disease” and that “the vaccines with all their immunological aspects were the cause of [Olivia’s] GBS/CIPD.” While the support in the report for that conclusion may be inadequate to compel the grant of relief based on the evidence of record at this time, as noted above, the conclusion at least makes clear that Dr. Shoenfeld believes that a vaccine induced autoimmunity in Olivia.

In sum, we conclude that while special masters are given broad authority over the manner in which they conduct Vaccine Act proceedings, that authority may not be used in a way that deprives a party of procedural rights provided by the Vaccine Act and the Vaccine Rules, such as the rights attendant to conventional summary judgment procedures. *See Jay v. Sec'y of the Dep't of Health & Human Servs.*, 998 F.2d 979, 983 (Fed. Cir. 1993).

3

While we agree with the Simanskis that the dismissal order in this case should be overturned, we do not endorse the extended remarks in the Simanskis' brief accusing the special master of "cross[ing] the line' from being an impartial jurist, to being an advocate for the respondent" and having a "predisposition to find against Olivia." As we have noted, it was entirely reasonable for the special master to suggest that the Simanskis supplement Dr. Shoenfeld's initial report.

III

Because we conclude that the special master should not have dismissed the Simanskis' petition due to their failure to supplement Dr. Shoenfeld's reports, and because the special master's analysis of the merits should have been conducted in accordance with conventional summary judgment standards, we reverse the judgment of the Court of Federal Claims. We remand with instructions for the special master to address the merits of the Simanskis' claim, either by applying appropriate summary judgment standards or by conducting a hearing and resolving the compensation claim on the merits.

REVERSED and REMANDED