

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

DR. YULIYA DOBRYDNEVA and
DR. BORIS DOBRYDNEV, Parents of
ILYA DOBRYDNEV, a Minor,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 04-1593V
The Honorable Susan G. Braden
Special Master Christian J. Moran

Filed: October 27, 2010
For Publication: Dec. 16, 2011

entitlement, hepatitis B vaccine,
chronic fatigue syndrome, remand

Mark P. Friedlander, Jr., McLean, VA, and Mark Greenspan, Norfolk, VA, for petitioners;
Heather L. Pearlman, and Rebecca J. Trinrud, United States Dep't of Justice, Washington, DC,
for respondent.

PUBLISHED DECISION ON REMAND DENYING ENTITLEMENT*

Yuliya Dobrydneva and Boris Dobrydnev claim that a dose of the hepatitis B vaccine caused their son, Ilya, to develop chronic fatigue syndrome. Dr. Dobrydneva and Dr. Dobrydnev seek compensation pursuant to the National Childhood Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 et seq. (2006). The United States Court of Federal Claims vacated an earlier decision, which had denied compensation for failing to establish one of the three elements

* This decision was filed on October 27, 2010, and the parties were given an opportunity to propose redactions within the time set in Vaccine Rule 18(b). Neither party proposed redactions. Thus, the decision should have been posted to the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

However, due to an administrative oversight, this decision was not made available to the public as required by 42 U.S.C. § 300aa-12(d)(4)(B). Consequently, this decision is being made available now, although the Court has reviewed this October 27, 2010 decision in the interim. Memorandum Opinion and Final Order, 98 Fed. Cl. 190 (2011).

No changes to the October 27, 2010 decision were made, except to this footnote.

set forth in Althen v. Sec’y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Memorandum Opinion and Order, 94 Fed. Cl. 134 (2010).

As part of its order, the Court found that Ilya’s chronic fatigue syndrome “occurred after the November 5, 2001 vaccine and manifested symptoms well within the time period accepted by expected by the medical community.” Opinion and Order, 94 Fed. Cl. at 146. The Court’s finding resolves two issues that had previously been disputed – whether chronic fatigue syndrome is an appropriate diagnosis and whether Dr. Dobrydneva and Dr. Dobrydnev fulfilled the third prong of Althen. The Court did not make any findings regarding the first two prongs from Althen. Instead, the Court remanded the case for findings on these elements after conducting supplemental evidentiary proceedings.¹

These evidentiary proceedings have been conducted. An analysis of the entire record (both before and after remand) indicates that the petitioners have not met their burden of proof. Thus, they are not entitled to compensation.

I. Factual and Procedural History²

Ilya was born in 1991. He experienced relatively frequent colds, ear infections, and sore throats as a child. A more significant problem was apparent by February 2001, when a doctor diagnosed Ilya as in the “convalescent phase” of a “recent EBV [Epstein-Barr virus] infection.” Exhibit 5 at 40. In June 2001, Ilya again tested positive for an acute infection with EBV. Id. at 37.

On November 5, 2001, Ilya received a fourth dose of the hepatitis B vaccine. Exhibit 9 at 3. As stated by the Court, “according to Ilya’s mother, he experienced malaise, fever, sore throat, lymph node swelling, and marked pallor.” Opinion and Order, 94 Fed. Cl. at 138, citing tr. 47 and exhibit 3 at 1-2.

On November 19, 2001, Ilya saw Dr. Fink for a “2-3 day history of low grade temperature elevation along with a sore throat,” and “some degree of nasal congestion with minimal cough.” Dr. Fink diagnosed Ilya as having “febrile illness/viral pharyngitis.” Exhibit 5 at 36.

On November 26, 2001, Ilya saw Dr. Fink again because Ilya had yellow nasal discharge and a frontal headache. Dr. Fink diagnosed Ilya as having sinusitis and prescribed Augmentin. Id.; see also tr. 83; tr. 189-90 (testimony of Dr. Fink). It appears that the Court recognized Ilya’s

¹ The Court also ordered an award of attorneys’ costs on an interim basis to pay Dr. Oleske. This order was issued on August 10, 2010.

² The March 12, 2010 decision and the July 30, 2010 order set forth the facts about Ilya’s medical history and the procedural history of this case in detail.

headache as one manifestation of what eventually became diagnosed as chronic fatigue syndrome. Opinion and Order, 94 Fed. Cl. at 146.

On November 30, 2001, Ilya experienced severe dizziness and nausea. Exhibit 10 at 1. At a hospital, Ilya was diagnosed with vestibular neuronitis. A doctor stated that “the most likely cause of injury is herpes virus.” Exhibit 11 at 2. Ilya was given a prescription for two drugs, one of them Acyclovir. Id. at 2.

In December 2001, Ilya saw his pediatrician multiple times. On December 3, 2001, Dr. Fink recommended that Ilya continue taking the prescription medications, including Acyclovir. On December 6, 2001 and December 10, 2001, Ilya saw a doctor for a sore throat. Exhibit 5 at 35-36. On December 26, 2001, Dr. Dobrydneva reported that Ilya had pus on his tonsils. Exhibit 5 at 54.

On December 27, 2001, Ilya had blood drawn. Testing showed that the IgM titers for EBV were slightly in the positive range. A positive test result means that a chronic Epstein-Barr virus was active or that the person was re-exposed to the Epstein-Barr virus. Exhibit 6 at 326; see also tr. 563-64; tr. 1095-98.

In January 2002, Ilya saw pediatricians several times. The notes from these doctors record a history that Ilya was having muscle weakness, feeling tired, and feeling dizzy, among other problems. Exhibit 5 at 32-34. The Court found that these reports constituted a basis for finding that Ilya had chronic fatigue syndrome. Opinion and Order, 94 Fed. Cl. at 146.

On January 17, 2002, Ilya was tested for EBV with a procedure involving a polymerase chain reaction. This test, which was capable of detecting as much as 100 copies per 100,000 cells, did not show that Ilya had EBV. Exhibit 6 at 272.

Other visits to doctors in February through April 2002 were summarized by the Court. Order and Opinion, 94 Fed. Cl. at 139. These doctors describe Ilya’s symptoms but provide relatively little information about the cause of Ilya’s problems.

At the hearing in 2010, Dr. Fink stated that Ilya was studying at Old Dominion University. The school was accommodating his disabilities but Ilya still became fatigued easily. Ilya was earning good grades. Tr. 1009-14.

Dr. Dobrydneva and Dr. Dobrydnev filed their petition in 2004, claiming that the hepatitis B vaccine caused Ilya to suffer chronic fatigue syndrome.³ Dr. Dobrydneva and Dr. Dobrydnev submitted a memorandum, written by their attorneys, arguing that they were entitled

³ The procedural history largely omits the considerable dispute over whether Ilya suffered from chronic fatigue syndrome. The accuracy of this diagnosis has been at least implicitly accepted by the Court.

to compensation. Dr. Dobrydneva and Dr. Dobrydnev also supported their claim with a report by Dr. David Bell. Dr. Bell stated that the “current thinking is that global central nervous system injury and antigenic stimuli are the direct causes of CFS.” Exhibit 17 at 2. Dr. Bell also asserted that the “Hepatitis B vaccine will stimulate an antigenic response, and as such can be assumed to cause CFS, just as any antigenic stimulus can.” Id. at 3.

In response, Respondent filed a report from Dr. Raoul Wientzen. Dr. Wientzen disagreed with the diagnosis of chronic fatigue syndrome. He also maintained that if chronic fatigue syndrome were an appropriate diagnosis, then “the precipitating event would have been not the vaccine he was given, but one of the two closely spaced viral illnesses that occurred between that night and the onset of vestibular neuronitis.” Exhibit A at 5.

Dr. Dobrydneva and Dr. Dobrydnev obtained a report from a different expert, Dr. James Oleske. Dr. Oleske stated that he found “it quite reasonable to assume that the vaccine’s hepatitis B antigen and the vaccine adjuvant created an excessive immunologic response in this child resulting in the acute illness that followed the injection.” Pet’r Expert Rep’t, filed Feb. 23, 2006, at 2. According to Dr. Oleske, Ilya’s “acute illness was typical of the first days and weeks of CFS, characterized by malaise, vestibular neuritis, and then all of the symptoms associated with his current persistent illness.” Id. Dr. Oleske referenced an “inflammatory cascade of cytokines” as part of the etiology of chronic fatigue syndrome.

Respondent matched petitioners’ submission by also retaining a second expert. Respondent filed a report from Dr. Alan I. Brenner, a rheumatologist. Dr. Brenner disputed the theory offered by Dr. Bell as to how chronic fatigue syndrome is caused in general and also stated that the hepatitis B vaccine was not a potential cause for chronic fatigue syndrome. Dr. Brenner also asserted that there was “rather robust evidence” suggesting that Epstein-Barr virus can cause chronic fatigue syndrome. Exhibit D at 9-10.

Before hearing the testimony of the different experts, the special master ordered the parties to submit articles on which their experts relied. Order, filed Feb. 15, 2007. On March 30, 2007, petitioners submitted a compact disc containing 53 articles, although petitioners did not assign an exhibit number to this submission. On April 10, 2007, petitioners revised their list of articles, identifying 41 articles.⁴

A hearing was held on April 25-26, 2007, to allow Dr. Bell, Dr. Oleske, Dr. Wientzen, and Dr. Brenner to explain their views. Other witnesses at this hearing were Dr. Dobrydneva and Dr. Fink, who was Ilya’s pediatrician. The presiding official for this hearing was Special Master Edwards.

⁴ This decision provides the reference number as given on petitioners’ original list of articles, not the reference from the compact disc.

During the hearing, an emphasized point was whether Ilya was properly diagnosed with chronic fatigue syndrome. (As noted above, the Court has found that Ilya suffers from chronic fatigue syndrome.) Comparatively less testimony was directed to whether hepatitis B vaccine can cause chronic fatigue syndrome.

Special Master Edwards completed his tenure as a special master before resolving this case. Consequently, the case was transferred to the undersigned. The undersigned ordered the parties to file briefs addressing the elements of petitioners' case. Dr. Dobrydneva and Dr. Dobrydnev filed a brief, and respondent did as well.

A decision was issued on March 12, 2010. This decision found that petitioners had failed to establish, by a preponderance of the evidence, the accuracy of many assertions made by Dr. Dobrydneva. In particular, the March 12, 2010 decision found that "a preponderance of evidence supports a finding that Ilya was in his usual state of health, and did not have a fever, between November 5, 2001 and November 7, 2001." The March 12, 2010 decision also found that the petitioners did not meet their burden of proof for the third element of the Althen test. Therefore, the petitioners were not entitled to compensation. Decision, 2010 WL 2143481.

The petitioners filed a motion for review with the Court. The Court vacated the March 12, 2010 decision, held that the petitioners should have been given an opportunity to present testimony at a second hearing, and found that the petitioners had established the appropriate temporal relationship.⁵ The Court remanded with instructions to afford the petitioners another hearing and to issue another decision addressing the first and second elements of Althen within 90 days. Memorandum Opinion and Order, 94 Fed. Cl. at 149.

As permitted by the Court's order, another hearing was held. At the September 29, 2010 hearing, Dr. Fink, Dr. Bell, and Dr. Oleske testified. Respondent did not call either of the two witnesses who had testified at the first hearing because both were not available. Dr. Brenner had died and Dr. Wientzen was traveling outside the country. After the hearing, the petitioners filed

⁵ The Court's order vacating the March 12, 2010 decision makes void any findings of fact contained in that decision. Although there appears to be no precedent discussing the effect of a vacatur by the Court of Federal Claims of a special master's decision in the Vaccine Program, cases from other contexts indicate that a vacatur renders void the factual findings contained in the earlier, vacated decision. See Friends of the Everglades v. South Florida Water Management District, 570 F.3d 1210, 1218 (11th Cir. 2009) ("Parts of decisions that are vacated and have not been reinstated 'have no legal effect whatever. They are void.'"); Tollett v. City of Kemah, 285 F.3d 357, 366 (5th Cir. 2002) ("It goes without saying that, as a result of the revised sanctions [order] being vacated, the findings of fact and conclusion of law in the district court's post-remand orders, . . . are vacated as well."); Zeneca Ltd. v. Novopharm Ltd., 919 F.Supp. 193 (D. Md. 1996) ("As a general rule, a vacated judgment and the factual findings underlying it have no preclusive effect; the judgment is a legal nullity.").

one article that Dr. Oleske identified during his testimony and an initial brief.⁶ The parties submitted briefs on an expedited schedule and the case is ready for re-adjudication.

II. Standards for Adjudication

The Court set forth the elements of petitioners' case and the burden of proof. Two elements that remain disputed are: "(1) a medical theory causally connecting the vaccination and the injury, [and] (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Opinion and Order, 94 Fed. Cl. at 144 (citations omitted). The burden of proof, as set in 42 U.S.C. § 300aa-13, is the "preponderance of the evidence." "Preponderance of the evidence," in turn, means that the "existence of a fact is more probable than its nonexistence." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010).

III. Analysis

The Court's instructions on remand direct an analysis on the first two prongs of Althen.⁷ These are addressed in the following two sections.

A. Althen prong 1

The first prong of Althen requires petitioners to establish "a medical theory causally connecting the vaccination and the injury." Althen, 418 F.3d at 1278. As recently explained by

⁶ Although at the September 29, 2010 hearing Dr. Bell mentioned that additional medical literature existed, petitioners did not attempt to file such literature either before or after the hearing. See order, filed September 30, 2010 (offering petitioners an opportunity to file additional literature); Pet'r Brief, filed Oct. 12, 2010, at 5 n.4 (acknowledging that they did not file additional literature). If petitioners had proposed to file literature after the hearing, it would have been incumbent on petitioners to submit articles in such a way that (a) respondent would have a fair opportunity to respond to the articles and (b) permitted compliance with the Court's order requiring a decision on remand within 90 days. A special master is not required to accept an expert's assertion that medical articles support the expert's opinion when those articles have not been filed into the record. See Moberly v. Sec'y of Health & Human Servs., 85 Fed. Cl. 571, 605 (2009), aff'd, 592 F.3d 1315 (Fed. Cir. 2010).

⁷ Petitioners argue that the Court "did favorably consider both Dr. Bell's opinion (page 7 of [the] Opinion) and Dr. Oleske's [opinion] (at page 8 of [the] Opinion). Pet'r Brief, filed Oct. 12, 2010, at 17. This argument fails to appreciate the context of the Court's statements about Dr. Bell and Dr. Oleske. On pages 7-8, the Court essentially summarized Dr. Bell's opinion and Dr. Oleske's opinion. Similarly, on pages 9-10, the Court presented Dr. Brenner's opinion and Dr. Wientzen's opinion. The undersigned does not perceive the Court's recitation of the experts' opinions as implying a favorable (or unfavorable) view of those opinions.

the Federal Circuit, this element is tied specifically to the injury that is alleged to have been caused by the vaccine. Broekelschen v. Sec’y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). In this case, Dr. Dobryднеva and Dr. Dobryднеv claim that Ilya suffered chronic fatigue syndrome. Thus, this condition is discussed before the analysis of the theories offered by Dr. Dobryднеva and Dr. Dobryднеv.

1. Chronic Fatigue Syndrome

A definition of chronic fatigue syndrome was given in the Court’s order. The Court stated that chronic fatigue syndrome is “persistent debilitating fatigue lasting longer than six months, with other known medical conditions having been ruled out by clinical diagnosis, accompanied by at least four of the following: significantly impaired short term memory or concentration; muscle weakness, pain in multiple joints without swelling or redness, sore throat, tender lymph nodes, headaches, unrefreshing sleep, and malaise, that lasts more that 24 hours following exertion.” Opinion and Order, 94 Fed. Cl. at 146, quoting Dorland’s Illustrated Medical Dictionary (30th ed. 2003) at 1851 (emphasis supplied by the Court).

The cause or causes of chronic fatigue syndrome are not known. Tr. 261-62; tr. 654; tr. 1039. Medical science has recognized that infections frequently precede the onset of the fatigue that is the hallmark of chronic fatigue syndrome. Tr. 297; tr. 578-79; tr. 653. One virus that is typically associated with chronic fatigue syndrome is the Epstein-Barr virus. The potential role of the Epstein-Barr in causing chronic fatigue syndrome was recognized by all the experts. Tr. 262 (Dr. Bell); tr. 298 (same); tr. 579 (Dr. Brenner); tr. 653 (Dr. Wientzen).⁸ Other conditions that have been considered as causes include Lyme disease, parvovirus, Z fever, and Ross River virus. Tr. 262.

In addition to the lack of identification of the agents that cause chronic fatigue syndrome, there is also a lack of understanding about how any potentially causative agent actually leads to chronic fatigue syndrome. Several theories have been advanced, yet no theory appears to explain the pathogenesis adequately. Dr. Bell advanced the theory that a foreign substance, known as an antigen, stimulates a person’s immune system to produce an overabundance of cytokines. Exhibit 17 at 1; tr. 262; tr. 314; tr. 1129-30. Dr. Oleske, too, offered the cytokine theory. Report, filed Feb. 23, 2006, at 2; tr. 477.

As to the theory that a cytokine cascade causes chronic fatigue syndrome, the evidence is mixed. Some evidence supports the theory while other evidence does not support the theory. Supporting evidence includes Dr. Bell’s opinion, which seems based upon at least some medical

⁸ During the hearing after remand, Dr. Oleske stated that “we really do not have any evidence that EBV causes chronic fatigue syndrome,” tr. 1033; and there is “more evidence” for hepatitis B vaccine as a cause of chronic fatigue syndrome than for Epstein-Barr virus causing chronic fatigue syndrome. Tr. 1034. He later clarified that some cases of chronic fatigue syndrome are due to Epstein-Barr virus. Tr. 1074.

articles. Tr. 310. Opposing evidence includes Dr. Brenner's opinion, which seems to be based upon other medical articles that show inconsistent results for cytokines. Tr. 581-82; see also tr. 522-23 (Dr. Oleske's testimony that investigations that he has performed have not shown any "conclusive" evidence of adverse immune activation in people with chronic fatigue syndrome).

Whether cytokines truly cause chronic fatigue syndrome is difficult to determine with any certainty. However, petitioners are not required to establish their medical theories with certainty. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 547 (Fed. Cir. 1994). In this case, petitioners presented sufficient evidence to make the validity of the cytokine theory a "close call" that should be resolved in favor of petitioners. Althen, 418 F.3d at 1280; see also Knudsen, 35 F.3d at 549. A finding that cytokines are likely to contribute to the cause of chronic fatigue syndrome does not satisfy petitioners' burden with respect to the first prong of Althen. The petitioners also must establish a causal connection with the vaccine.

2. Hepatitis B Vaccine and Chronic Fatigue Syndrome

The vaccine that Ilya received is the hepatitis B vaccine. The hepatitis B vaccine contains only one portion of the hepatitis B virus, known as the hepatitis B surface antigen. Pet'r Ref. 5 (I. Grotto, Major adverse reactions to yeast - derived hepatitis B vaccines - a review, 16 Vaccine 329 (1998)). The hepatitis B vaccine produces a weaker response in the immune system than vaccines that contain killed viruses or attenuated viruses. Tr. 569, relying upon Pet'r Ref. 19 (Mark T. Dertzbaugh, Genetically Engineered Vaccines: An Overview, 39 Plasmid 100, 105 (1998)). The hepatitis B vaccine is inert, meaning that it does not replicate inside the body. This lack of replication distinguishes the hepatitis B vaccine from viruses, which do replicate inside a person. See tr. 474; tr. 1144.

Dr. Bell and Dr. Oleske offered written opinions that the hepatitis B vaccine can cause chronic fatigue syndrome. Exhibit 17 (Dr. Bell's report) at 2-3; report, filed Feb. 23, 2006, at 2.⁹ The written reports of both doctors provide scant information as to the causal theory connecting the hepatitis B vaccine. For example, Dr. Oleske stated that he "finds it quite reasonable to assume that the vaccine's hepatitis B antigen and the vaccine adjuvant created an excessive immunologic response in this child resulting in the acute illness that followed the injection." Report, filed Feb. 23, 2006, at 2. Similarly, Dr. Bell stated that the "Hepatitis B vaccine will stimulate an antigenic response, and as such can be assumed to cause CFS, just as any antigenic stimulus can." Exhibit 17 at 2. Assumptions such as the ones made by Dr. Oleske and Dr. Bell, without reliable evidence to support the assumptions, fall short of constituting reliable expert opinions. General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997) (indicating that pursuant to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), a district court may reject the testimony of an expert "that is connected to existing data only by the ipse dixit of the

⁹ Petitioners' attorneys discussed the Gulf War syndrome. See Pet'r Brief, filed May 18, 2009, at 8-9. However, neither Dr. Bell nor Dr. Oleske compared Ilya's condition to Gulf War syndrome.

expert.”); see also Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999) (holding that a special master may assess an expert’s testimony using the Daubert factors).

During their testimony in April 2007 and in September 2010, both experts had an opportunity to assert a causal theory connecting the hepatitis B vaccine to chronic fatigue syndrome and an opportunity to explain why, based upon reliable scientific evidence, this theory is plausible. In his direct testimony, Dr. Bell maintained that any antigenic challenge can cause chronic fatigue syndrome and because hepatitis B vaccine is one type of antigen, it can cause chronic fatigue syndrome. Tr. 263. In contrast, when asked on cross-examination whether any infectious agent can cause chronic fatigue syndrome, Dr. Bell stated that “The current thinking is that there is a relatively restricted list of things that can cause chronic fatigue.” Tr. 298. If it is true that the potential causes of chronic fatigue syndrome are a “relatively restricted list,” then Dr. Bell’s opinion contains a gap. He did not explain why the hepatitis B vaccine belongs on the “relatively restricted list.”

The only article in this record that addresses the precise question raised in Ilya’s case – whether the hepatitis B vaccine can cause chronic fatigue syndrome – reports the results of a study conducted by an independent group of researchers from Canada. Due to its focus, the Canadian study warrants particular attention.

The Canadian researchers concluded that “there was no evidence justifying the allocation of funds for research projects on the possible relationship between CFS and hepatitis B vaccination.” Exhibit BB (Gilles Dillage et al., Report of the Working Group on the Possible Relationship between Hepatitis B Vaccination and the Chronic Fatigue Syndrome, 149(3) Can. Med. Assoc. J 314, 316 (1993)). The study came to this conclusion after making several observations about the data, including

3. The proportion of CFS patients having received HBV vaccine within 3 months of onset of symptoms is similar to the proportion of the general Canadian population having received a recent dose of HBV vaccine. Therefore, there is no evidence of an increased rate of hepatitis B vaccination among CFS patients: an increased rate of vaccination would be expected if HBV vaccine administration was an important cause of CFS.
4. There is no biological evidence to support the hypothesis that hepatitis B vaccine can cause CFS. . . .
5. . . . Furthermore, we would expect that cases of CFS following hepatitis B vaccination would be reported by many investigators, since CFS is a fairly frequent syndrome and since many investigators are actively working in this field. This is not the case.

Id. at 315-16.

This Canadian study, in turn, has been cited in other articles. E.g., Pet'r Ref. 8 (Irving E. Salit, Precipitating Factors for the Chronic Fatigue Syndrome, 31 J Psychiat. Res. 59, 62 (1997)) (stating "Immunization, generally, or with any specific vaccine was . . . no more common in the CFS group than in the controls."); Pet'r Ref. 43 (Philippe Duclos, Safety of immunisation and adverse events following vaccination against hepatitis B, 2(3) Expert Opinion. Drug Saf. 225, 227 (2003)) (stating "In Canada, during 1993-1994, a rumour was also raised that vaccination against hepatitis B was responsible for chronic fatigue syndrome, but no epidemiological data have ever confirmed this allegation.").

Two of the doctors who testified in this case indicated that the Canadian study did not support a finding that the hepatitis B vaccine can cause chronic fatigue syndrome. Dr. Fink, Ilya's pediatrician, stated that the Canadian report showed that "there was no definitive link between hepatitis B vaccine and chronic fatigue syndrome." Tr. 322. Dr. Brenner, one of respondent's experts, also indicated that the Canadian study showed no association between hepatitis B vaccine and chronic fatigue syndrome. Tr. 582-83.

A potentially dissenting view was raised by Dr. Oleske. Dr. Oleske stated, contrary to the opinion expressed by the article's authors, that the Canadian literature shows that "hepatitis B is considered one of those suspect agents that can cause adverse reactions post-immunization, that include chronic-like fatigue syndrome." Tr. 1041. To the extent that Dr. Oleske meant that the Canadian study showed that the hepatitis B vaccine "can cause" chronic fatigue syndrome, this interpretation is not supported by the article itself.¹⁰ The article rejected that theory, stating "[t]here is no biological evidence to support the hypothesis that hepatitis B vaccine can cause CFS." Exhibit BB at 315.

In sum, the literature that was filed into the record in this case does not support a finding that the hepatitis B vaccine, more likely than not, can cause chronic fatigue syndrome. The Canadian study rejected that hypothesis as lacking "biological evidence." More recent reviews, Salit and Duclos, have relied on the conclusions of the Canadian study.

After the hearing on remand, petitioners introduced one additional exhibit, which is number 54. This article does not state that hepatitis B vaccine causes chronic fatigue syndrome. Instead, the authors indicate that there is uncertainty. "While some studies have suggested that vaccination against HBV might be associated with CFS onset (most of the published articles are written in French), others have rejected this possibility, arguing that the vaccine is safe with minimal adverse effects." Exhibit 54 ((Oscar-Danilo Ortega-Hernandez and Yehuda Shoenfeld, Infection, Vaccination and Autoantibodies in Chronic Fatigue Syndrome, Cause or Coincidence,

¹⁰ Perhaps Dr. Oleske meant that the hepatitis B vaccine was once considered a "suspect" for causing chronic fatigue syndrome. The Duclos article describes a "rumour" about chronic fatigue syndrome that the Canadian researchers dispelled in 1994.

Annals of New York Acad. of Sciences 600, 602 (2009)). Other than this article, Dr. Oleske recognized that no studies support a causal connection. Tr. 517; tr. 1077.¹¹

According to Federal Circuit precedent, a special master may consider the lack of support from medical articles in weighing an expert's opinion. Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 (Fed. Cir. 1994) (stating petitioners "no longer had a reasonable basis for claiming causation in-fact because the expert opinion was grounded in neither medical literature nor studies. . . . The special master did not require counsel to verify the validity of the expert's opinion, but only required the opinion to be more than unsupported speculation."). Recently, another judge of the Court of Federal Claims has affirmed that the lack of support is one factor a special master may consider: "[T]he special master relied on the dearth of medical literature supportive or dismissive of Dr. Steel's hypothesis to bolster his conclusion that Ms. Davis had not met her burden under Althen. In doing so, the special master weighed the evidence of record and made determinations as to persuasiveness in accord with law." Davis v. Sec'y of Health & Human Servs., 94 Fed. Cl. 53, 68 (2010) (affirming a denial of compensation under the abuse of discretion standard).

Here, the most relevant article, the Canadian study, indicates that the hepatitis B vaccine does not cause chronic fatigue syndrome. There is a dearth of literature that supports the theory that the hepatitis B vaccine causes chronic fatigue syndrome. This absence of literature is not necessarily fatal to petitioners' claim because the submission of medical articles is not required for petitioners to prevail. Althen, 418 F.3d at 1280. "But to say that proof in the form of epidemiological studies or well-established medical experience is not mandatory does not mean that special masters in Vaccine Act cases are precluded from inquiring into the reliability of testimony from expert witnesses." Moberly, 592 F.3d at 1325. The inquiry in this case yields the result that petitioners have not established the reliability of the theory that the hepatitis B vaccine can cause chronic fatigue syndrome.

¹¹ Petitioners argue that "the entire record . . . does include medical literature." Pet'r Reply, filed Oct. 22, 2010, at 9. This statement is accurate in the sense that the petitioners filed many articles into the record. The record, however, lacks any articles supporting the theory that hepatitis B vaccine causes chronic fatigue syndrome.

In addition to the article by Dr. Ortega-Hernandez and Dr. Shoenfeld, petitioners' briefs cite two other articles, which are Pet'r Ref. 13 (F. Deisenhammer et al., "Acute Cerebellar Ataxia after Immunisation with Recombinant Hepatitis B Vaccine, 89 Acta Neurologica Scandinavica 462 (1994)) and Pet'r Ref. 14 (L. Herroelen et al., "Central-nervous-system Demyelination after Immunisation with Recombinant Hepatitis B Vaccine, 338 Lancet 1174 (1991)). The relevance of these articles is not clear because (a) petitioners have not cited any evidence showing that Ilya suffered from either cerebellar ataxia or demyelination in his central nervous system, and (b) neither Dr. Bell nor Dr. Oleske discussed these articles during their testimony. See Moberly, 85 Fed. Cl. at 598 (indicating that a special master is not required to interpret a study that has not been explained by an expert).

Dr. Dobrydneva and Dr. Dobrydnev also appear to argue that because Dr. Bell and Dr. Oleske have excellent qualifications, their opinions that the hepatitis B vaccine can cause chronic fatigue syndrome should be accepted. Pet'r Reply, filed Oct. 22, 2010, at 9-11. There is no dispute that Dr. Bell and Dr. Oleske possess strong credentials. For example, each acted as chair of a committee on chronic fatigue syndrome, which was established by the Department of Health and Human Services. Tr. 232-33 (Dr. Bell); tr. 458 (Dr. Oleske). Their qualifications, however, do not automatically make the opinions of Dr. Bell and Dr. Oleske persuasive. Hathaway v. Bazany, 507 F.3d 312, 318 (5th Cir. 2007) (stating “[W]ithout more than credentials and a subjective opinion, an expert’s testimony that ‘it is so’ is not admissible” (citation omitted) and affirming trial court’s exclusion of expert opinion). Further, the qualifications of Dr. Bell and Dr. Oleske also must be compared to the qualifications of Dr. Brenner and Dr. Wientzen. Dr. Wientzen also has excellent qualifications. Among Dr. Wientzen’s achievements is being a medical director at a foundation that administered the hepatitis B vaccine to teenagers in Russia. According to Dr. Wientzen, this program vaccinated more than two million children. Tr. 632; tr. 643. This background gives weight to Dr. Wientzen’s opinion that the hepatitis B vaccine did not cause Ilya’s chronic fatigue syndrome. Tr. 655. Dr. Brenner has seen thousands of patients with chronic fatigue syndrome and served on a committee established by the Department of Defense studying an anthrax vaccine. Tr. 557-58. Dr. Brenner, too, said that the hepatitis B vaccine did not cause Ilya’s chronic fatigue syndrome. Tr. 583.

Although Dr. Wientzen’s opinion and Dr. Brenner’s opinion were contrary to petitioners’ claims and have been considered in determining whether Dr. Dobrydneva and Dr. Dobrydnev met their burden of proof, see Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1353 (Fed. Cir. 2008), the more significant flaw is the lack of material presented by petitioners. Petitioners have not presented a persuasive case that the hepatitis B vaccine can cause chronic fatigue syndrome. Petitioners rely upon the unsupported statements of Dr. Oleske and Dr. Bell, an “ipse dixit” that does not have to be credited by a finder of fact. Actually, the opinions of Dr. Oleske and Dr. Bell are less than unsupported because their theory has been tested and found not valid in the Canadian study. In short, the record as a whole does not support a finding that the hepatitis B vaccine can cause chronic fatigue syndrome. Petitioners have failed to meet their burden of proof with regard to Althen prong 1.

B. Althen prong 2

In addition to making findings regarding the first prong of Althen, the Court’s order also instructs the undersigned to make findings regarding the second prong. The second prong is “a logical sequence of cause and effect showing that the vaccination was the reason for the injury.” Althen, 418 F.3d at 1278.

This prong of Althen was discussed in a recent Federal Circuit decision that affirmed a special master’s decision that had found that the petitioners had failed to meet their burden of proof. The Federal Circuit repeated that “neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of

the injury suffices, without more, to meet the burden of showing actual causation.” Moberly, 592 F.3d at 1323, quoting Althen, 418 F.3d at 1278. This guidance from the Federal Circuit is important because petitioners’ experts seem to employ this (discredited) logic.¹²

¹² The government argues that “petitioners’ logical sequence of cause and effect is premised on erroneous facts.” Resp’t Br., filed Oct. 18, 2010, at 25 (capitalization changed without notation). This argument is premised on an asserted dichotomy between, on the one hand, what Dr. Bell and Dr. Oleske assumed to be accurate and, on the other hand, the facts as found in this proceeding. For the reasons that follow, respondent’s argument is not tenable because the Court’s findings of fact support the assumptions made by Dr. Bell and Dr. Oleske.

Dr. Bell and Dr. Oleske explained the assumptions that they made about Ilya’s health. Both assumed that Ilya had a fever and was ill for a few days immediately following his November 5, 2001 hepatitis B vaccination. See tr. 329-30 (Dr. Bell); tr. 502-07 (Dr. Oleske); tr. 1039 (Dr. Oleske); tr. 1055 (same); tr. 1109; tr. 1131-32 (Dr. Bell); tr. 1144 (Dr. Bell). Both Dr. Bell and Dr. Oleske considered the relatively short amount of time between the hepatitis B vaccination and the beginning of Ilya’s symptoms as important. Tr. 329 (Dr. Bell); tr. 506 (Dr. Oleske); tr. 1148 (Dr. Bell).

The set of assumptions made by Dr. Bell and Dr. Oleske must be compared to the findings of fact in this case. Respondent maintains that “There are no facts in the controlling record that demonstrate that Ilya experienced adverse symptoms on the night of and the days following vaccination. To the contrary, the binding facts are ‘Ilya was in his usual state of health, and did not have a fever, between November 5, 2001 and November 7, 2001.’” Resp’t Br., filed Oct. 18, 2010, at 26, citing Decision, 2010 WL 2143481 at *9-10.

Respondent’s citation to the March 12, 2010 decision makes the reasoning flawed. The March 12, 2010 decision is no longer effective because it was vacated by the Court. See footnote 5, above. Since the March 12, 2010 decision has been vacated, the only determination about facts for Ilya’s case is found in the Court’s Order.

The Court’s findings indicate that after the November 5, 2001 vaccination, “according to Ilya’s mother, he experienced malaise, fever, sore throat, lymph node swelling, and marked pallor.” Opinion and Order, 94 Fed. Cl. at 138, citing tr. 47 and exhibit 3 at 1-2. In reference to Dr. Dobrydneva’s testimony the Court stated that it “does not mean to require a Special Master to accord a parent’s observations or prognosis, even one with related medical training, with more credibility than that given to contemporaneous medical records, the opinion of independent treating medical professionals, or medical experts.” Id. at 147. Respondent argues that this statement does not constitute a finding of fact by the Court. See Resp’t Brief, filed Oct. 18, 2010, at 26 n.32. In light of the Court’s instructions, the undersigned concludes that the Court intended to credit Dr. Dobrydneva’s testimony as accurately describing Ilya’s symptoms after the November 5, 2001 vaccination. See Engel Industries, Inc. v. Lockformer Co., 166 F.3d 1379, 1383 (Fed. Cir. 1999) (lower tribunal must abide by the spirit of the mandate). This interpretation of the Court’s findings validates the assumptions about Ilya’s health after the November 5, 2001 vaccination made by Dr. Bell and Dr. Oleske. Therefore, respondent’s argument that petitioners’ experts have assumed an erroneous set of facts is rejected.

However, this interpretation of the Court’s statements may be erroneous. If the Court did

According to Dr. Bell and Dr. Oleske, each concluded that the hepatitis B vaccine must have caused Ilya's chronic fatigue syndrome after each had ruled out other possible causes. Tr. 259 (Dr. Bell); tr. 507-08 (Dr. Oleske); tr. 1033 (Dr. Oleske); tr. 1167 (Dr. Bell); 1174 (Dr. Bell). Respondent has proposed two possible causes for Ilya's chronic fatigue syndrome, his infection with the Epstein-Barr virus and his infection that was manifest at the end of November 2001. Regardless of whether petitioners bear the burden of ruling out alternative causes, they actually have done so for the reasons that follow.

1. Proposed Alternative Cause Number 1 – Epstein-Barr virus

A prominent potential cause of Ilya's chronic fatigue syndrome was his infection with Epstein-Barr virus. Respondent argues that "Ilya had active EBV, a known cause of CFS, at the time he received his vaccination." Resp't Br., filed Oct. 18, 2010, at 20 (capitalization changed without notation). The facts do not support this argument about Ilya's health.

A preponderance of the evidence supports a finding that Ilya's Epstein-Barr infection was dormant, rather than active, in November 2001. The record shows that Ilya was tested for signs of Epstein-Barr infection three times in 2001 – February, June, and December. On all three occasions, the test result indicated that he had an active infection. Exhibit 6 at 326, 351, 371; see also tr. 1168-69 (Dr. Bell). Respondent argues that because Ilya had an active infection in June and he had an active infection in December, Ilya also had an active infection in November. Resp't Br., filed Oct. 18, 2010, at 31-32.

The inference about Ilya's condition in November that respondent draws from what is known about Ilya's health in June and December, although reasonable, is not supported by other facts. Ilya's health in November does not resemble his health during times when his Epstein-Barr virus infection was active. For example, in early 2001, Ilya reported being "tired for two months" and missed many days of school. Exhibit 5 at 40; exhibit 7 at 6 (school records).

not find that Ilya suffered a fever and malaise in the days immediately following the November 5, 2001 vaccination as assumed by Dr. Bell and Dr. Oleske, then petitioners' case becomes even less sustainable. When an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's opinion. See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 (1993) (stating "When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict."); Perreira, 33 F.3d at 1376 n.6 (stating "An expert opinion is no better than the soundness of the reasons supporting it."). Moreover, an expert's assumption about the accuracy of a fact witness's testimony does not "substantiate" the testimony of the fact witness. Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1574 (Fed. Cir. 1993).

Ilya's condition in November 2001 was different. The medical records do not record Ilya as tired or fatigued. See exhibit 5 at 37. Respondent's expert, Dr. Brenner, recognized that Ilya's symptoms in November 2001 were not manifestations of an active Epstein-Barr virus. Tr. 566-67 (stating "The two visits are quite different than what one would expect in the course of EB viral infection and they're quite different from what Ilya manifested during acute EB viral infection."). For these reasons, respondent's arguments attributing causation to the Epstein-Barr virus are mistaken.¹³

2. Proposed Alternative Cause Number 2 – November 2001 Infection

The second cause of Ilya's chronic fatigue syndrome proposed by respondent is an infection that Ilya had in November 2001. Although Ilya did have an infection, he began having this infection after he began experiencing chronic fatigue syndrome according to the Court's findings of fact. Therefore, as a matter of logic, the earlier chronic fatigue syndrome could not have been caused by Ilya's later infection. The reasons for this conclusion follow.

In mid-November 2001, Ilya had various (minor) health problems, as recognized by the Court. See Opinion and Order, 94 Fed. Cl. at 138. On November 19, 2001, Dr. Fink saw Ilya for a "2-3 day history of low grade temperature elevation along with a sore throat," and "some degree of nasal congestion with minimal cough." Dr. Fink diagnosed Ilya as having "febrile illness / viral pharyngitis." One week later, Ilya had yellow nasal discharge and a frontal headache. Dr. Fink diagnosed sinusitis. Dr. Fink prescribed Augmentin. Exhibit 5 at 36; see also tr. 189-90 (Dr. Fink's testimony discussing the office visit on November 26, 2001). Dr. Dobrydneva reported that after taking Augmentin, Ilya improved within two hours. Exhibit 5 at 37.

There is strong evidence that Ilya was suffering from some kind of infection, either from a virus or a bacteria. The primary evidence is that Dr. Fink's diagnoses included a "viral pharyngitis" and "sinusitis." Because Dr. Fink observed Ilya's condition, his "medical record . . . [is] favored." Capizzano, 440 F.3d at 1326. Additional evidence comes from how Ilya responded to Augmentin. Augmentin is an antibiotic that has particular effectiveness against the bacteria that causes pneumococcal sinusitis. Tr. 645 (Dr. Wientzen); tr. 1067 (Dr. Oleske); tr. 1026 (Dr. Fink); tr. 1151 (Dr. Bell). Ilya's rapid improvement in health after taking Augmentin

¹³ Dr. Dobrydneva and Dr. Dobrydnev focus on another piece of datum relevant to Ilya's Epstein-Barr virus infection, the PCR test performed on January 17, 2002. Exhibit 6 at 310. Although some effort was made to determine the significance of this reading in light of Ilya's taking of Acyclovir, see tr. 675 (Dr. Wientzen); tr. 718-22 (same); tr. 1032 (Dr. Oleske); tr. 1071-73 (same); tr. 1114-18 (Dr. Oleske), the PCR test is ultimately a distraction. A PCR test administered in January 2002 gives little, if any, information about the status of Ilya's Epstein-Barr infection two months earlier in November 2001. To the extent that any inferences were to be drawn, the basis of inferences should be the test closer in time absent any expert testimony to the contrary.

strongly suggests, if not proves, that he had a pneumococcal infection. Finally, the testimony of the experts tends to corroborate the findings made by Dr. Fink. See tr. 302 (Dr. Bell); tr. 507-09 (Dr. Oleske indicating that a runny nose is not associated with chronic fatigue syndrome); tr. 566 (Dr. Brenner); see also tr. 1066-67 (Dr. Oleske noting that not every symptom in November 2001 was a reaction to the vaccine and stating that Augmentin does not help with chronic fatigue syndrome); tr. 1111 (Dr. Oleske); tr. 1150-51 (Dr. Bell stating that Augmentin treats bacterial infections). All these facts contribute to finding that Ilya suffered from a viral infection, complicated by a pneumococcal infection, from approximately November 17, 2001, and continuing until approximately November 27, 2001.

The finding that Ilya had an infection complicates the analysis of any contributory role played by the hepatitis B vaccine. It is possible that the source of the infection, and not the hepatitis B vaccine, caused Ilya's chronic fatigue syndrome. Respondent argues that Dr. Dobrydneva and Dr. Dobrydnev have failed to account for this infection that developed shortly before Ilya's vestibular neuronitis.¹⁴ Resp't Br., filed Oct. 18, 2010, at 32-36.

Petitioners failed to answer this argument. Dr. Dobrydneva and Dr. Dobrydnev assert that "it is the government's position that the only possible cause of Ilya's CFS was the Epstein-Barr virus." Pet'r Reply, filed Oct. 22, 2010, at 11. This characterization of the government's position is not accurate because the respondent discussed Ilya's illness at the end of November as a possible cause for Ilya's chronic fatigue syndrome.

Whether the virus at the end of November could have been the cause of Ilya's chronic fatigue syndrome depends, in part, on when Ilya's chronic fatigue syndrome began. If the Court found that Ilya began suffering from chronic fatigue syndrome before November 19, 2001, then the viral illness that was manifest at the end of November could not be the cause of the chronic fatigue syndrome. In contrast, if the Court found that the chronic fatigue syndrome began after Ilya had this infection in November 2001, then the infection certainly could have been the cause of the chronic fatigue syndrome. See tr. 1173 (Dr. Bell acknowledging that the virus that causes the common cold or a pneumococcal bacteria could stimulate the production of antigens that leads to chronic fatigue syndrome).

¹⁴ Many aspects of vestibular neuronitis were debated. These disputes are largely immaterial because Dr. Dobrydneva and Dr. Dobrydnev do not seek compensation for vestibular neuronitis, which appears, in any event, to have resolved relatively quickly and without consequences lasting longer than six months. Rather Dr. Dobrydneva and Dr. Dobrydnev claim that the hepatitis B vaccine caused Ilya's chronic fatigue syndrome. Because they have failed to establish their entitlement on this particular claim, whether Ilya's vestibular neuronitis was a manifestation of the chronic fatigue syndrome as claimed by Dr. Bell and Dr. Oleske or was a separate condition caused by a virus as claimed by Dr. Brenner and Dr. Wientzen is an academic issue.

A close reading of the Court's decision suggests that the Court placed the onset of Ilya's chronic fatigue syndrome as within days of Ilya's hepatitis B vaccination. The Court appeared to credit Dr. Dobrydneva's representation that Ilya suffered from "malaise" within days of the hepatitis B vaccination. This interpretation comes from the Court's emphasis that one of the symptoms of chronic fatigue syndrome is "malaise." Opinion and Order, 94 Fed. Cl. at 146. The only source of information about Ilya's malaise cited by the Court is Dr. Dobrydneva's testimony. Id. at 138, citing tr. 47. Furthermore, the Court considered "malaise" in reaching the conclusion that Ilya had chronic fatigue syndrome. Id. at 146. Collectively, these passages from the Court's analysis appear to support an interpretation that Ilya's chronic fatigue syndrome began before his viral illness in mid-November 2001. Consequently, given that the Court found that Ilya's chronic fatigue syndrome began within days of his vaccination, respondent's argument that the source of the late November 2001 illness caused Ilya's chronic fatigue syndrome is not sustainable.

The rejection of proffered possible alternative causes supports the claim of Dr. Dobrydneva and Dr. Dobrydnev. However, as noted above, "neither a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." Moberly, 592 F.3d at 1323 (citation and quotation marks omitted). To the extent that the Federal Circuit has required "more" than the elimination of other causes and a proximate temporal relationship, the Federal Circuit has suggested that the "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (citation omitted).

Here, Dr. Dobrydneva and Dr. Dobrydnev have not identified any treating doctor who opined that the hepatitis B vaccine caused Ilya's chronic fatigue syndrome. (Dr. Fink, Ilya's pediatrician, testified about his treatment of Ilya, and he did not testify that the hepatitis B vaccine caused Ilya's chronic fatigue syndrome. See Pet'r Pre-hearing Memorandum, filed March 30, 2007, at 19-20 (identifying Dr. Fink as a witness and explaining the scope of his anticipated testimony)).

Instead, some treating doctors were aware that Ilya's family was concerned that the hepatitis B vaccination caused his chronic fatigue syndrome but these doctors did not ratify the parents' theory. See, e.g., exhibit 5 at 11 (record from Dr. Fink dated June 16, 2003); exhibit 5 at 23 (record from Dr. Fink dated Aug. 5, 2002); exhibit 6 at 43-44 (record from Dr. Randall Fisher, a specialist in pediatric infectious diseases, dated June 10, 2003); exhibit 6 at 276-77 (record from Dr. Cynthia Kelly, a pediatric immunologist, dated Jan. 23, 2002). In regard to the lack of support from treating doctors, the present case resembles Moberly. In that case, "when [the child's] treating physicians addressed the question of causation, they declined to provide a diagnosis linking the seizures to the DPT vaccination." Moberly, 592 F.3d at 1323 (ruling that the special master was not arbitrary in finding that no treating doctor connected the vaccine to the injury).

In sum, even if it were assumed that Dr. Dobrydneva and Dr. Dobrydnev had met their burden of establishing, by a preponderance of the evidence, that the hepatitis B vaccine can cause chronic fatigue syndrome, which they have not for the reasons explained in section III.A., Dr. Dobrydneva and Dr. Dobrydnev still do not meet their burden on Althen prong 2. It is certainly the case that some evidence supports the petitioners' claim, including the evidence relied upon by the Court in finding that there was a proximate temporal relationship between Ilya's vaccination and the onset of his chronic fatigue syndrome. Other supporting evidence includes the opinions of Dr. Bell and Dr. Oleske. Nevertheless, this supporting evidence is outweighed by other evidence, including the opinions of Dr. Brenner, Dr. Wientzen, and, most importantly, Ilya's treating physicians who did not accept the idea that the hepatitis B vaccine caused Ilya's chronic fatigue syndrome. Cf. Doe 11 v. Sec'y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (indicating that the presence of some evidence contradicting the special master's finding that petitioner failed to meet her burden of proof does not mean that the special master's finding was arbitrary or capricious).

IV. Conclusion

The Court found that Dr. Dobrydneva and Dr. Dobrydnev established the third prong of Althen, which concerns the amount of time between the vaccination and the onset of symptoms. Opinion and Order, 94 Fed. Cl. at 136. This finding does not satisfy petitioners' burden of proof because a "proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." Id. at 144, quoting Grant, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Consequently, the Court remanded for additional fact-finding with regard to Althen prong 1 and Althen prong 2.

For Althen prong 1, petitioners have failed to present "some indicia of reliability to support" the theory that the hepatitis B vaccine can cause chronic fatigue syndrome. See Moberly, 592 F.3d at 1324. The most probative study on this question rejected the hypothesis offered by Dr. Bell and Dr. Oleske. For Althen prong 2, petitioners have not presented a preponderance of evidence showing that the hepatitis B vaccine was the cause of Ilya's chronic fatigue syndrome. According to Moberly, 592 F.3d at 1323, petitioners must do more than eliminate other causes and this has not been done here. In sum, petitioners have not met their burden of proving, by a preponderance of evidence, all the elements set forth in Althen. Thus, they are not entitled to compensation.

The Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. The Clerk's Office is also instructed to deliver this decision to the presiding judge. See Vaccine Rule 28A.

IT IS SO ORDERED.

S/ Christian J. Moran
Christian J. Moran
Special Master