

IN THE MATTER OF an appeal filed
pursuant to the *Rules for Appeals* under
the *Pre-1986/Post-1990 Hepatitis C
Settlement Agreement* and its *Protocols*

CLAIM FILE: 07-00697

REASONS FOR DECISION

INTRODUCTION

[1] The Claimant has appealed a decision of the Administrator dated March 24, 2009, in which his claim for compensation under the *Pre-1986/Post-1990 Hepatitis C Settlement Agreement* (“*Settlement Agreement*”) was denied on the basis that the further evidence of first infection did not establish an infection for the first time with HCV by a blood transfusion in Canada during the Class Period.

[2] The claim file contains documents in both English and French. Since almost all of the hospital records are in English, I have written the decision in English.

FACTS

[3] On October 1, 2007, the Claimant delivered an application for compensation under the terms of the *Settlement Agreement*. In the General Information Form, he stated that he was a Primarily-Infected Person who was infected with the Hepatitis C virus through a blood transfusion received during the Class Period. In an amended page 16 of the form delivered on October 31, 2007, he noted dialysis as a risk factor in “Section G – Other Risk Factors”, but stated that he was already infected with Hepatitis C when he began dialysis. The Treating Physician Form was prepared by a specialist in nephrology who had treated the Claimant for seven years. She indicated that the Claimant was at Disease Level 3. Although she noted dialysis as a risk factor, she stated that his infection

with HCV had preceded his renal failure; he had no other risk factors for Hepatitis C. In the Blood Transfusion History Form, the Claimant stated that he was transfused with blood on December 11, 1981 during surgery. He has received compensation under a provincial program and the *Canadian Red Cross Settlement* in the amounts of \$25,000.00 and \$6,880.00 respectively.

i) documents delivered on October 1, 2007

[4] On October 1, 2007, the Claimant delivered documents in support of the application for compensation, including two hospital records relating to his diagnosis with hepatitis: a Summary Sheet dated February 8, 1982 and a Clinical Report dated December 17, 1990. He also delivered a letter from a physician dated December 16, 1998, and a public health laboratory report confirming a positive Hepatitis C antibody test on November 27, 1998.

[5] A hospital Summary Sheet was signed on February 8, 1982 by the physician who treated him at the hospital for jaundice and hepatitis. It indicated, among other things, that the Claimant was admitted to the hospital on January 29 1982 and discharged on February 5, 1982. The parts of the form entitled “Provisional Diagnosis” and “Final Diagnosis” both stated “Hepatitis (probably type B)”. In the part of the form entitled “Supplementary notes on hospitalization”, a doctor wrote:

Jaundice and enzymes + Alk [Alkaline] Phosphatase resolved [illegible] no complications
[Emphasis Added]

[6] A hospital Clinical Report dated December 17, 1990 stated, in part, as follows:

[...] I still have not received the official hepatitis C result and only got a verbal report after several phone calls. (In any case [the Claimant] is positive for hepatitis C antibody. This is no doubt related to the transfusions which he had several years ago).

[7] The letter from a physician dated December 16, 1998 stated, in part, as follows:

[The Claimant] has been known to me since May 9/79, subsequently seen 25/08/81 for recurrent history of epistaxis and BP 140/80 and this was verified by IVP which confirmed bilateral chronic pyelonephritis of the mega-ureter, hypertension was secondary to this.

He was transferred then to [the nephrologist] where he had bilateral ureteropexy and transplantation of the ureters for bilateral mega-ureter and during the operation developed complication of unusual prolonged bleeding requiring blood transfusion which [sic] subsequently within few weeks after developed hepatitis C 29.01.82. [Emphasis Added]

TRACEBACK

[8] By letter dated January 14, 2008, the Canadian Blood Services forwarded the final report for the Traceback (“Traceback”) to the Administrator, together with the Transfusion Summary prepared by the Canadian Blood Services and three documents: two hospital transfusion records, each entitled “Chart Transfusion Record and Claim Slip” (“Transfusion Record”); and a Request for Records Search from the provincial plan application.

[9] The first hospital Transfusion Record indicated that on December 11, 1981 at 16:49, the Claimant was transfused with “Antihemophilic factor”; at 18:34, he was transfused with 300 grams of packed cells, pack serial number 16769.

[10] The second hospital Transfusion Record indicated that on December 11, 1981 at 20:51, he was transfused with 340 grams of packed cells, pack serial number 16749. On December 12, 1981 at 2:14, he was transfused with “Antihemophilic factor”; on the same date at 9:05, he was transfused with “Antihemophilic factor”.

[11] The Request for Records Search from the provincial plan application contained sections that were to be completed by the records department of the hospital and the Canadian Blood Services. The records department completed its part of the form on

January 28, 1999 and attached the Transfusion Records described in paragraphs 9 and 10. The second part of the form, completed by the Canadian Blood Services, was dated March 17, 1999. In “Box A”, it indicated that records were available for all of the units and contained the note “two donors total”. In “Box B”, number 3 was checked and a note stated “one donor cleared by subsequent donation, one to be re-tested”. In “Box C: Fractionated products”, there was a note “Anti-Hemophilic Factor given”.

[12] The Transfusion Summary of the Canadian Blood Services was dated January 11, 2008 and confirmed that unit numbers A 16769-1 and A 16749-7 of packed cells were transfused to the Claimant on December 11, 1981. It also stated that the “HCV status” of the donors was “negative”.

PRELIMINARY DECISION OF THE ADMINISTRATOR

[13] In a preliminary decision dated August 5, 2008, the Administrator advised the Claimant that his claim would be rejected unless he provided further evidence that he “[...] was infected for the first time with HCV by Blood received in Canada during the Class Period.”

FURTHER EVIDENCE OF FIRST INFECTION

[14] On August 15, 2008, the Claimant signed the Further Evidence of First Infection Form. The further evidence of first infection was delivered to the Administrator in three parts, on August 19, August 27 and September 16, 2008, and included copies of several documents that were already in the file. The relevant further evidence of first infection consisted of several additional hospital records and a letter dated August 12, 2008 from a physician. Two of the hospital records related to his hospitalization in December 1981,

during the course of which he received the transfusions; the remaining records were nephrology reports.

[15] A hospital Summary Sheet indicated, among other things, that the Claimant was admitted to the hospital on December 8, 1981 and was discharged on December 24, 1981; the final diagnosis was “primary megaureter” and the secondary diagnosis was “hypofibrinogenemia”. A Surgical Summary dated December 9, 1981 described the details of the surgical procedure, but made no reference to any transfusions received by the Claimant.

[16] A hospital Discharge Summary, dictated on February 16, 1982, indicated that the Claimant was admitted to the hospital on December 8, 1981 and discharged on December 24, 1981. The Discharge Summary confirmed that the Claimant was diagnosed with hypofibrinogenemia and was “treated with cryoprecipitate” for the bleeding problem. The Discharge Summary stated, in part, as follows:

DIAGNOSIS:	Primary megaloureter.
SECONDARY DIAGNOSIS:	Hypofibrinogenemia.
OPERATION:	Cystoscopy and pyelogram Bilatering of tapering of ureters

[The Claimant] was admitted to hospital for investigation of primary megaureter. He presented with a nose bleed six months ago, was found to have an elevated blood pressure and was referred to [a specialist]. His blood pressure was indeed elevated. An IVP was done and this showed that he had bilateral pyelonephritic changes and bilateral primary megaloureter. He is admitted to hospital for further investigations and treatment of this.

[...]

On the 11th of December he underwent primary, bilateral ureteric tapering to the pelvic brim and ureteric reimplantation with splinting of the ureters. The procedure was uneventful.

In the Recovery Room, he experienced quite moderate bleeding with lack of blood clotting. He was seen in consultation by [another doctor] and a

hyperfibrinogenemia was diagnosed. Indeed, the fibrinogen level was only 87. He was treated with cryoprecipitate and the bleeding ceased.

From the operative point of view his postoperative course was uneventful and he had no further bleeding in hospital. [...] [Emphasis Added]

[17] A hospital Nephrology Report dated April 3, 1986 stated, in part, as follows:

This is a 21 year old man who has been seen periodically since October 1981 when he was referred because of renal function impairment. Following demonstration of megaureters a ureteric reimplantation procedure was then performed. Other problems include some persisting disturbance in liver enzyme and also on occasion he was treated for gouty arthritis by his personal physician.

[18] A hospital Nephrology Report dated September 6, 1986 stated, in part, as follows:

No detailed examination performed today. [...] Some marginal elevation in transaminase is again recalled but no hepatitis B antigen identified in course of repeated screening.

[19] A hospital Nephrology Report dated October 22, 1987 stated, in part, as follows:

This is a 23 year old man who was referred and initially seen in October 1981 because of renal function abnormalities. [...] He had then been referred to our Urology Service and reimplantation with tapering of ureters was then attempted as a measure to possibly delay progression of renal function impairment. Unfortunately there had been some bleeding problems during the procedure and postoperatively he eventually went on to some brief episode of clinical hepatitis although the hepatitis B markers were never detectable. [Emphasis Added]

[20] A hospital Nephrology Report dated April 14, 1988 stated, in part, as follows:

This is a 23 year old man who is seen for periodic evaluation because of some mild renal function impairment. He underwent bilateral ureteric tapering because of megaureters and it is recalled that postoperatively there was some unexplained bleeding, most likely some DIC activity for uncertain reason and he then required considerable blood product derivatives and he developed some hepatitis a few weeks later. No hepatitis B marker has been detected in the course of follow-up although the transaminase has been marginally disturbed. [Emphasis Added]

[21] A hospital Nephrology Report dated April 6, 1989 stated, in part, as follows:

It has now been seven years since this 24-year-old man underwent tapering and re-implantation of ureters because of primary hydronephrosis and hydroureter. [...]

Following the urological procedure described above, he had developed a peculiar bleeding diathesis for which he received considerable blood products and subsequently developed some acute hepatitis. The hepatitis B markers were never

detectable and it was only after several years that the transaminase abnormalities have become gradually corrected with most recent ALT and AST of 49 and 53 units/L. It is presumed that this represented a non A, non B hepatitis.
[Emphasis Added]

[22] A hospital Nephrology report dated November 9, 1989 repeated some of the information contained in the previous reports, but added nothing of any relevance.

[23] A hospital Nephrology Report dated December 10, 1998 stated, in part, as follows:

[The Claimant] is a patient with chronic renal insufficiency. [...] Today, I filled a form for him to claim for hepatitis C. He had a blood transfusion in 1981 while having an operation. After that, he developed jaundice and at that time, they diagnosed non-A, non-B hepatitis. He is hepatitis-C positive. [Emphasis Added]

[24] An undated hospital record entitled "Continuation Sheet" described the Claimant's medical history and stated, in part, that he had Hepatitis C because of a blood transfusion.

[25] A letter dated August 12, 2008 from a physician stated as follows:

[TRANSLATION]

At [the Claimant's] request, I have reviewed his history and medical file. He suffered from jaundice in January 1982, shortly after receiving post-operative transfusions.

According to my review, there is no doubt that the jaundice was caused by a contamination with the Hepatitis C virus as a result of transfusions received in December 2001 [sic]. (Note- There is no other identifiable risk factor or possible explanation).
[Emphasis Added]

UPDATED TRACEBACK

[26] By letter dated October 8, 2008, the Canadian Blood Services forwarded the updated final report for the Traceback ("Updated Traceback") to the Administrator, together with a Transfusion Summary and the three documents provided with the initial Traceback, described in paragraphs 9 to 11.

[27] The Transfusion Summary dated January 11, 2008 stated as follows:

Comments: The following products were determined to be transfused, and matched against CBS records to determine if Donor status is known.

Unit Number	Product Name	Transfusion Date	HCV Status Donor if known
A 16769-1	Packed cells	1981-12-11	Negative
A 16749-7	Packed cells	1981-12-11	Negative

Note: [The provincial plan] documents show in addition to the blood above [the Claimant] received:

Antihemophilic Factor Lot # 0591T042 AA at 17:45 on December 11, 1981
(4x238 units)

Antihemophilic Factor Lot # 0591T042 AA at 11:10 on December 12, 1981
(2x238 units)

Antihemophilic Factor Lot # 0591T025 AA at 11:10 on December 12, 1981
(2x238 units)

Antihemophilic factor is not a product investigated by CBS.

FINAL DECISION OF THE ADMINISTRATOR DATED MARCH 24, 2009

[28] In a decision dated March 24, 2009, the Administrator denied the claim for compensation, stating as follows: [TRANSLATION]

We are writing to advise you that your claim has been denied for compensation under the Pre-1986/Post-1990 Hepatitis C Settlement Agreement. The reasons for denial are set out below.

Insufficient Further Evidence of First Infection During the Class Period – Final Decision

The Settlement Agreement provides compensation for class members first infected by a Blood transfusion in Canada prior to and including December 31, 1985 and between July 2, 1990 and September 28, 1998.

You will recall that in our last letter to you, we wrote that in the absence of further evidence, your claim would be denied. One of two circumstances applies to your case and may be summarized as follows:

- 1) You did not provide any further evidence to the Administrator; OR

- 2) The further evidence that was submitted failed to overturn the preliminary determination that your claim did not meet class membership criteria.

The results of the Traceback confirmed that the two donors of the blood transfusions that you received at the [hospital] in December 1981 have tested negative for the HCV antibody. The Traceback also confirmed that you received Anti-hemophilic factor on December 11 and 12, 1981, but that the Canadian Blood Services does not investigate this product. Given these results, the Administrator must reject your claim for compensation. In response to our first letter, you indicated that you would provide further evidence of first infection. The Administrator has carefully examined all of the documentation that you have submitted in support of your claim, but the further evidence cannot permit the results of the Traceback to be overturned. [Emphasis Added]

REQUEST FOR REVIEW

[29] On April 17, 2009, the Claimant delivered a Request for Review in which he requested an extension of time to deliver supplementary evidence from a specialist.

SUPPLEMENTARY EVIDENCE ON APPEAL

[30] On May 4, 2009, the Claimant delivered supplementary evidence on appeal, including a letter from a specialist in hepatology concerning the source of the Claimant's Hepatitis C infection, together with recent laboratory results. He also delivered an article entitled "Inherited Abnormalities of Fibrinogen"; I have read the article, but it is unnecessary for me to make further reference to it.

[31] The letter dated April 24, 2009 from the specialist in hepatology stated as follows:

[The Claimant] has chronic Hepatitis C. He is HCV RNA positive with transiently elevated ALT, over the years.

He, no doubt, acquired this infection from the blood products (Anti-Hemophilic factor) which he received in 1981, postoperatively. He became jaundiced several weeks later. He has absolutely no other risk factors for Hepatitis C. [Emphasis Added]

[32] By letter dated May 14, 2009, the Fund Counsel transmitted the following information to the Claimant:

[TRANSLATION]

With consent [...], I discussed your claim with the Administrator. According to the Administrator, to succeed on the appeal, you must demonstrate that you fall within the definition of a “primarily infected hemophiliac”. You must therefore deliver evidence to demonstrate that you have an anomaly or congenital deficiency relating to a coagulation factor. [Emphasis Added]

[33] On May 25, 2009, the Claimant’s sister wrote the following letter:

My name is [...], sister of [the Claimant]. I am a retired Medical Laboratory Technologist. I previously worked at [a health centre on the province], have some information concerning my brother’s medical history that I would like to share with you. When [he] underwent surgery on December 11th, 1981, he had at that time a clotting factor fibrinogen (documented in his file) which had not yet been diagnosed. I remember the surgeon [...], telling my parents after the surgery, there had been complications that [his] blood would not coagulate. I was in my first year of college [...] at that time and I immediately asked him if it was his platelets that were low. He was surprised at my question and said no, and that it was his fibrinogen. If you look in my brother’s file, there is a written note from [the surgeon] stating he had low fibrinogen level and that the bleeding ceased after he was given blood products (cryoprecipitate).

If you look at [his] blood chart, it confirms that he received 2 units of whole blood APOS and he **ALSO** received blood products, anti-hemophilic factor (AHF), also known as factor VIII which is given to *hemophiliac* to stop bleeding.

On that day, before they confirmed that [he] had hypofibrinogenaemia, the hospital suspected [him] to be a possible hemophiliac. The reason I am saying this is I actually saw Marc’s blood bank chart in 1983. I was training at the [...] Hospital, in my third year of Laboratory Technology. The hospital kept patient files for five years. I asked if I could look at his file. They agreed. I remember it like it was yesterday. There was the word HEMOPHILIAC with a big question mark written across the front of his chart. I would be willing to swear under oath that this is fact.

So, on December 11th, 1981, [he] was given anti-hemophilic factor but it is the fibrinogen present in the units of blood products that was responsible for the completion of the “coagulation process” therefore stopping the bleeding.

Blood products are obtained from a pool of human blood donors. It is well documented in the literature, to name a few “Public Health Agency of Canada”, “Canadian Liver Society”, “Canadian Blood Services” (CBS), “Canadian Hemophilia Society” that recipients of human blood products in those years were at HIGH RISK of contracting HCV.

In the Crawford Settlement Agreement, they define blood as:

“Blood means:

(a) in the case of Primarily-Infected Persons, except those Primarily-Infected Persons who have or had Thalassemia Major, whole blood and the following

blood products: packed red cells, platelets, plasma (fresh frozen and banked), white blood cells and cryoprecipitate.”

He, no doubt, acquired this infection from the blood products (Anti-Hemophilic factor) which he received in 1981, postoperatively. He became jaundiced several weeks later. He has absolutely no other risk factors for Hepatitis C.

FIBRINOGEN is a component of the following blood products “plasma” and “cryoprecipitate” as stated in the definition.

My brother [...] is a very special case. On December 11th, 1981, he received whole blood **and** blood products containing fibrinogen and factor VIII (AHF). He was discharged and readmitted to the hospital on January 29th, 1982 with jaundice, a well known side effect of Hepatitis C (HCV). He was then diagnosed with HCV.

If we lived in a perfect world, there would be no exceptions to the rules. But, this is not a perfect world and my brother truly is an exception! What makes my [brother's] case even more special is that he received a kidney transplant in August of 2000. His immune system is suppressed because of his daily anti-rejection medication therefore making it very hard for him to fight the HEPATITIS C VIRUS, we are positive he contracted through tainted blood products in 1981. [Emphasis by author of letter]

[34] On October 7, 2009, the Claimant delivered, also as supplementary evidence on appeal, a letter dated August 6, 2009 from a specialist in hematology that described, among other things, the transfusions received by the Claimant during his hospitalization in December 1981. The specialist in hematology stated, among other things, that the Claimant had received transfusions of two units of packed red cells and “2068 units of plasma derived Factor VIII”. He also stated that the Claimant did not have congenital hemophilia. The letter stated as follows:

I am hoping that this letter will help in clarifying [the Claimant's] request for hepatitis C compensation.

As per the notes already submitted to you by [the Claimant] you will recall that he was admitted between December 8 and December 24, 1981. During the course of that admission, he developed a bleeding complication and was diagnosed with hypofibrinogenemia. As a result of this bleeding complication, he was transfused 2 units of packed red blood cells, and he received a total of 2068 units of plasma derived factor VIII concentrate- of two different lot numbers to correct the hypofibrinogenemia. Approximately a month later, he was treated at [a] Hospital for symptoms related to hepatitis (jaundice, elevated liver enzymes).

Subsequently, he was found to be hepatitis C positive. A trace back was done and cleared the two units of packed red cells. However, it is a well-known fact that plasma derived factor VIII concentrate administered prior to 1985 transmitted the hepatitis C virus. While it is true that [the Claimant] does not have congenital hemophilia, at the time he did have an acquired coagulation disorder that needed to be treated with a blood derivative. Having reviewed his file, there is no doubt in my mind that he contracted hepatitis C from one of these two lots of factor VIII. Please find enclosed literature, which supports this fact. [Emphasis Added]

The scientific article enclosed with the letter was entitled “Hepatitis C virus and haemophilia: the natural history of HCV in haemophilic patients” and stated, among other things, that:

[...] before the introduction of heat treatment of clotting factor concentrates in the mid 1980's, virtually 100% of patients who received clotting-factor concentrate for the first time developed non-A non-B hepatitis (HCV).

ISSUE

[35] The issue to be determined is whether the Administrator erred in denying the claim for compensation.

ANALYSIS

[36] The principal provisions of the *Settlement Agreement* that govern the present claim are subsection 2.01 and various definitions contained in section 1.01. Given the results of the traceback procedure, the Administrator was also required to apply section 5.04 and the relevant provisions of the *Traceback Protocol for Primarily-Infected Persons* (“*Traceback Protocol*”) to permit the Claimant to deliver further evidence to establish that he was infected with Hepatitis C for the first time by a blood transfusion.

i) Section 2.01 of the Settlement Agreement and related definitions

[37] Under the terms of the judicially approved *Settlement Agreement*, a person claiming to be a Primarily-Infected Class Member, such as the Claimant, must satisfy the

eligibility requirements in section 2.01 in order to make a successful claim for compensation. Section 2.01 states, in part, as follows:

2.01 Eligibility – Primarily-Infected Class Member

(1) A person claiming to be a Primarily-Infected Class Member must deliver to the Administrator an application form prescribed by the Administrator together with:

- a) medical, clinical, laboratory, hospital, The Canadian Red Cross Society, Canadian Blood Services or Hema-Quebec records demonstrating that the claimant received Blood in Canada during the Class Period; [...]

[38] Paragraph 2.01(1)(a) of the *Settlement Agreement* requires, among other things, that a person claiming to be a Primarily-Infected Class Member must have received Blood in Canada during the Class Period in order to be eligible for compensation. The term “Primarily-Infected Class Member” is defined in section 1.01 of the *Settlement Agreement*, in part, as follows:

“Primarily-Infected Class Member” means collectively “Primarily-Infected Person” and “Primarily-Infected Hemophiliac”. [...]

The term “Primarily-Infected Person” is defined, in part, as follows:

“Primarily-Infected Person” means a person who received Blood in Canada during the Class Period, including a person who has or had Thalassemia Major, and who is or was infected with HCV unless:

- (a) such person is a Primarily-Infected Hemophiliac; [...] [Emphasis Added]

The term “Primarily-Infected Hemophiliac” is defined as follows:

“Primarily-Infected Hemophiliac” means a person who:

- (a) has or had a congenital clotting factor defect or deficiency including a defect or deficiency in Factors V, VII, VIII, IX, XI, XII, XIII or von Willebrand factors;
- (b) received or took Blood during the Class Period; and
- (c) is or was infected with HCV unless:

- (i) such person used non-prescription intravenous drugs, and such person has failed to establish on the balance of probabilities that he or she was infected for the first time with HCV by Blood; or
- (ii) such person opts out or is deemed to have opted-out of the Class Action in which he or she would otherwise be a Class Member; [Emphasis Added]

The term “Blood” contains two separate definitions: one to be applied in the case of Primarily-Infected Persons, and one to be applied in the case of Primarily-Infected Hemophiliacs. The definition states as follows:

“**Blood**” means:

- (a) in the case of Primarily-Infected Persons, except those Primarily-Infected Persons who have or had Thalassemia Major, whole blood and the following blood products: packed red cells, platelets, plasma (fresh frozen and banked), white blood cells and cryoprecipitate. Blood does not include Albumin 5%, Albumin 25%, Factor VIII, Porcine Factor VIII, Factor IX, Factor VII, Cytomegalovirus Immune Globulin, Hepatitis B Immune Globulin, Rh Immune Globulin, Varicella Zoster Immune Globulin, Immune Serum Globulin, (FEIBA) FEVIII Inhibitor Bypassing Activity, Autoplex (Activate Prothrombin Complex), Tetanus Immune Globulin, Intravenous Immune Globulin (IVIG) and Antithrombin III (ATIII); and
- (b) in the case of Primarily-Infected Hemophiliacs and those Primarily-Infected Persons who have or had Thalassemia Major, whole blood and blood products including packed red cells, platelets, plasma (fresh frozen and banked), white blood cells and cryoprecipitate and clotting factor products including Factor VII, Factor VIII and Factor IX, supplied, directly or indirectly, by the Canadian Red Cross Society. Blood does not include Albumin 5%, Albumin 25%, Cytomegalovirus Immune Globulin, Hepatitis B Immune Globulin, Rh Immune Globulin, Varicella Zoster Immune Globulin, Immune Serum Globulin, Tetanus Immune Globulin, Intravenous Immune Globulin (IVIG) and Antithrombin III (ATIII); [Emphasis Added]

[39] The definitions of these four terms in section 1.01, when read together and in their proper context in the *Settlement Agreement*, mean that a person claiming to be eligible for compensation under section 2.01 as a Primarily-Infected Class Member must fall within the definition of either a Primarily-Infected Person or a Primarily-Infected Hemophiliac; that person also must have received “Blood”, as that term is defined in the *Settlement*

Agreement, in Canada during the Class Period. In the context of the present appeal, it is significant to note that the definition of the term “Blood”, in the case of a Primarily-Infected Person, includes cryoprecipitate, but does not include Factor VIII. In the case of a Primarily-Infected Hemophiliac, both cryoprecipitate and Factor VIII are included in the definition of “Blood”.

ii) Section 5.04 of the Settlement Agreement and the Traceback Protocol for Primarily-Infected Persons

[40] In the Reasons for Decision on the appeal in Claim File 07-03319, I analysed the provisions in section 5.04 of the *Settlement Agreement*, as well as various sections in the *Traceback Protocol for Primarily-Infected Persons* (“*Traceback Protocol*”), and stated, in part, as follows:

[18] With respect to the procedure to be followed in considering a claim made under paragraph 2.01(1)(a), paragraph 3(a) of the *Traceback Protocol* requires the Administrator to obtain and assess the results of a Traceback Procedure. Paragraph 3(a) states as follows:

3. In making its decision whether the Claim in respect of a person claimed to be a Primarily-Infected Person should be approved, the Administrator shall:

a. obtain and assess the results of the stage or stages of the Traceback Procedure required by such of paragraphs 5 through 9 of this Protocol as are applicable to the claim in question;
[Emphasis Added]

[19] The term “Traceback Procedure” is defined in both section 1.01 of the *Settlement Agreement* and paragraph 1(a) of the *Traceback Protocol*. For the purposes of the present appeal, it is unnecessary to refer to the definition in the *Traceback Protocol*. The definition in section 1.01 of the *Settlement Agreement* states as follows:

“Traceback Procedure” means a targeted search for and investigation of the donor and/or the units of Blood received by an HCV Infected Class Member”.

The results of a Traceback Procedure therefore provide information that is crucial in determining the central question of whether a person claiming to be a Primarily-Infected Person was infected with Hepatitis C by Blood received through the blood system in Canada during the Class Period.

[20] As part of the claim forms prescribed by the Administrator, a claimant must sign a “Form 4 – Authorization to Initiate Traceback Procedure and/or to Release Traceback Information”. Form 4 authorizes the Canadian Blood Services and/or Héma Québec, among other things, to initiate a Traceback Procedure for Blood or blood products received by that person in Canada.

[21] In circumstances where the results of the Traceback Procedure do not support the claim, subsections 5.04(1) and (2) apply and state as follows:

5.04 Traceback Procedure

(1) Notwithstanding any other provision of this Agreement but subject to the provisions of Sections 5.04(2) and (3), the Administrator must reject the Claim of a Primarily-Infected Person (and all Claims pertaining to such Primarily-Infected Person or Primarily-Infected Opt-out Person, including Claims of Secondly-Infected Persons, HCV Personal Representatives, Dependants and Family Members) if the results of a Traceback Procedure demonstrate that:

(a) where the Primarily Infected Person did not receive Blood prior to January 1, 1986, one of the donors or units of Blood received at any time between January 1, 1986 and July 1, 1990 inclusive, by the Primarily-Infected Person was HCV antibody positive; or

(b) that none of the donors or units of Blood received by the Primarily-Infected Person during the Class Period is or was HCV antibody positive.

(2) A claimant may prove that the relevant Primarily-Infected Person or Primarily-Infected Opt-out Person was infected, for the first time, with HCV by receiving Blood in Canada during the Class Period, notwithstanding the results of the Traceback Procedure. For greater certainty, the costs of obtaining evidence to refute the results of a Traceback Procedure must be paid by the claimant unless otherwise ordered by a Court. [Emphasis Added]

[22] Where the results of the Traceback Procedure demonstrate that none of the donors or units of Blood received during the Class Period was HCV antibody positive, paragraph 5.04(1)(b) of the *Settlement Agreement* requires the Administrator, in mandatory terms, to reject the claim. Paragraph 5.04(1)(b) must be read in conjunction with paragraph 8(a) of the *Traceback Protocol* which reiterates the obligation of the Administrator to reject a claim in such circumstances. Paragraph 8(a) of the *Traceback Protocol* states as follows:

8. After reviewing the available Traceback Procedure Information, if any, and the results of the Unit Number Search or Records Search, if such were required, the Administrator shall:

a. where all of the donors or units of the Blood received by the person claimed to be a Primarily-Infected Person during the Class Period

are determined not to be HCV antibody positive, reject the Claim as provided in Section 5.04(1) of the Settlement Agreement, subject to the claimant's right to provide evidence to refute the Traceback Procedure result as provided in Section 5.04(2) of the Settlement Agreement and paragraphs 15 to 18 of this Protocol;

[23] Despite the requirement in subsection 5.04(1)(b) of the *Settlement Agreement* and paragraph 8(a) of the *Traceback Protocol* to reject the claim, subsection 5.04(2) nevertheless permits a claimant to prove that the Primarily-Infected Person was infected with HCV, for the first time, by receiving blood in Canada during the Class Period, notwithstanding the results of the Traceback Procedure. In the same vein, paragraph 8(a) of the *Traceback Protocol* refers to the right of a claimant to provide evidence to refute the Traceback Procedure result under both subsection 5.04(2) of the *Settlement Agreement* and paragraphs 15 to 18 of the *Traceback Protocol*.

[24] Paragraph 15 of the *Traceback Protocol* requires the Administrator, after making a determination to reject the claim based on the Traceback Procedure result, to advise the claimant of the right to provide "further evidence of first infection", failing which the claim will be rejected. The expression "further evidence of first infection" is used in paragraphs 15 to 18 of the *Traceback Protocol*; it is not specifically defined in either section 1.01 of the *Settlement Agreement* or paragraph 1 of the *Traceback Protocol*. However, paragraph 15 of the *Traceback Protocol* refers to "further evidence of first infection" as evidence establishing that the claimant "[...] was infected for the first time with HCV by a Blood transfusion received in Canada during the Class Period notwithstanding the Traceback Procedure result [...]". Paragraph 15 also makes reference to subsection 5.04(2), the provision in the *Settlement Agreement* that permits a claimant to prove first infection, notwithstanding the results of the Traceback Procedure. Paragraph 15 of the *Traceback Protocol* provides as follows:

15. The Administrator shall, after determining in accordance with the provisions of Section 5.04(1) of the Settlement Agreement and paragraph 8(a) or 8(c)(i) above that a Claim must be rejected based upon the Traceback Procedure result, advise the claimant that, unless the claimant provides further evidence of first infection ("Further Evidence of First Infection") which establishes to the satisfaction of the Administrator that the person claimed to be the Primarily-Infected Person was infected for the first time with HCV by a Blood transfusion received in Canada during the Class Period notwithstanding the Traceback Procedure result in accordance with Section 5.04(2) of the Settlement Agreement, his or her claim shall be rejected (a "Section 5.04 Letter").

[25] Paragraph 16 of the *Traceback Protocol* requires the Administrator to send a letter to the claimant under section 5.04 advising of the right to elect to provide Further Evidence of First Infection and the obligation to return the election form within a prescribed time period, failing which the claim will be rejected. Paragraph 17 provides, among other things, that a claimant who elects

to provide Further Evidence of First Infection must submit the evidence within a period of six months, unless the time period is extended.

[26] In circumstances where a claimant provides Further Evidence of First Infection, paragraph 18 of the *Traceback Protocol* requires the Administrator to accept or reject the claim “[...] based upon all of the information available and section 5.04 of the *Settlement Agreement*”. In addition, a claim will be rejected where a claimant fails to provide the Further Evidence of First Infection within the prescribed or extended time period. Paragraph 18 of the *Traceback Protocol* states as follows:

18. The Administrator shall, following receipt and consideration of the Further Evidence of First Infection received from a claimant, accept or reject his or her Claim based upon all of the information available to the Administrator and Section 5.04 of the Settlement Agreement. If the claimant who elected to provide Further Evidence of First Infection does not provide the Further Evidence of First Infection within the six months following his or her election, or such further time as has been agreed or ordered, his or her Claim shall be rejected.

[27] In the present appeal, the related provisions in paragraph 5.04(1)(b) and subsection 5.04(2) of the *Settlement Agreement*, as well as paragraphs 3, 8(a) and 15 to 18 of the *Traceback Protocol*, must be read together. A textual reading of those provisions in their context and in conjunction with one another confirms that, where a Traceback Procedure demonstrates that none of the donors or units of Blood received by a Primarily-Infected Person during the Class Period is or was HCV antibody positive, a claimant has the opportunity to provide Further Evidence of First Infection in accordance with the requirements in the *Traceback Protocol*. The Further Evidence of First Infection must establish, to the satisfaction of the Administrator, that the person claiming to be the Primarily-Infected Person was infected for the first time with HCV by a Blood transfusion received in Canada during the Class Period; otherwise, the claim for compensation must be rejected. This interpretation is also consistent with the purpose of the *Settlement Agreement*, which is to settle all claims relating to or arising from the infection of persons with Hepatitis C through the Blood system in Canada during the Class Period, on the terms set out in the *Agreement*.

iii) Did the Administrator err in rejecting the claim for compensation?

[41] Section 5.04 of the *Settlement Agreement* and section 15 of the *Traceback Protocol* require the Administrator, among other things, to reject a claim for compensation of a Primarily-Infected Person where none of the donors of blood received is or was HCV antibody positive, unless further evidence establishes an infection with HCV for the first time by a blood transfusion. Section 18 of the *Traceback Protocol*

requires the Administrator, after receiving and considering the evidence of first infection, to accept or reject the claim “[...] based upon all of the information available[...]”. The Administrator must therefore consider the further evidence of first infection in the context of all available evidence in the claim file.

[42] The evidence in the Updated Traceback, described in paragraphs 26 and 27, indicated that the donors of the two units of blood received by the Claimant on December 11, 1981 were HCV antibody negative. It also confirmed that the Claimant had received a total of “8 x 238 units” of Antihemophilic factor, a product not investigated by the Canadian Blood Services.

[43] In the final decision dated March 24, 2009, reproduced in paragraph 28, the Administrator referred to the two separate findings in the Updated Traceback: the donors of the two units of blood had tested negative for the HCV antibody, and the Claimant was transfused with Antihemophilic factor. Given the results in the Updated Traceback, the Administrator stated that it was required to reject the claim for compensation. It concluded the decision by stating that the further evidence of first infection “[...] cannot permit the results of the Traceback to be overturned”, but made no reference to any of the evidence and provided no justification for its conclusion.

[44] By virtue of section 5.04 of the *Settlement Agreement* and sections 15 and 18 of the *Traceback Protocol*, the Administrator was required to reject the claim to the extent that it was based on the transfusions of the two units of blood donated by donors who were negative for the Hepatitis C virus. However, with respect to the Antihemophilic factor transfused to the Claimant, the Administrator was required to assess the further evidence of first infection in the context of all available evidence in order to determine

whether the Claimant had established, to its satisfaction, that he was infected with the Hepatitis C virus for the first time by a blood transfusion.

[45] In order to determine whether the Administrator erred in rejecting the application for compensation, the evidence concerning the blood and blood products received by the Claimant during his hospitalization in December 1981 must be reviewed.

[46] The further evidence of first infection delivered by the Claimant is summarized in paragraphs 14 to 25 and includes significant evidence concerning the Antihemophilic factor blood products transfused to the Claimant; this evidence must be considered in the context of the other evidence that was before the Administrator at the time of the making of the final decision.

[47] The transfusion evidence that was before the Administrator when the final decision was made consisted of hospital Transfusion Records, the Discharge Summary, two Nephrology Reports and the Updated Traceback. The two hospital Transfusion Records, described in paragraphs 9 and 10, confirmed that the Claimant was transfused on December 11, 1981 with packed cells and Antihemophilic factor; on December 12, 1981, he was again transfused with Antihemophilic factor. Significantly, the hospital Discharge Summary, dictated on February 16, 1982 and reproduced in paragraph 16, stated, among other things, that the Claimant was treated with cryoprecipitate to stop the bleeding. The two hospital Nephrology Reports, dated April 14, 1988 and April 16, 1989, reproduced in paragraphs 20 and 21, respectively stated that the Claimant had required “considerable blood product derivatives” and “considerable blood products” for his postoperative bleeding. The Updated Traceback of the Canadian Blood Services included a Transfusion Summary, dated January 11, 2008 and reproduced in paragraph 27, stating

that, in addition to the transfusion of the two units of blood donated by donors who tested negative for the Hepatitis C virus, the Claimant had received 4 x 238 units of Antihemophilic factor on December 11, 1981, and a further total of 4 x 238 units on December 12, 1981. The Updated Traceback noted that Antihemophilic factor was not a product investigated by the Canadian Blood Services, but made no reference to the fact that the Claimant was transfused with cryoprecipitate.

[48] Under subsection 5.04(2) of the *Settlement Agreement*, the Claimant was entitled to prove that, as a Primarily-Infected Person, he was infected with the Hepatitis C virus, for the first time, by receiving blood in Canada during the Class Period. The term “Blood” is defined in section 1.01, in the case of Primarily-Infected Persons, to include cryoprecipitate. In the final decision dated March 24, 2009, the Administrator made no reference to the evidence in the Discharge Summary stating that the Claimant had received cryoprecipitate. The evidence that the Claimant received transfusions of cryoprecipitate was highly relevant to the central issue to be decided on the claim. The Administrator therefore erred by misapprehending or not considering the evidence that cryoprecipitate was the blood product transfused to the Claimant in December 1981. In the circumstances, the decision of the Administrator cannot be permitted to stand. However, before determining the proper disposition to be made, it is necessary to consider the supplementary evidence delivered by the Claimant on appeal.

iv) The supplementary evidence on appeal

[49] The Claimant delivered supplementary evidence on appeal that included letters from two medical specialists concerning the transfusions. The first letter, dated April 24, 2009 and reproduced in paragraph 31, was from a specialist in hepatology who

stated, among other things, that the Claimant had acquired his Hepatitis C infection as a result of “blood products (Anti-Hemophilic factor)” received postoperatively in 1981. The second letter, dated August 6, 2009 and reproduced in paragraph 34, was from a specialist in hematology who stated, among other things, that the Claimant had received transfusions of two units of packed red cells and “2068 units of plasma derived Factor VIII”.

[50] The statement made in the letter dated August 6, 2009 by the specialist in hematology that the Claimant had received “2068 units of plasma derived factor VIII” was the first reference in the evidence to Factor VIII, and appears to contradict the evidence in the hospital Discharge Summary that the Claimant had received transfusions of cryoprecipitate. However, there is nothing in the letter of the specialist in hematology or the other evidence in the claim file to indicate any knowledge on his part of the statement in the hospital Discharge Summary that the Claimant had received transfusions of cryoprecipitate.

[51] In considering what appears to be a contradiction in the evidence concerning the Antihemophilic factor transfused to the Claimant, I have concluded that the hospital Discharge Summary is reliable evidence that is entitled to significant evidentiary weight as it was dictated on February 16, 1982, approximately two months after the transfusions were received by the Claimant. Furthermore, the evidence in the hospital Transfusion Records and the Updated Traceback indicating that the Claimant was transfused with Antihemophilic factor in 1981 is consistent with the receipt of cryoprecipitate. In the circumstances, the statement of the specialist in hematology that the Claimant had received transfusions of “plasma derived factor VIII concentrate” is entitled to little, if

any, weight. It is also of interest to note that the letter of the specialist in hepatology, dated April 24, 2009 and reproduced in paragraph 31, stated that the Claimant had acquired the Hepatitis C infection from transfusions of “the blood products (Anti-Hemophilic factor)”; he made no reference to Factor VIII. The evidence in the record, when considered in its totality, therefore demonstrates that the Claimant received transfusions of the Antihemophilic factor cryoprecipitate on December 11 and 12, 1981.

v) *Decision*

[52] Given my complete review of the evidence, I have decided to make the decision in this matter, rather than returning it to the Administrator for disposition.¹

[53] An issue arose in the claim file as to whether the Claimant fell within the definition in section 1.01 of a Primarily-Infected Person or a Primarily-Infected Hemophiliac. The evidence demonstrates that the Claimant satisfies all of the requirements in the definition of a Primarily-Infected Person in section 1.01, including the receipt of blood. In particular, the Claimant received cryoprecipitate, a blood product that is included in the definition of Blood in section 1.01 in the case of a Primarily-Infected Person. The question of whether the Claimant could meet the requirements in the definition of a Primarily-Infected Hemophiliac is therefore irrelevant.

[54] With respect to the decision to be made under section 5.04 of the *Settlement Agreement* and sections 15 and 18 of the *Traceback Protocol*, I have already concluded that the hospital records demonstrate that the Claimant received blood transfusions of cryoprecipitate on December 11 and 12, 1981. Furthermore, there is an abundance of

¹ See, by way of analogy, the approach taken by Rothstein J. in *Apotex v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at paragraph 72.

evidence in the claim file to establish that the Claimant, who had no other risk factors, was infected with the Hepatitis C virus as a result of his transfusions in December 1981. In particular, the Claimant was admitted to the hospital and diagnosed with jaundice and hepatitis on January 29, 1982, approximately one and a half months after his transfusions, at a time when the Hepatitis C virus was unknown. He was repeatedly tested for Hepatitis B over the course of several years and was finally diagnosed with Hepatitis C in or about 1990. The letters of the specialists in hepatology and hematology, reproduced in paragraphs 31 and 34, unequivocally state that the Claimant acquired Hepatitis C as a result of his transfusions in 1981, as does a letter from another physician, reproduced in paragraph 25. I am therefore satisfied, on the basis of the evidence in its totality, that the Claimant was infected with the Hepatitis C virus for the first time by a blood transfusion.

CONCLUSION

[55] The appeal is allowed.

"D. McGillis"

The Honourable D. McGillis, Q.C.
Appeals Officer

DATED January 7, 2010

TO: Claimant
Fund Counsel
Administrator

Received January 7, 2010