C A N A D A
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

NO : 500-06-000016-960

SUPERIOR COURT
Class action

DOMINIQUE HONHON

Plaintiff

-vs-

THE ATTORNEY GENERAL OF CANADA
THE ATTORNEY GENERAL OF QUÉBEC
THE CANADIAN RED CROSS SOCIETY

Defendants

-and-

MICHEL SAVONITTO, in the capacity of the Joint Committee member for the province of Québec

Petitionner

-and-
FONDS D'AIDE AUX RECOURS COLLECTIFS
-and-
LE CURATEUR PUBLIC DU QUÉBEC

Mis-en-cause

C A N A D A
PROVINCE OF QUÉBEC
DISTRICT OF MONTRÉAL

NO : 500-06-000068-987

SUPERIOR COURT
Class action

DAVID PAGE

Plaintiff

-vs-

THE ATTORNEY GENERAL OF CANADA
THE ATTORNEY GENERAL OF QUÉBEC
THE CANADIAN RED CROSS SOCIETY

Defendants

-and-

FONDS D'AIDE AUX RECOURS COLLECTIFS
-and-
LE CURATEUR PUBLIC DU QUÉBEC

Mis-en-cause

APPLICATION FROM THE JOINT COMMITTEE FOR APPROVAL OF MODIFICATIONS TO THE MEDICAL EVIDENCE COURT APPROVED PROTOCOL WITH RESPECT TO HCV COMPENSABLE DRUG THERAPY

(Section 9.02 b) and 10.01(1)h) of the Settlement Agreement)

TO THE HONOURABLE JUSTICE CHANTAL CORRIVEAU DESIGNATED TO HEAR MOTIONS IN THESE CASES, THE PETITIONER RESPECTFULLY SUBMITS:

A- CONTEXT

1. The Transfused HCV Plan and the Hemophiliac HCV Plan of the 1986-1990 Hepatitis C Agreement (the "Agreement") and the proposed HCV Late Claims Benefit Plan (together, the "Plans") provide for compensation triggered by class members reaching certain disease levels. Compensation is progressive in nature in the sense that a class member can receive additional compensation if he or she progresses from one disease level to a higher disease level;

2. One of the ways that the Disease Level 3 requirement in section 4.01(1)(c) of the Plans is triggered relates to Compensable HCV Drug Therapy as it is defined in section 1.01 of the Plans. Where class members have been treated with Compensable HCV Drug Therapy within the meaning of the Plans, or, have met or meet a protocol for Compensable HCV Drug Therapy (regardless of whether that treatment is recommended or taken) they are classified at Disease Level 3 and are eligible for a payment of $30,000 (indexed) under the Plans;

3. In addition, pursuant to section 4.05 of the Plans, class members who receive Compensable HCV Drug Therapy are entitled to be paid $1,000/month (indexed) for each completed month of such treatment;

4. Prior to the June 2016 joint hearings of the courts on allocating excess capital, the Joint Committee recognized that the 2013 medical model indicated a large number of class members would undergo treatment with direct-acting antiviral agent ("DAA") (with or without ribavirin or interferon), including those at Disease Level 2. The Joint Committee also recognized that, while the medical model provided for Disease Level 2 to Disease Level 3 transition based on disease progression, it did not account for Disease Level 2 to Disease Level 3 transition based on having taken or met a protocol for treatment with Compensable HCV Drug Therapy as provided for in the Plans;

5. Accordingly, the Joint Committee sought to ensure that the liabilities accounted for this and served motions requesting that the Courts declare that the amount of excess capital available for allocation was a lesser amount than originally determined, namely, $206,920,000;

6. The basis for the request for a reduction in excess capital was a belief on the part of the Joint Committee that an additional sufficiency liability in respect of Disease Level 2 claimants who are reclassified as Disease Level 3 claimants and become eligible for the $30,000 (1999 dollars) Disease Level 3 fixed payment based on taking or meeting a protocol for taking Compensable HCV Drug Therapy should be reflected in the financial position of the Trust;

7. The responding material served by the federal government included affidavit #4 of Peter Gorham attaching the Morneau Shepell *Actuarial Report on Proposed Allocation of the Actuarially Unallocated Funds as of 31 December 2013*. In that report, Mr. Gorham raised the issue of the appropriateness of Disease Level 2 to Disease Level 3 transition "by reason only of taking the new treatment..." Mr. Gorham suggested in his report that "the situation be reviewed to determine whether the court approved protocol regarding these payments should be revised."

8. The current application seeks to address this outstanding issue and one other issue in respect of compensable HCV Drug Therapy;

B- THE RELEVANT PROVISIONS OF THE PLANS AND THE MEDICAL EVIDENCE PROTOCOL

9. Compensable HCV Drug Therapy is defined in section 1.01 of the Plans as follows:

> *«Compensable HCV Drug Therapy" means interferon or ribavirin, used alone or in combination, or any other treatment that has a propensity to cause adverse side effects and that has been approved by the courts for compensation. »*
>
> *« médication indemnisable au titre du VHC », l'interféron ou la ribavirine, utilisé seul ou en combinaison, ou tout autre traitement qui est susceptible d'avoir des effets indésirables et que les tribunaux ont approuvé à des fins d'indemnisation; »*

10. In 2010, the Courts approved the "Medical Evidence Protocol" developed by the Joint Committee in consultation with medical experts entitled *Revised Medical Evidence for Section 4.01(1) and Section 4.01(2) of Article 4 the Transfused HCV Plan and the Hemophiliac HCV Plan*, a copy of which is appended as Exhibit A to the affidavit #17 of Heather Rumble Peterson alleged in support thereof as **Exhibit R-1**;

11. The Medical Evidence Protocol provides instruction to the Administrator in respect of evidence acceptable for the various disease level approvals, including for Disease Level 3;

12. Presently, option B of Disease Level 3 of the Medical Evidence Protocol provides that claimants may satisfy the medical evidence requirement at section 4.01(1)(c) of the Plans (triggering the payment of $30,000), if the class member delivers a satisfactorily completed form indicating the HCV Infected Person has undergone one of the following types of Compensable HCV Drug Therapy:

(i) interferon therapy;

(ii) combination interferon and ribavirin;

(iii) interferon combined with a drug other than ribavirin; or

(iv) ribavirin combined with a drug other than interferon.

13. Presently, option D of Disease Level 3 of the Medical Evidence Protocol provides that where options A to C have not been met, a class member can satisfy the medical evidence requirement in section 4.01(1)(c) of the Plans by:

> «(i) (d) certification from a gastroenterologist, hematologist, infectious disease specialist or internist that:
>
> a. the Approved HCV Infected Person has met or meets a protocol for Compensable HCV Drug Therapy consistent with the treatment decision factors set out in the most recent Canadian Association for the Study of the Liver (CASL) Consensus Guidelines for the Management of Hepatitis C, including some HCV disease indicator(s) in addition to a positive PCR test;
>
> b. and which the certifying physician asserts is within generally accepted medical standards for recommending treatment) »

14. Option D was added to the Medical Evidence Protocol in 2010 to cover the circumstance where options A to C in the Medical Evidence Protocol do not apply and a treating specialist determines a class member appropriate for treatment based on a more subjective assessment of his or her condition in accordance with the factors delineated in the CASL Guidelines;

15. At the time option D was added to the Medical Evidence Protocol, the factors delineated in the CASL Guidelines related to interferon and ribavirin therapy, and so the option D alternate Disease Level 3 trigger was directly linked to Compensable HCV Drug Therapy as currently defined, as appears from a copy of these Guidelines in place from 2007 until May 2012 appended as Exhibit B to the affidavit #17 of Heather Rumble Peterson (R-1);

16. The Treating Physician Form completed by the physician to provide information to classify a person at the appropriate disease level, including Disease Level 3, provides a check list of options for the physician to complete that identify what drugs the patient is using for their treatment. The Medical Evidence Protocol and Treating Physician Form each reference the CASL Consensus Guidelines as one of the options to trigger the Disease Level 3 determination, as appears from a copy of the Treating Physical Form is appended as Exhibit C to the affidavit #17 of Heather Rumble Peterson (R-1) ;

C- THE EVOLUTION IN TREATMENT UTILIZING DAAs

17. In 2011, Health Canada approved certain DAAs for use in treatment of HCV. Those drugs were prescribed with interferon or ribavirin or both. Since then, several DAAs have been approved for treatment with HCV. Some of the more recent DAAs are prescribed without interferon or ribavirin;

18. Affidavit evidence of Dr. Vincent Bain Professor, Division of Gastroenterology, Department of Medicine at the University of Alberta (retained by the Joint Committee) and Dr. Sam Lee, professor of medicine, University of Calgary (retained by Canada) filed by the parties in support of the December 31, 2013 financial sufficiency application and the June 2016 joint hearings of the courts on allocating excess capital outline the development of DAAs, their efficacy and their side effects, a copy of the affidavits of **Dr. Bain** is alleged in support thereof as **Exhibit R-2** and a copy of the affidavit from **Dr. Lee** as **Exhibit R-3;**

19. From 2000 to approximately 2011, the standard antiviral therapy offered to patients infected with HCV was pegylated interferon plus ribavirin. The pegylated interferon and ribavirin regimen was associated with cure rates of 50% for patients infected with the dominant genotype 1 subtype of HCV. The regimen typically required forty-eight weeks of subcutaneous injections of pegylated interferon in addition to oral medications. Both interferon and ribavirin can cause significant side effects. The number and adverse nature of the side effects are more pronounced with interferon. Many HCV patients had to abandon their therapy because of these side effects, or because of the complications which arose from the side effects.. In addition, these drugs are contra-indicated for people with other medical conditions, co-morbidities or who are taking certain other drugs. Accordingly, there has been extensive research into DAAs which are effective without interferon and/or ribavirin, as appears from paragraphs 19-20 of Exhibit R-3 and paragraphs 36 and 50 of Exhibit R-2A;

20. The first generation of DAA were protease inhibitors called telaprevir and boceprevir and they were approved for treatment in 2011. They were prescribed with pegylated interferon and ribavirin. These drugs were associated with severe side effects, described more fully below, and are rarely prescribed in Canada anymore, as appears from paragraph 37 of Exhibit R-2A and paragraph 5 of Exhibit R-2B;

21. In 2013 and 2014, Health Canada granted regulatory approvals to new all-oral DAAs that make possible treatment regimens having a much shorter duration and without reliance on the use of pegylated interferon. However, Dr. Bain notes that in some cases, these DAA regimens were prescribed with interferon and/or ribavirin. The most common combinations of DAA prescribed starting in 2014 were called Harvoni and Holkira Pak, as appears from paragraphs 22-23 of Exhibit R-3, from paragraphs 40, 46 and 51 of Exhibit R-2A and from paragraph 6 of Exhibit R-2B;

22. In 2012 and 2015 new CASL Guidelines were developed and published. The current CASL Guidelines include treatment regimens that are based on DAAs without interferon or ribavirin, as appears from a copy of these documents appended as Exhibit D to the affidavit #17 of Heather Rumble Peterson (R-1);

23. On January 19, 2016 Health Canada granted regulatory approval for another all-oral DAA combination regimen, Zepatier, for treatment of patients with HCV genotypes 1 and 4. On July 14, 2016, Health Canada approved Epclusa, a once-daily pan-genotypic single dose tablet regimen for treatment of adults with genotype 1-6 chronic hepatitis C virus. In August 2017, Health Canada approved Vosevi, a combination of Sofosbuvir, Velpatasvir and Voxilaprevir for treatment of HCV genotypes 1 through 6. In January 2017 (and revised in August 2017), Health Canada approved Maviret, a combination of Glecaprevir and Pibrentasvir for treatment of genotypes 1 through 6, as appears from the documents appended as Exhibit H, Exhibit I and Exhibit J to the affidavit #17 of Heather Rumble Peterson (R-1);

24. Compensable HCV Drug Therapy, as currently defined in the Plans, does not capture the DAAs used for the treatment of HCV except in the circumstance where they are used in combination with interferon or ribavirin;

25. Class members who are receiving DAA drug therapy without interferon or ribavirin do not qualify for the $30,000 payment pursuant to section 4.01(1)(c) of the Plans (unless they meet other criteria, ie. option A or C which trigger Disease Level 3). In addition, these class members are not presently eligible for the $1000/month payment under section 4.05 of the Plans;

D- ADVERSE SIDE EFFECTS OF DAAs

26. The Joint Committee consulted with Dr. Vincent Bain and Dr. Bernard Willem on the issue of adverse side effects and DAA treatment. The Joint Committee's understanding following these consultations is that DAA treatment cause far fewer adverse side effects than treatment with interferon or ribavirin in terms of the number of patients who suffer side effects and in terms of the severity of the side effects experienced by those who experience them, but some adverse side effects do occur;

27. In some instances the success of the first generation of the DAAs was qualified. Not all HCV genotypes responded equally well to DAA treatment, and for some genotype infections optimal responses required the addition of ribavirin. There were severe side effects associated with these drugs including rashes that in some cases became life threatening, nausea, joint pain, anemia, low white blood cell counts, and anal problems such as itching, burning and hemorrhoids. Dr. Bain noted that many more patients than anticipated during the trial phase could not tolerate the full course of therapy and so treatment was discontinued in such patients prior to the prescribed length at the outset. Dr. Bain notes that in those patients with severe side effects, the treatment burden increased and the health outcomes decreased compared to pegylated interferon and ribavirin alone. The first generation of DAA are rarely prescribed in Canada anymore, as appears from paragraph 5 of Exhibit R-2B, paragraph 21 of Exhibit R-3 and paragraph 37 of Exhibit R-2A;

28. Dr. Lee does not believe there are discernible side effects associated with the DAAs approved in 2013 and 2014 or that there is a medical reason to suggest that any patient would undergo a hardship following either Holkira PAK or Harvoni treatment regimens. Dr. Lee notes that Holkira PAK may have to be supplemented with ribavirin when treating certain HCV genotypes. Dr. Lee believes that if some side effects result from the Holkira PAK regimen that might be avoided through the use of Harvoni, they nevertheless are minimal, as appears from paragraphs 22-24 of Exhibit R-3;

29. Dr. Bain offers the following qualifications to Dr. Lee's statement with regard to 2013 and 2014 DAAs "that there are no discernible side effects" and no patient would undergo "any hardship":

    (a) DAAs approved in 2013, simeprevir and sofosbuvir, were combined with pegylated interferon and ribavirin and so those treatment regimens did not avoid the side effects associated with pegylated interferon and ribavirin although the treatment duration was shorter;

(b) one of the DAA treatment combinations approved in 2014 known commonly as Holkira Pak (it is a combination of ombitasvir, dasabuvir, partitaprevir and a boosting agent called ritonavir) must be taken with ribavirin for patients with genotypes 1a (which is very common). When combined with ribavirin, the side effects of ribavirin are not avoided and are discernible;

(c) among the patients Dr. Bain treated with Harvoni and Holkira Pak, Dr. Bain has noted some patients experiencing side effects including mild to moderate fatigue, headache, insomnia, nausea, pruritis (itchiness), diarrhea and asthenia (lack of energy). The impact of the side effects is markedly less and the side effects do not generally impact day to day functioning compared to pegylated interferon and ribavirin, telaprevir or boceprevir regimes;

as appears from paragraph 51 of Exhibit R-2A and paragraphs 6-7 of Exhibit R-2B;

30. The product monographs of the most commonly prescribed DAA drugs describe adverse reactions when the drugs are taken without ribavirin or interferon:

(a) Harvoni
  (i) headache; and
  (ii) fatigue;

(b) Holkira Pak
  (i) fatigue;
  (ii) nausea;
  (iii) asthenia; and
  (iv) headache

(c) Zepatier
  (i) fatigue;
  (ii) headache; and
  (iii) nausea.

(d) Epclusa
  (i) headache; and
  (ii) fatigue

(e) Vosevi
  (i) headache;
  (ii) fatigue;
  (iii) diarrhea;
  (iv) insomnia; and
  (v) asthenia

(f) Maviret
  (i) headache;
  (ii) fatigue;
  (iii) nausea;
  (iv) diarrhea; and
  (v) pruritis.

as well as long lists of adverse reactions observed in a smaller number of persons during clinical trials, as more fully detailed in paragraphs 26-33 of the affidavit #17 of Heather Rumble Peterson and in the documents appended to it as Exhibits E, F, G, H, I and J;

31. The product monographs for Vosevi and Marivet contain a warning that cases of Hepatitis B virus reactivation have been reported in patients co-infected with Hepatitis C and Hepatitis B and treated with DAAs, as appears from these product monographs appended as Exhibits I and J to the affidavit #17 of Heather Rumble Peterson (R-1);

32. During the class member consultation process prior to the June 2016 joint hearings of the courts on allocating excess capital, the Joint Committee received some information from class members during the townhall sessions and in written submissions sent by class members that some class members have experienced side effects as a result of undergoing treatment with DAAs. The verbal exchanges and written submissions do not allow the Joint Committee to be confident that all of these reports were made about treatment that excluded interferon and ribavirin, but it was clear that class members were experiencing fatigue and possibly other symptoms such as muscle soreness and headaches while taking DAAs without interferon ribavirin, as explained in paragraph 23 of the affidavit #17 of Heather Rumble Peterson (R-1);

33. The Administrator does not hear from a great deal of claimants complaining of side effects, those who do are saying they experienced headaches, nausea, fatigue and muscle/joint pain. One class member has indicated that she is considering an appeal of the Administrator's decision to deny the claim for the $1,000 per month payment based on having experienced extreme fatigue, joint pain and headaches which interfered with her ability to care for her son and required her husband to take time off work. These

assertions are supported by her treating physician. Two other class members have written letters to the Administrator regarding side effects while taking Harvoni including nausea, headaches, muscle pain and fatigue, as mentioned in paragraph 24 of the affidavit #17 of Heather Rumble Peterson (R-1);

34. There is currently an appeal of the Administrator's refusal to approve the $1,000 per month payment in circumstances where the claimant claims to have suffered adverse side effect to DAA treatment without interferon or ribavirin. The adverse side effects on which the appeal is based are: the requirement to use birth control during the treatment and for six months after the treatment which delayed the plans of this class member and his wife to try to have children; weight gain; difficulty sleeping; fatigue; flu-like symptoms; and increased sensitivity to exposure to sunlight, as mentioned in paragraph 25 of the affidavit #17 of Heather Rumble Peterson (R-1);

35. Health Canada has conducted a safety review of Galexos (simeprevir), a DAA, in response to a Japanese publication that connected the use of simeprevir with liver problems. As a result of this review, the manufacturer of Galexos (simeprevir) has updated prescribing information to warn about the risk of severe liver problems and related death. While the connection between simeprevir and this side effect is not certain, the Joint Committee is concerned that some of the potential side effects of the DAA may not yet be fully known to or understood by the medical community, as appears from paragraph 35 of the affidavit #17 of Heather Rumble Peterson (R-1) and from the documents appended to it as Exhibit K;

E- LEGAL CONSIDERATIONS

36. The testimony from Drs. Lee and Bain suggests that the range and severity of side effects of the DAA treatments is not yet subject to consensus in the medical community. However, it is clear to the Joint Committee that class members do and could in the future suffer adverse side effects as a result of undergoing treatment with DAAs;

37. The debates regarding the rate of side effects, nature of side effects and severity of the side effects of these drugs is made more complex by the fact that the development and regulatory approval of DAAs is occurring rapidly;

38. Since Compensable HCV Therapy is defined as drugs which have a propensity (in English) / are susceptible (in French) to cause adverse side effects, it is appropriate to DAA drugs, which cause adverse side effects in some but not all persons treated with them, as Compensable HCV Therapy where the treating physician certifies that the person suffered adverse side effects due to the treatment;

39. If DAAs are added to the definition of Compensable HCV Drug Therapy in the limited circumstances proposed, class members will be eligible to advance to Disease Level 3 in circumstances where the class members have experienced adverse side effects associated with DAA drug treatments. Such class members will also be entitled to the $1,000 per month payment that class members who take interferon and/or ribavirin receive.

40. The Joint Committee proposes that the Medical Evidence Protocol pertaining to Disease Level 3 be revised to add the following incidental changes to items iii and iv and to add item v, all of which are set out in bold below:

> « **DISEASE LEVEL 3** To satisfy the medical evidence requirement at Section 4.01(1)(c) of the applicable Plan, the Approved HCV Infected Person must deliver to the Administrator a satisfactorily completed TRAN2/HEMO2 Treating Physician Form which indicates that the HCV Infected Person has either:
>
> (...)
>
> (b) undergone one of the following types of Compensable HCV Drug Therapy:
>
> i. interferon therapy;
> ii. combination interferon and ribavirin therapy;
> iii. **treatment with** interferon combined with a drug other than ribavirin;
> iv. **treatment with** ribavirin combined with a drug other than interferon;
> v. **treatment with at least one direct-action anti viral ("DAA") that has been approved by Health Canada in circumstances where the Treating Physician certifies that the HCV Infected Person suffered adverse side effects as a result of taking a DAA treatment.** »

41. The Joint Committee also recommends that the section of the Medical Evidence Protocol pertaining to Disease Level 3 be revised by eliminating the CASL Guidelines as an option to satisfy the Disease Level 3 criteria of the Medical Evidence Protocol;

42. As discussed above, the current CASL Guidelines recommend some treatment regimens that do not include interferon or ribavirin and, as such, they no longer serve the purpose they were intended to serve as a proxy for meeting a protocol for treatment with Compensable HCV Drug Therapy as it is currently defined;

43. If the Courts accept the Joint Committee's proposal that DAA treatment qualify as Compensable HCV Drug Therapy in those circumstances where the treating physician certifies the class member suffered adverse side effects as a result of taking the DAA drugs, the CASL Guidelines will still be too broad to serve as a protocol to assess

progression to Disease Level 3 as they do not reflect the limited circumstances in which DAA treatment will be considered Compensable HCV Drug Therapy as proposed by the Joint Committee;

44. The current CASL Guidelines recommend treatment for virtually all persons who are RNA positive. This would include persons who would be classified at Disease Level 1 or Disease Level 2 under the Plans and eliminate the current requirement under option D of the Medical Evidence Protocol that persons experience "some HCV disease indicator(s) in addition to a positive PCR test", ie. some disease indicators that they have progressed beyond Disease Level 2. As such, the CASL Guidelines no longer serve the purpose they were intended to serve as identifying progression from one disease stage to a higher disease stage;

45. There are no adverse financial sufficiency implications in including DAA treatment as Compensable HCV Drug Therapy in the limited manner proposed as advancement to Disease Level 3 and the payment of the $1,000 per month are already considered in the restated liabilities ordered by the Courts in August 2016;

46. The proposed amendments to the Medical Evidence court approved protocol are in the best interests of the class members and meet the criteria of being generally medically accepted as stipulated in the Plans;

47. Based on the foregoing, the Joint Committee recommends approval of treatment with DAAs as Compensable HCV Drug Therapy pursuant to s.1.01 of the Transfused HCV Plan, the Hemophiliac HCV Plan and the proposed HCV Late Claims Benefit Plan where a Treating Physician certifies the HCV Infected Person suffered adverse side effects as a result of treatment with at least one DAA treatment approved by Health Canada;

48. The Joint Committee also recommends approval of the modifications to the Protocol on Medical Evidence in the form filed in support thereof as Exhibit **R-4**;

49. Similar Joint Committee applications will be filed before the Superior court of Ontario and the Supreme court of British-Columbia.

50. The present application is well founded in facts and in law.

FOR THESE REASONS, MAY IT PLEASE THE COURT:

GRANT Petitioner's present application;

APPROVE treatment with DAAs as Compensable HCV Drug Therapy pursuant to s.1.01 of the Transfused HCV Plan, the Hemophiliac HCV Plan and the proposed HCV Late Claims Benefit Plan where a Treating Physician certifies the HCV Infected Person suffered adverse side effects as a result of treatment with at least one DAA treatment approved by Health Canada;

APPROVE the amendments to the Court Approved Protocol or Medical Evidence in the form attached hereto as Schedule A;

ORDER for such further and other relief as counsel may request and this Honourable Court may direct;

ORDER that the judgment to be rendered shall not be effective unless and until corresponding orders are made by the Supreme Court of British Columbia and the Ontario Superior Court of Justice;

THE WHOLE without costs.

Montréal, October 13, 2017

SAVONITTO & ASS. INC.
Attorneys for Petitioner

AFFIDAVIT

I, the undersigned, **MARTINE TRUDEAU**, lawyer, practicing in the law firm of Savonitto & Ass. Inc. located at 468, rue St-Jean Street, Suite 400, in the city and district of Montreal, solemnly affirm the following:

1. I assist the Member of the Joint Committee for Quebec acting as applicant for the purposes of this application;

2. All the facts alleged in this application are true.

AND I HAVE SIGNED

MARTINE TRUDEAU

Affirmed before me
In Montreal this October 13, 2017

Line Gagnon #141094
Commissioner of oaths for Quebec

Commissaire à l'assermentation
Line Gagnon
141 094
Pour le Québec

LIST OF EXHIBIT

EXHIBIT R-1 : Affidavit #17 of Heather Rumble Peterson made on October 13, 2017 including the following exhibits;

A: Revised Medical Evidence for Section 4.01(1) and Section 4.01(2) of Article 4 the Transfused HCV Plan and the Hemophiliac HCV Plan (October 2010);

B : CASL Consensus Guidelines in place from 2007 until May 2012;

C : Treating Physician Form;

D : 2012 and 2015(current) CASL Guidelines;

E : Product monograph for DAA Harvoni;

F : Product monograph for DAA H Holkira Pak;

G : Product monograph for DAA Zepatier;

H : Product monograph for DAA Epclusa;

I : Product monograph for DAA Vosevi;

J : Product monograph for DAA Maviret;

K : Health Canada Summury Safety Review-Galexos (Simeprevir) – Assessing the Potential risk of severe liver problems;

EXHIBIT R-2 : **A :** Affidavit #1 of Dr. Vincent Bain, made March 11, 2015 ;

B : Affidavit #2 of Dr. Vincent Bain, made March 31, 2016;

EXHIBIT R-3 : Affidavit #1 of Dr. Samuel S. Lee made January 26, 2016;

EXHIBIT R-4 : Revised protocol for Medical Evidence.

Montréal, October 13, 2017

Savonitto & Ass. inc.

SAVONITTO & ASS. INC.
Attorneys for Petitioner

NOTICE FOR PRESENTATION

Me Nathalie Drouin
Me Stéphane Arcelin
PROCUREUR GÉNÉRAL DU CANADA/
ATTORNEY GENERAL OF CANADA
Complexe Guy Favreau Tour Est
200, boul. René Lévesque Ouest, 5e étage
Montréal (Québec) H2Z 1X4

Me Serge Ghorayeb
BERNARD, ROY (JUSTICE-QUÉBEC)
Ministère de la Justice du Québec
Service du contentieux
1, rue Notre-Dame Est
Bureau 8.00
Montréal (Québec) H2Y 1B6

Me Mason Poplaw
Me Kim Nguyen
McCARTHY TÉTRAULT
1000, rue de la Gauchetière Ouest
Bureau 2500
Montréal (Québec) H3B 0A3

TAKE NOTICE that the present *Application from the Joint Committee for the approval of Modifications to the Protocol on Medical Evidence regarding HCV Compensable Drug Therapy* will be presented for adjudication before the Honourable Chantal Corriveau, J.C.S., at the joint hearing specifically scheduled to take place on November 22 and 23, 2017, in Toronto at a location to be determined.

DO GOVERN YOURSELVES ACCORDINGLY.

Montréal, October 13, 2017

SAVONITTO & ASS. INC.
Attorneys for Petitioner

N° : 500-06-000016-960

SUPERIOR COURT (Class Action
Province of Quebec
District of **MONTRÉAL**

DOMINIQUE HONHON

Plaintiff

-vs-

THE ATTORNEY GENERAL OF CANADA
THE ATTORNEY GENERAL OF QUEBEC
THE CANADIAN RED CROSS SOCIETY

Defendants

-and-

ME MICHEL SAVONITTO, in the capacity of the Joint Committee member for the province of Quebec

Petitioner

FONDS D'AIDE AUX RECOURS COLLECTIFS
-and-
LE CURATEUR PUBLIC DU QUÉBEC

Mis-en-cause

N° : 500-06-000068-987

SUPERIOR COURT (Class Action
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APPLICATION FROM THE JOINT COMMITTEE FOR APPROVAL OF MODIFICATIONS TO THE MEDICAL EVIDENCE COURT APPROVED PROTOCOL WITH RESPECT TO HCV COMPENSABLE DRUG THERAPY

ORIGINAL

Savonitto
468, St-Jean street, #400
Montreal (Quebec) H2Y 2S1
Tél. : 514-843-3125, #214
Fax. : 514-843-8344
email : mtrudeau@savonitto.com
Notification : notification@savonitto.com

Me Martine Trudeau
🗁 : 20475 BS2448