IMPORTANT NOTE: *This version is a translation of the original French version.*

SPORT DISPUTE RESOLUTION CENTRE OF CANADA (SDRCC)
CENTRE DE RÈGLEMENT DES DIFFÉRENDS SPORTIFS DU CANADA (CRDSC)

Nº SDRCC DT 15-0232

Doping Tribunal

Between:

Canadian Centre for Ethics in Sport (CCES)
Judo Canada

AND

Ana Laura Portuondo-Isasi

Athlete

AND

The Government of Canada
World Anti-Doping Agency (WADA)

Observers

Tribunal: Patrice Brunet (Sole Arbitrator)

Hearing dates: January 28, January 29 and February 3, 2016

Appearances

For the CCES: Annie Bourgeois, Yann Bernard and Érika Pouliot

For the Athlete: Antoine Michaud-Soret

DECISION WITH REASONS

I. INTRODUCTION

1. On May 17, 2015, Ana Laura Portuondo-Isasi (the "Athlete"), a 19-year-old judoka, participated in the Canadian Championships held in Saint-Jean-sur-Richelieu. During the competition, she was awarded the gold medal for her category (-78 kg).

2. On June 4, 2015, the Athlete was notified of an adverse analytical finding under Article 7.3.1 of the 2015 Canadian Anti-Doping Program rules (the "CADP"). The notice stated that she had committed an anti-doping violation based on the sample provided during the competition.

3. The Canadian Centre for Ethics in Sport ("CCES") certifies that the analysis of the sample provided by the Athlete revealed salbutamol concentration exceeding the threshold of 1000 ng/mL.

4. On June 25, 2015, the Athlete submitted to a controlled pharmacokinetic study reproducing the key circumstances of her salbutamol intake of May 17, 2015. This study did not produce adverse findings.

5. The Athlete is not disputing the fact that her sample analysis reveals salbutamol concentration exceeding the threshold. She recognized the violation on July 11, 2015 and accepted a provisional suspension on July 13, 2015.

6. However, she is challenging the 2-year sanction imposed by the CCES and pleads that she bears no significant fault or negligence.

7. Consequently, she is requesting a significant reduction of the ineligibility period.

II. THE PARTIES

8. Under Article 8.2.3 of the CADP: *"The parties before the Doping Tribunal are the Athlete or other Person the CCES asserts to have committed an anti-doping rule violation, the CCES and the relevant Sport Organization. The Athlete or other Person's International Federation, WADA and the Government of Canada may attend the hearing as observers if they elect to do so".*

A. CCES and Judo Canada

9. Based in Ottawa, the CCES is the national anti-doping organization responsible for adopting and enforcing anti-doping rules and regulations in Canada. It is responsible for collecting samples and managing findings from anti-doping tests across Canada. In this respect, the CCES manages the CADP.

10. Judo Canada is the national sport governing body for the sport of judo in Canada. It has overall authority to provide implement rules of conduct in the promotion and development of judo and to select and prepare Canadian teams for international competition.

B. The Athlete

11. Ana Laura Portuondo-Isasi (the "Athlete") began practising judo in 2004. She joined the Canadian judo team in 2011 at age 16. She is an elite Canadian athlete focusing mainly on international events. However, as a carded athlete, the Canadian Judo Federation requires her to participate in the Canadian Championships.

12. The Athlete ranks first in Canada in her category (-78 kg).

C. The Observers

13. Based in Montreal, the World Anti-Doping Agency ("WADA") is the international organization responsible for managing the World Anti-Doping Program which includes the World Anti-Doping Code. WADA did not take part in the hearing,

14. The Government of Canada did not attend the hearing either.

III. FACTUAL BACKGROUND

15. In 2012, the Athlete was diagnosed with asthma following a medical consultation at Charles-Lemoyne Hospital.

16. The physician prescribed two drugs to be administered as needed using an inhaler, specifically Ventolin (salbutamol) and Flovent.

17. Ventolin is a bronchodilator while Flovent is an anti-inflammatory.

18. During the hearing, the Athlete stated that she did not use Flovent because she did not like the residual taste of the product in her mouth after inhalation.

19. She also stated that she took Ventolin using an aerochamber, a device that controls mist delivery of Ventolin before it enters the patient's mouth. The aerochamber also limits the amount of medicine that ends up in the mouth, reducing the potential for side effects and maximizing drug delivery to the lungs.

20. In the latest version of the *World Anti-Doping Agency Prohibited List* and under Article 4.2.2 of the CADP, salbutamol is a Specified Substance subject to a threshold of 1000 ng/mL (or 1600 µg per day). In the World Anti-Doping Agency's Prohibited List, the excerpt pertaining to this substance states:

> *S3. BETA-2 AGONISTS*
>
> *All beta-2 agonists, including all optical isomers, e.g. d- and l- where relevant, are prohibited.*
>
> *Except:*
> - *Inhaled salbutamol (maximum 1600 micrograms over 24 hours); […]*
>
> *The presence in urine of salbutamol in excess of 1000 ng/mL or formoterol in excess of 40 ng/mL is presumed not to be an intended therapeutic use of the substance and will be considered as an Adverse Analytical Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of the therapeutic inhaled dose up to the maximum indicated above.*

21. Since January 1, 2010, a Therapeutic Use Exemption (a "TUE") is no longer required for salbutamol when taken by inhalation (WADA document entitled: *Medical Information to Support the Decisions of TUECs - Asthma*).

22. In March 2015, the Athlete was referred to Dr. Claude Poirier, pneumologist at Notre-Dame Hospital by Dr. Suzanne Leclerc, Medical Director at the Institut National du Sport ("INS") with respect to the medical tests done at the INS.

23. Dr. Poirier confirmed the asthma diagnosis of 2012 and instructed the Athlete to take salbutamol regularly, before every physical effort, be it for training or competition.

24. Dr. Poirier is familiar with anti-doping policies that elite athletes must comply with and had been informed of the Athlete's status.

25. Further to this prescription, the Athlete's pharmacist recommended inhaling two doses of salbutamol, four times per day as needed. Given that the Athlete was prescribed 100 µm per inhalation, her maximum daily dosage was 800 µm (or 2 doses, 4 times daily à 100 µm per dose).

26. This daily dose corresponds to half the threshold of 1600 µm (per 24 hours) authorized by the *World Anti-Doping Agency Prohibited List.*

27. The Athlete claims to have always taken the prescribed dosage of salbutamol and for the sole purpose of treating her asthma.

28. On May 17, 2015, the Athlete won the gold medal in her category at the 2015 Canadian Championships in Saint-Jean-sur-Richelieu. On the morning of the competition, the Athlete claims to have inhaled the usual dose of salbutamol, i.e. 4 inhalations. Although these exceed the physician's prescribed dose, they remain well below WADA's authorized daily limit.

29. The Athlete stated that she did not take salbutamol the day before the competition, i.e. May 16, 2015.

30. At the end of the competition, she underwent a doping control by the CCES. At that time, the Athlete declared on the doping control form that she was taking "Teva-salbutamol".

31. On June 4, 2015, the Athlete was notified of an adverse analytical finding. The notice stated that she had committed an anti-doping violation during the competition of May 17, 2015.

32. The certificate of analysis of the Athlete's A sample indicated a salbutamol concentration of:

> *"1.3 ± 0.2 µg/mL, U (k=2), greater than the decision limit at 1.2 µg/mL (specific gravity: 1.029)"*

33. On June 25, 2015, the Athlete underwent a controlled pharmacokinetic study, as described in the *WADA Prohibited List*.

34. The study must be conducted in a controlled environment (i.e. under medical

supervision) to ensure rigorous and independent monitoring of drug administration (route, dose, prescribed dosage, etc.) and compliance with the sample collection protocol (matrix, volume and dosage).

35. Before the administration of the substance, a washout period was defined before collecting a benchmark sample of urine or blood, i.e. the athlete does not take the substance before the test (except for health-related reasons).

36. Thereafter, the athlete takes the medication as per the treatment indicated on the doping control form.

37. Urine samples are collected when the athlete is ready, but no less than once every two hours.

38. The samples are then analyzed by a WADA-accredited laboratory using proven and compliant methods. A correction for specific gravity is applied in compliance with the International Standard for Laboratories (ISL) and related technical documentation.

39. Finally, the WADA-accredited laboratory issues a detailed report of analytical findings and their interpretation, as required.

40. The pharmacokinetic study undergone by the Athlete involved, among others, a washout period of 24 to 48 hours, inhalation observed by a physician, a waiting period equivalent to the one observed on the day the relevant sample collection, and the analysis of samples.

41. In essence, the objective of the pharmacokinetic study was to reproduce as accurately as possible the circumstances and conditions when salbutamol was taken on the day of the competition of May 17, 2015.

42. The findings from this study were the following:

    Hour 0: salbutamol in trace amounts

    Hour 2 (two hours later): salbutamol measured at 220 ± 30 ng/mL (k = 2)

Hour 4 (four hours later): salbutamol measured at 180 ± 26 ng/mL (k = 2)

Hour 6 (six hours later): salbutamol measured at 58 ± 7 ng/mL (k = 2)

43. In a letter dated July 8, 2015. Prof. Christiane Ayotte, Director of the Doping Control Laboratory at the Institut Armand-Frappier (INRS) explains that analytical findings of the four (4) samples collected on June 25, 2015, show salbutamol levels significantly lower than the threshold.

44. Prof. Ayotte indicates that a routine out-of-competition sample provided by the Athlete in May 2015 showed a salbutamol level of 216 ng/mL (specific gravity: 1.013). She cites scientific literature supporting a hypothesis that the maximum dose of salbutamol tolerated in a sample is generally exceeded when an athlete takes a dose of salbutamol of 1600 µg.

45. She concludes that she cannot, scientifically, provide a plausible and reasonable explanation to justify the Athlete's analytical finding.

46. On July 11, 2015, the Athlete voluntarily admitted to an anti-doping rule violation resulting from the presence of a salbutamol concentration exceeding the threshold and accepted a provisional suspension on July 13, 2015.

47. On July 15, 2015, the CCES agreed that if the Tribunal imposed an ineligibility period, it should begin May 17, 2015.

IV. PROCEDURAL BACKGROUND

A. Preliminary Stages

48. On July 8, 2015, the CCES issued a notification of anti-doping violation in compliance with CADP Rule 7.3.1. At paragraphs 1 and 2 of the notice, the CCES states the following facts: *"The Canadian Centre for Ethics in Sport*

(CCES) asserts that Ms. Anna Laura Portuondo-Isasi, an athlete affiliated with Judo Canada, has committed an anti-doping rule violation.
The sample giving rise to the adverse analytical finding was collected in-competition on May 17, 2015 in St-Jean-sur-Richelieu, QC, in accordance with the Doping Control Rules of the CADP. The adverse analytical finding was received by the CCES from the World Anti-Doping Agency (WADA) accredited laboratory on May 29, 2015."

49. On July 8, 2015, during an administrative meeting held by teleconference by the SDRCC, the Parties agreed that the request would proceed under the 2015 CADP Rules, as recorded in the notes of the administrative meeting by teleconference.

50. The Panel constituting the Anti-Doping Tribunal, having been duly designated and constituted in accordance with Rule 8.1.1 of the CADP, summoned the Parties to a preliminary hearing by telephone on July 13, 2015, in order to resolve outstanding procedural matters and set a procedural timetable for the hearing process. In a letter dated July 14, 2015, the SDRCC confirmed in writing the issues discussed and the procedural instructions ordered during this preliminary meeting.

51. In accordance with the directions issued by the Tribunal, the Parties were informed of the following timetable:

- August 14, 2015 at 4 p.m. (EDT): submissions of the Athlete;
- September 4, 2015 at 4 p.m. (EDT): submissions of the CCES;
- September 15, 2015 at 4 p.m. (EDT): deadline for submissions before the hearing;
- September 22, 2015 at 10 a.m. (EDT): hearing at the SDRCC office in Montreal.

52. On September 9, 2015, the Athlete requested a postponement of the hearing,

to which the CCES agreed, that would afford her enough time to complete the process of obtaining rebuttal evidence. On September 10, 2015, a second conference call took place and the following timetable was set:

- October 21, 2015 at 4 p.m. (EDT): deadline for the Athlete to file additional evidence – Expert Report;
- October 23, 2015 at 4 p.m. (EDT): CCES' confirmation of the tentative date for the hearing, or request for an additional delay;
- October 29, 2015 from 10 a.m. (EDT): tentative date for the hearing at the SDRCC office in Montreal;
- November 6, 2015 from 10 a.m. (EDT): alternative date for the hearing at the SDRCC office in Montreal.

53. The undersigned then notified the Parties that the revised date to file submissions for the hearing was:

- October 22, 2015 at 4 p.m. (EDT), if the hearing is to be on October 29, 2015;

or

- October 30, 2015 at 4 p.m. (EDT), if the hearing is to be on November 6, 2015.

54. The objective of these alternative dates was to allow the CCES to examine the counter-expertise report, the content of which was yet unknown.

55. On October 16, 2015, a third preliminary conference call was held. The Athlete requested further time to discuss matters with her lawyer before setting a date for the hearing.

56. The undersigned agreed to postpone the decision on the hearing date and convened Parties to another conference call to take place one week later in order to settle outstanding preliminary issues.

57. On October 21, 2015, a fourth preliminary conference call was held. The

Athlete indicated that she had approached an expert to obtain a toxicology report. She asked the Tribunal to postpone the deadlines until she could obtain the expert report.

58. The CCES representative raised no objections and I agreed to postpone the deadlines. Parties agreed to reconvene by conference call on November 10, 2015 for a progress update.

59. On November 10, 2015, a fifth preliminary conference call was held. The Athlete informed the Parties that an expert toxicologist had agreed to help her and to provide a report. However, she could not provide a specific date for the issuance of such report.

60. The undersigned informed the Parties that the case had already extended several months while the CADP states that generally "the hearing process shall commence no later than forty-five (45) days from the date of the CCES' notification asserting an anti-doping rule violation".

61. The undersigned also reminded the Parties that he had the authority to impose deadlines, but would prefer to avoid having to do so.

62. Instead, I invited Parties to agree no later than November 24, 2015, on a deadline for the production of the expert report, on a date for the CCES to advise if a further extension is required in order to examine the report, and on a date for the hearing.

63. On November 24, 2015, Ms. Bourgeois, counsel for the CCES, emailed to the SDRCC the dates agreed upon by the Parties.

64. On November 27, 2015, I issued the following procedural order for the timetable:

[Translation]
"Considering that the proposed timetable is acceptable, the Arbitrator acknowledges it and hereby ORDERS the following:

1) The Athlete has until January 4, 2016, to produce the expert witness' report.

2) If the CCES chooses to produce a rebuttal report, it will have until January 20, 2016, to do so.

3) The Tribunal upholds the right of the CCES to request an additional delay if, further to the examination of the rebuttal report, it requires the presence of an expert other than Prof. Christine Ayotte.

4) The in-person hearing will begin at 10 a.m. on January 28, 2016 at the office of the Sport Dispute Resolution Centre of Canada (SDRCC). "

65. On January 3, 2016, the Athlete produced the report of her expert witness, Mr. Samer Mouksassi.

66. On January 17, 2016, I emailed the following message to the Parties:

[translation]
To all Parties,

I am writing in response to the expert report of the Athlete dated January 3, 2016.

Without in any way imposing or suggesting a legal strategy to the Athlete, the Tribunal considers it possible that the Athlete's intent is to challenge the scientific validity of a WADA standard.

Over the last few days, the Tribunal conferred with the SDRCC to reflect on the applicability or non-applicability of Subsection 7.12(a) of the SDRCC Code and of Rule 3.2 of the Canadian Anti-Doping Program. The question was to determine if the Athlete, or the SDRCC on its own initiative, was obligated to inform WADA (or CAS) in a case where scientific validity is challenged.

The SDRCC contacted WADA regarding this technical issue and shares its response

with the Parties as follows:

[in English in original decision]
"As a preliminary matter, the intention of Article 3.2.1 of the Code was that it would only apply to CAS proceedings since it is the last and final instance. Consequently, WADA does not consider that Article 3.2.1 applies at the National level and, at this stage, we will not intervene in the SDRCC proceedings. WADA could, however, decide to intervene before or appeal to CAS in relation to any decision that is rendered at the National level.

[…]

In light of the above, WADA does not consider that it is necessary that we are formally notified of the athlete's challenge."

67. On January 18, 2016, Mr. Antoine Michaud-Soret notified the Tribunal by email that [translation] "the Athlete and its representatives intended to challenge the scientific validity of WADA's standard under Article 7.12 of the Code."

68. On January 20, 2016, the CCES produced a counter-expertise report prepared by Prof. Christiane Ayotte.

B. The Hearing

69. As agreed between the Parties and confirmed by procedural order issued November 27, 2015, the hearing took place in Montreal at the offices of the SDRCC, on January 28, 2016. The hearing began around 10 a.m.

70. At the beginning of the hearing, I asked the Parties if they wished to exclude the witnesses during the proceedings. Since the only witnesses present in the hearing room were the Athlete and the respective experts of the Parties, the Parties did not request to exclude the witnesses, as they were essential to the

conduct of the proceedings for both sides.

71. The Athlete and her expert, Mr. Mouksassi, testified during the first day of the hearing. Around 4:30 p.m., I adjourned the hearing to the next morning.

72. On January 29, 2016, the hearing resumed from 9:30 a.m. to noon with the testimony of the CCES' expert, Prof. Christiane Ayotte. Around noon, I adjourned the hearing to February 3, 2016.

73. On February 3, 2016, the hearing resumed at 9:30 a.m. at the offices of the SDRCC. Each Party presented its oral submissions. The hearing concluded around noon.

C. Short Decision

74. On February 8, 2016, I issued a short decision in writing, concluding in particular the following:

> [Translation]
> *[…]*
>
> *She [the Athlete] was unable to demonstrate, on a balance of probabilities, how salbutamol was found in her body in a concentration in excess of 1000 ng/mL.*
>
> *[…]*
>
> *The burden of proof rested on the Athlete to demonstrate how the Specified Substance entered her body in quantities exceeding the prescribed threshold. She did not discharge herself of that burden.*
>
> *[…]*
>
> *In accordance with Article 10.5.1.1 [of the CADP], I could not proceed to an analysis of no significant fault or negligence. Accordingly, it is not possible to*

reduce the 2-year ineligibility period prescribed under Article 10.2.2 of the CADP;

[…]

CONSEQUENTLY, Ana Laura Portuondo-Isasi is declared ineligible for a period of two (2) years, effective retroactively from May 17, 2015 until midnight on May 16, 2017.

V. JURISDICTION

75. The Sport Dispute Resolution Centre of Canada (SDRCC) was created by Federal Bill C-12, on March 19, 2003[1].

76. Under this Act, the SDRCC has exclusive jurisdiction to provide to the sport community, among others, a national alternative dispute resolution service for sport disputes.

77. In 2004, the SDRCC assumed responsibility for doping disputes in Canada.

78. All Parties have agreed to acknowledge the SDRCC's jurisdiction in the present matter.

VI. SUBMISSIONS

79. This section summarizes the oral and written submissions of the Parties, including expert testimonies. Although this is not a detailed record, I carefully examined all submissions presented by the Parties.

[1] The *Physical Activity and Sport Act*, S.C. 2003, c. 2

A. The Athlete

Submissions of the Athlete

80. The Athlete is requesting a significant reduction of the imposed two-year (2) ineligibility period.

81. Firstly, she submits that the current method used to analyze the collected urine samples and to calculate salbutamol concentrations in the urine of athletes, as required by WADA and applied by the CCES, is not scientifically valid.

82. In fact, the Athlete argues that the current method should be modified to include a correction for specific gravity for each athlete.

83. According to her, if the anti-doping sample collected during the relevant competition had been corrected for urine specific gravity, the resulting value would have been 0.9 µg/mL instead of 1.3 µg/mL given her state of dehydration.

84. Consequently, the finding would fall below the 1000 ng/mL threshold after correcting for specific gravity, whereby she would not have been in violation of anti-doping rules.

85. The Athlete further submits that, on a balance of probabilities, she bears "no significant fault or negligence" under Article 10.5.1.1 and Appendix 1 of the CADP.

86. The Athlete claims to have always taken salbutamol as recommended by a qualified specialist and for the sole purpose of treating her asthma.

87. In fact, the Athlete consulted Dr. Claude Poirier in March 2015 upon referral from Dr. Suzanne Leclerc. Dr. Poirier is a pneumologist at Notre-Dame Hospital.

88. The Athlete specified that Dr. Poirier was informed of her status as an elite athlete and that he recommended taking salbutamol regularly, i.e. before every physical effort in order to treat her asthma. Accordingly, she had no other choice but to follow these instructions so as to not compromise her health.

89. Given that a TUE is no longer required for inhaled salbutamol, she argues that she could not reasonably take other measures or additional precautions, other than those provided by Dr. Poirier.

90. In support of her defence, the Athlete also submits the following elements:

- She derived no benefit from refusing to comply with Dr. Poirier's and/or her pharmacist's medical directives during the Canadian Championships, since she was already part of the national team.

- She uses her inhaler for health-related reasons, and not to enhance her performances.

- She did not make prohibited use of her inhaler, considering that WADA authorizes a salbutamol intake up to 1600 µm per 24-hour period.

- She had previously submitted to anti-doping tests which were all negative.

- She regularly declared using Ventolin (trademark) or salbutamol (generic name) on the doping control form of the various tests to which she submitted during her budding career, including at the Canadian Championships on May 17, 2015.

- In addition, she only slightly exceeded the salbutamol threshold. On that point, she cites *Filippo Volandri* vs. *International Tennis Federation*, Arbitration CAS 2009/A/1782.

91. During the hearing, the Athlete described the sequence of events on May 17, 2015 which can be summarized as follows:

- The day before the Canadian Championships, she did not take salbutamol.
- On the morning of the competition, around 9:45 a.m., she took her usual dose of salbutamol, i.e. two inhalations taken twice, for a total of four (4) inhalations of 100 µm (for a total inhalation of 400 µm).
- Around 4:30 p.m., the Athlete was preparing to compete in the finals for her category (-78 kg). She did not feel the need to use the inhaler again because she was feeling fine.
- She won the finals and was awarded the gold medal.
- The Athlete testified that she was dehydrated during the competition. It was very warm and she found it difficult to urinate for the doping control to which she submitted after the competition.

92. According to the Athlete, her state of dehydration on the day of the competition largely accounts for the fact that she exceeded the 1000 ng/mL threshold.

93. The Athlete further explains that dehydration influences the specific gravity of a person's urine, which significantly impacts urine concentrations of salbutamol.

94. According to her, it is plausible to have reached 1300 ng/mL with an intake of 400 µm of salbutamol.

95. In essence, the Athlete submits that [translation] “based on a balance of probabilities, she inhaled four (4) puffs corresponding to a dose of 400 µm and, given her urinary gravity at the time of sample collection, the value of

the salbutamol in the sample under dispute exceeded the 1000 ng/mL threshold."

96. According to her, this explains how salbutamol was found in her body at a concentration exceeding the prescribed threshold of 1000 ng/mL.

97. During her testimony, the Athlete also argued that the protocol of the controlled pharmacokinetic study of June 25, 2015 did not correctly reproduce the existing conditions on the day of the competition.

98. She explained that during the pharmacokinetic study, she had a concussion, did not have time to warm up and drank large quantities of water in order to urinate, which diluted the collected samples.

Testimony of the Athlete's Expert, Mr. Samer Mouksassi

99. Mr. Mouksassi earned his Ph.D. in pharmaceutical sciences from Université de Montréal in 2012. Previously, he graduated with a Masters in Biological and Medical Sciences from Saint-Joseph University in Beirut, Lebanon, in 2003.

100. He has been active in the field of drug analysis for the past fifteen (15) years. Most of his customers are pharmaceutical companies.

101. Mr. Mouksassi is currently "Director, Pharmacometrics" at Pharsight Consulting Services, a firm where he has been working since June 2007.

102. Mr. Mouksassi was previously a hospital clinical pharmacist.

103. At Pharsight, he helps companies improve their pharmacokinetic and pharmacodynamic studies on various drugs. He also studies appropriate dosages for patients.

104. Mr. Mouksassi is very familiar with salbutamol and knows it as a beta-agonist. He is particularly interested in the bio-equivalence of this substance.

105. However, Mr. Mouksassi recognized that he had never studied salbutamol in the context of doping.

106. This is his first time testifying and producing an expert report in a doping case. In addition, he has never been trained in anti-doping rules.

107. Although Mr. Mouksassi has published dozens of scientific articles on various drugs during his career, he never published an article on the effects of substances with respect to doping.

108. During his testimony, Mr. Mouksassi described the method he followed to analyze the Athlete's case. After establishing the sequence of event, he reviewed the findings of the INRS laboratory. He then reviewed the scientific literature on the subject, including cases from the US Food and Drug Administration (the "FDA").

109. Mr. Mouksassi explained his report dated December 31, 2015, in which he concludes, among other things, that findings of 1.3 ± 0.2 µg/mL (k = 2) are 95% likely to fall within the confidence interval [1.1-1.5 µg/mL]. According to him, there is a 24.28% chance that an average salbutamol reading of 1.3 µg/mL actually falls below the 1.2 µg/mL threshold.

110. The Athlete's expert also pointed out the importance of accounting for urine specific gravity (urine concentration).

111. In fact, he said that urine concentrations of salbutamol can vary significantly between individuals. In other words, all bodies react differently to salbutamol intake. On that point, he cited the Sporer study[2].

[2] Benjamin C. **Sporer**, A. William Sheel, and Donald C. McKenzie, *Dose Response of Inhaled salbutamol on Exercise Performance and Urine Concentrations*, Official Journal of the American College of Sports Medicine, 2007

112. He explained that an individual's specific gravity will usually range from 1.020 to 1.030, while 1.020 can be considered a “normal specific gravity”.

113. The higher the specific gravity, the more concentrated is an individual's urine. The lower the specific gravity, the more diluted is an individual's urine.

114. On the day of the competition, the Athlete showed a specific gravity of 1.029, which, according to him, is significant and demonstrates that the Athlete was very dehydrated.

115. Mr. Mouksassi testified that the maximum specific gravity that he had ever observed was of 1.031, a value indicative of a state of extreme dehydration.

116. In his opinion, the Athlete’s specific gravity on the day of the competition should have been taken into account and the value should have been corrected accordingly (value: 1.3 µg/mL).

117. Based on his calculations, if the value had been corrected for specific gravity, findings for the Athlete would have been at 0.9 µg/mL instead of 1.3 µg/mL.

118. He found it surprising that WADA’s standards do not factor in the specific gravity of athletes. As an expert, he found it strange that such correction is not applied when analyzing urine samples.

119. In his opinion, a gravity correction factor is required in order to differentiate an excessive intake of salbutamol from a state of dehydration on the part of an athlete. He stated that it was unclear at what point a 1.2 µg/mL threshold unadjusted for specific gravity could differentiate a doped athlete from a dehydrated athlete who complied with the maximum dosage prescribed by his or her physician.

120. During his testimony, Mr. Mouksassi also argued that the pharmacokinetic study of June 25, 2015 did not succeed in reproducing the existing conditions

of the day of the competition. Among others, the Athlete was not significantly dehydrated during the pharmacokinetic study.

121. In addition, he submits that the findings of the study reflect the situation only partially because samples were collected over too short a period (6 hours in the present case).

122. To support this opinion, Mr. Mouksassi cited the Schweizer study[3] which extended over a 43-hour period and showed that the highest urine concentrations of salbutamol were observed at hours 12 and 34 of the study.

123. In his opinion, if samples had been collected over a longer period (48 hours for example), one might have "observed certain things".

124. Mr. Mouksassi also explained that when an individual inhales salbutamol, he also swallows a certain quantity of product which makes its way through the digestive system. Because the drug is metabolized in the digestive system, it can be found in urine after a longer period of time. For this reason, the monitoring period should have been longer than six (6) hours.

125. Finally, Mr. Mouksassi believes it is possible to reach a 1.3 µg/mL urine concentration of salbutamol without making prohibited use of the inhaler under WADA's standards, especially without any correction for specific gravity.

126. In his opinion, this phenomenon has previously been observed in other individuals. To support this claim, Mr. Mouksassi cites the aforementioned Schweizer study.

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[3] Carine **Schweizer**, MSC, Martial Saugy, PhD, and Matthias Kamber, PhD, *Doping Test Reveals High Concentrations of salbutamol in a Swiss Track and Field Athlete*, Clin J Sport Med, Volume 14, Number 5, September 2004.

B. Observations of the CCES

Submissions of the CCES

127. The CCES submits that the violation of the 2015 CADP by the Athlete has been admitted and that the conditions for the application of Rule 10.5.1.1 of the CADP and of the definition of "no significant fault or negligence" under Appendix 1 of the CADP to obtain a sanction reduction have not been fulfilled. According to the CCES, the two-year period of ineligibility is the appropriate sanction under the circumstances.

128. According to the CCES, the Athlete cannot obtain a reduced sanction because she failed to prove, on a balance of probabilities, that she bears "no significant fault or negligence". In this case, the Athlete did not discharge herself of the burden of proof as a condition for bringing the Arbitrator to reduce her ineligibility period.

129. Firstly, the Athlete has not demonstrate, on a balance of probabilities, how salbutamol reached concentration in excess of 1000 ng/mL in her body. As a result, the CCES submits that the Arbitrator cannot assess the Athlete's degree of fault to determine if there are grounds to grant a sanction reduction.

130. Citing decision *CCES and Alicia Brown*, SDRCC DAT 15-0006, the CCES submits that the Athlete must first demonstrate how the prohibited substance entered her body. The Athlete must prove a single theory of ingestion and cannot put forward several hypotheses to explain how the substance entered her body.

131. A concentration of salbutamol in excess of 1000 ng/mL in an athlete's urine is presumed to be an Adverse Analytical Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of the therapeutic dosage by inhalation, up to the maximum dose (1600 µm).

132. According to the CCES, the Athlete's claim that she complied with the prescribed dosage does not explain how she exceeded the salbutamol concentration threshold.

133. The controlled pharmacokinetic study undergone by the Athlete on June 25, 2015 did not demonstrate that the adverse finding of May 17, 2015 were a consequence of the use of a therapeutic dose by inhalation.

134. The CCES also submits that the Athlete did not put forth any valid hypothesis that could justify contaminated findings. In fact, it is not sufficient for the Athlete to claim that she does not know how the substance entered her body, given that she is responsible for anything that is found in it.

135. Citing decisions *Flavia Oliviera v. United States Anti-Doping Agency*, CAS 2010A/12107, and *CCES and Alicia Brown*, SDRCC DAT 15-0006, the CCES points out that case law requires the Athlete to provide a plausible explanation, credible on a balance of probabilities, rather than mere speculations as to how the substance entered her body.

136. In this case, the Athlete by her own admission could not explain how a concentration of salbutamol exceeding 1000 ng/mL was found in her body. She claimed to have inhaled only 400 µm of salbutamol on the day of the competition, which is not consistent with the findings.

137. Moreover, the CCES argues that the Athlete did not demonstrate that her actions bore “no significant fault or negligence”.

138. Firstly, because the Athlete failed to meet the precondition of proving how the prohibited substance entered her body, the CCES submits that the Tribunal does not need to make a determination on “no significant fault or negligence”.

139. Moreover, it is not possible for the Tribunal to assess the Athlete’s degree of fault since the Athlete did not produce a plausible hypothesis to support

how salbutamol entered her body. The Tribunal simply does not have sufficient information on the events to analyze this criterion.

140. Alternatively, should the Tribunal conclude that the Athlete did demonstrate how the prohibited substance entered her body, the CCES submits that the Athlete did not prove on a balance of probabilities that she bears "no significant fault or negligence" as a condition for reducing the 2-year sanction.

141. The CCES submits that the Athlete did not conduct herself in a manner free of "significant fault or negligence" given that she is a world-class athlete with a certain knowledge of anti-doping. In fact, evidence on record strongly suggest inadequate use of her inhaler by the Athlete.

142. Furthermore, the Athlete does not produce evidence to the contrary, in order to rule out the probability that she may have inhaled significantly more salbutamol than prescribed by her physician. In this case, only a significant fault or negligence on the part of the Athlete could account for the huge difference between her alleged intake of salbutamol and the salbutamol concentration in the urine sample.

143. The Athlete failed to comply with her obligation to take the necessary precautions in making adequate use of her inhaler.

144. Citing decisions *Volandri v. ITF, WADA v. Després, CCES & Bobsleigh Canada Skeleton v. Chris Korol,* and *CCES and Amanda Galle*, the CCES explains that athletes are responsible for ensuring they do not ingest prohibited substances and that the burden to prove no fault or negligence is heavy. Tribunals expect athletes to exercise the utmost care in this matter.

145. Inferences drawn from the evidence can only lead to the conclusion that such cases are limited to truly exceptional circumstances, an occurrence which has not been demonstrated in this case.

146. According to the CCES, “no fault or negligence” cases are limited to truly exceptional circumstances and do not apply in the vast majority of cases.

147. With respect to the analytical method that is being challenged under Subsection 7.12(a) of the SDRCC Code, the CCES submits that once the Athlete admits to a violation, she cannot withdraw an admission, especially more than six (6) months after the admission.

148. Consequently, the CCES submits that all evidence on record pertaining to the validity of WADA’s analytical method should be disregarded by this Tribunal.

149. Alternatively, to the extent that the Tribunal is not of the same opinion, the CCES submits that the evidence on file clearly demonstrates that the analytical method adopted by WADA (i.e. the pharmacokinetic study) to help exonerate an athlete is valid and confirms that the Athlete violated anti-doping rules.

150. According to the CCES, the Tribunal should accept Prof. Ayotte’s testimony on this matter because it is more convincing/compelling than that of the Athlete’s expert, Mr. Mouksassi.

151. In essence, the CCES submits that evidence on file (Athlete’s previous findings, pharmacokinetic study and scientific literature) clearly demonstrates that the pharmacokinetic analytical method adopted by WADA is scientifically valid and is not prejudicial to the Athlete.

152. Finally, the CCES believes that the Athlete did not demonstrate on a balance of probabilities that WADA’s analytical method was inadequate under Article 3.2.1 of the CADP and Subsection 7.12(a) of the SDRCC Code.

Testimony of the CCES Expert, Prof. Christiane Ayotte

153. Prof. Ayotte earned her Ph.D. in organic chemistry from Université de Montréal in 1983. She also completed post-doctoral studies in mass spectrometry.

154. She is currently employed by INRS – Institut Armand-Frappier in the capacity of Professor and Director of the Doping Control Laboratory.

155. The INRS Doping Control Laboratory is accredited by the World Anti-Doping Agency (WADA).

156. INRS – Institut Armand-Frappier analyzes some 25,000 samples annually for the presence of hundreds of prohibited substances and methods.

157. Prof. Ayotte is also a member of several committees and scientific groups, including the International Olympic Committee (IOC) and WADA. For example, Prof. Ayotte is or has been a member of the following WADA groups: Health, Medical and Research Committee Laboratory Expert Group and Prohibited List Expert Group which is responsible for providing expert advice, recommendations and guidance to the Health, Medical and Research Committee on the overall publication, management and maintenance of its annual International Standard of the Prohibited List (the List of Prohibited Substances and Methods).

158. During her career, Prof. Ayotte also served as witness before several courts, including the Court of Arbitration for Sport ("CAS") and well as local tribunals.

159. Although the CCES is a customer of INRS, Prof. Ayotte confirmed that she is an independent witness and employee of the Ministère de l'Éducation du Québec.

160. On that point, Prof. Ayotte underscored that she occasionally defends athletes (for example, she defended Australian swimmer Ian Thorpe because

she considered the findings scientifically untenable).

161. During her career, she also published several dozen scientific studies on doping, although none related to salbutamol.

162. I have no doubt that Prof. Ayotte has considerable experience and a vast expertise in matters of doping, most certainly among the foremost in the world.

163. During her testimony, Prof. Ayotte confirmed issuing three (3) expert reports on the case at hand. A first report was issued on July 8, 2015, another on November 25, 2015 and a third on January 20, 2016.

164. When the Athlete's sample labelled # 2953745A tested positive, her laboratory contacted the Athlete to confirm if she could provide explanations. She received a summary of the medical prescription indicating two doses of salbutamol at 100 µg as well as information suggesting inhalation on the morning of the competition which could explain the finding.

165. Based on her expertise and on scientific literature, she is of the opinion that this type of inhalation cannot explain why the sample tested positive on the laboratory's certificate of analysis.

166. She further examined the Athlete's previous samples in search of unusual findings. For example, on March 31, 2015, the Athlete tested at 216 ng/mL with a specific gravity of 1.025, a result that could still not explain why she tested positive at 1300 ng/mL.

167. The next step taken was to conduct a controlled pharmacokinetic study, also called a follow-up analysis.

168. Prof. Ayotte specified that the peak salbutamol concentration during the follow-up analysis of June 25, 2015, reached 220 ng/mL.

169. When questioned on whether a urine specific gravity of 1.029 was exceptional, she stated that it was not and indicated that she occasionally observed corrections of 1.035 and even 1.040.

170. In her opinion, a specific gravity of 1.029 cannot be considered abnormal.

171. Prof. Ayotte then discussed the application of a correction factor to account for urine specific gravity. According to her, even if she had applied a higher correction factor to the findings from the pharmacokinetic study, the highest adjusted result would have been 624 ng/mL, which is well below the 1000 ng/mL threshold and the 1200 ng/mL decision limit. In any case, the rules do not provide for a specific gravity correction because it is already factored into the 1000 ng/mL threshold.

172. As a subject-matter expert, Prof. Ayotte concludes that the results from the pharmacokinetic study cannot explain the Athlete's 1300 ng/mL finding. In addition, the Athlete's B sample (sample # 2953745B) confirmed the finding of A sample (# 2953745A).

173. Prof. Ayotte explained that salbutamol is an exogenous substance, i.e. a substance that is not produced naturally in the body.

174. She further explained that salbutamol was banned in the late 1980's and that it could be taken by inhalation but also orally.

175. She acknowledged that the effect of inhaled salbutamol does not improve an athlete's performance.

176. However, according to Prof. Ayotte, scientific studies showed that an oral formulation of salbutamol could have anabolic effects, and therefore could improve performance. This is why WADA included salbutamol in the Prohibited List, at this high quantity.

177. In her opinion, she could not conclude whether the Athlete took salbutamol orally or by inhalation, for lack of means to determine the route

of administration. In any case, she is of the opinion that the burden of proof does not rest on the CCES.

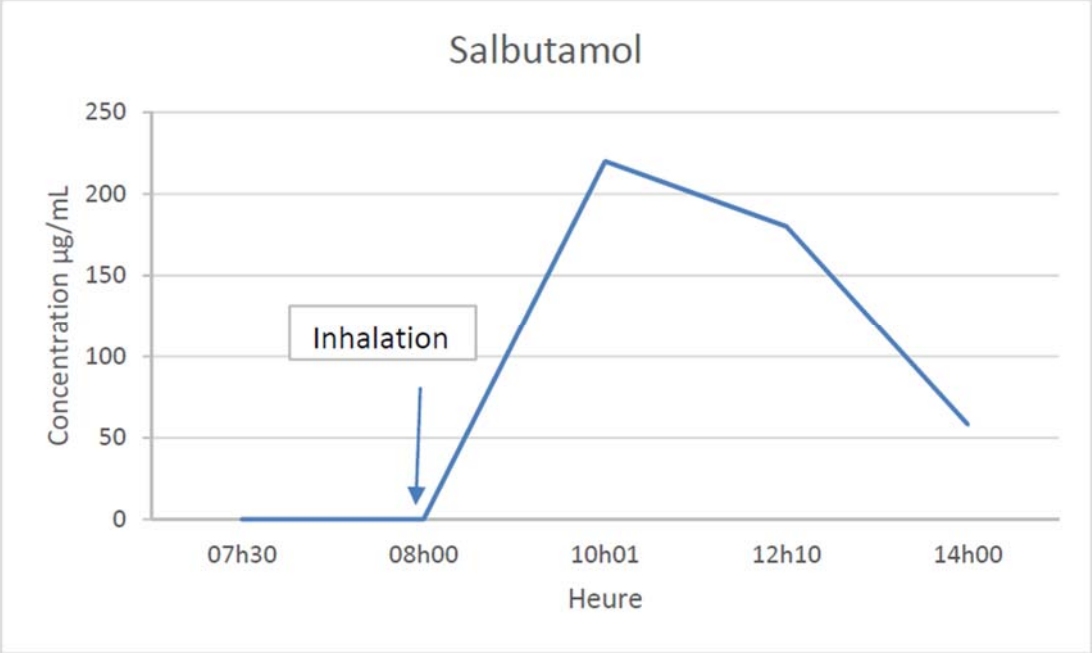
178. When questioned on the reasons that motivated a 1000 ng/mL threshold, Prof. Ayotte explained there was a consensus among the scientific community on this matter and that the purpose of the threshold is to differentiate individuals who make therapeutic use of inhaled salbutamol from those who take it orally. According to her, 1000 ng/mL is a reasonable threshold in this case.

179. She also indicated that results and observations from the Schweizer study were considered when determining such threshold.

180. According to her, the only instance where salbutamol concentration can exceed the 1000 ng/mL threshold is by taking a single and very high dose of the substance (i.e. over 1600 µg), as demonstrated in the Sporer study.

181. In her opinion, a pharmacokinetic test spanning six (6) hours gives plenty of time to draw scientifically sound conclusions.

182. According to her, and based on the scientific literature, it is possible to establish a representative excretion profile over a six (6) hour period. Consequently, the chart on page 4 of her expert report dated January 20, 2016 is quite reasonable. This chart is shown below:



183. To support this argument, Prof. Ayotte cites in particular the Haase[4] study which reports peak urine concentration of salbutamol at hour 4, followed by a decrease in concentration.

184. In the Schweizer study, Prof. Ayotte noted that monitoring of the subject was suspended at hour 8 and that the results of that study were never reproduced afterwards in the scientific literature. In her opinion, the analytical methods leading to these results are questionable firstly because the study was not controlled, and secondly because the athlete was subject to a suspension which may be a motive to produce adverse findings.

185. During her cross-examination, Prof. Ayotte specified that WADA factored in specific gravity when determining the 1000 ng/mL threshold.

186. For this reason, it is not permitted by WADA to apply a correction for

[4] Christoffer Bjerre **HAASE,** Vibeke Backer, Anders Kalsen, Sebastian Rzeppa, Peter Hemmersbach and Morten Hostrup, *The influence of exercise and dehydration on the urine concentrations of salbutamol after inhaled administration of 1600 µg salbutamol as a single dose in relation to doping analysis*, Drug Testing and Analysis (2015).

specific gravity.

187. In addition, she specified that the threshold should probably be lowered to 500 ng/mL if WADA decided to account for specific gravity.

188. Prof. Ayotte confirmed that the pharmacokinetic study reproduced the conditions when the Athlete obtained an adverse finding on the day of the competition. For example, the first dose was administered at around 9:45 a.m. and a sample was collected 6 hours later. In her opinion, the test was scientifically sound and was not unfair.

189. In her experience, athletes rarely exceed the decision limit of 1200 ng/mL.

190. For example, she explained that 200,000 samples were collected in 2013, both in and out of competition in the world, and only eleven (11) samples tested positive for salbutamol. In 2014, there were eight (8) samples out of 200,000 that were positive for salbutamol.

191. At her INRS laboratory, there were fewer than ten (10) cases in twelve (12) years.

192. In the interest of transparency, Prof. Ayotte declared that immediately after establishing the Athlete's adverse finding, her laboratory received another sample that tested positive for salbutamol at 1.9 µg/mL with a specific gravity of 1.036-1.037.

193. The explanation of that athlete to the laboratory was that he had inhaled "five times 2 or 3 puffs" before the game. Therefore the athlete claimed to have taken between 1300 and 1500 µg of salbutamol in a very short timeframe.

194. Prof. Ayotte determined that the athlete's explanations were reasonable and that athlete was not charged with doping.

195. When asked if there were other methods that could shed light on this

matter, Prof. Ayotte confirmed that there were none. According to her, the follow-up study, the scientific literature and the first test provide an accurate picture of the situation.

196. Moreover, the follow-up study alone cannot be conclusive without the first finding. It is the combination of both tests that is conclusive.

197. Finally, Prof. Ayotte explained the difference between a *decision limit* and a *threshold*. The threshold is 1.0 µg/mL while the decision limit is 1.2 µg/mL. For example, a value of 1.1 µg/mL would not constitute an adverse finding. The Athlete would not even be notified. Therefore, the Athlete's expert should have based his demonstration on the *threshold value* rather than the *decision limit* in his expert report dated December 31, 2015.

VII. APPLICABLE RULES

Canadian Anti-Doping Program (CADP)

198. The CADP is largely based on WADA's World Anti-Doping Code.

199. Under Article 1.3 of the CADP, Athletes and other Persons accept the CADP as a condition of participating in sport and shall be bound by the rules contained in the World Anti-Doping Code and the CADP.

200. An athlete is defined in the CADP definitions (Appendix 1) as someone who competes in sport at the international level or the national level. Ms. Portuondo-Isasi is an individual who fits this description, therefore she is bound by the CADP and there were no objections to this effect.

201. The following provisions of the 2015 CADP anti-doping rules are particularly relevant to the present proceedings. It should be noted that these provisions are repeated, almost word for word, in WADA's World Anti-Doping Code:

2.1 Presence of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample

2.1.1 It is each Athlete's personal duty to ensure that no Prohibited Substance enters his or her body. Athletes are responsible for any Prohibited Substance or its Metabolites or Markers found to be present in their Samples. Accordingly, it is not necessary that intent, Fault, negligence or knowing Use on the Athlete's part be demonstrated in order to establish an anti-doping rule violation under Rule 2.1.

[…]

10.2.1 The period of Ineligibility shall be four years where:

10.2.1.1 The anti-doping rule violation does not involve a Specified Substance, unless the Athlete or other Person can establish that the anti-doping rule violation was not intentional.
10.2.1.2. The anti-doping rule violation involves a Specified Substance and CCES can establish that the anti-doping rule violation was intentional.

10.2.2 If Rule 10.2.1 does not apply, the period of Ineligibility shall be two years.

(underline added)

[…]

10.5 Reduction of the Period of Ineligibility based on No Significant Fault or Negligence

10.5.1 Reduction of Sanctions for Specified Substances or Contaminated Products for Violations of Rule 2.1, 2.2 or 2.6.

10.5.1.1 Specified Substances
Where the anti-doping rule violation involves a Specified Substance, and the Athlete or other Person can establish No Significant Fault or Negligence, then the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and at a maximum, two years of Ineligibility, depending on the Athlete's or other Person's degree of Fault.

10.5.1.2 Contaminated Products
In cases where the Athlete or other Person can establish No Significant Fault or Negligence and that the detected Prohibited Substance came from a Contaminated Product, then the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and at a maximum, two years Ineligibility, depending on the Athlete's or other Person's degree of Fault.
[…]

APPENDIX 1 DEFINITIONS

> ***No Fault or Negligence:*** *The Athlete or other Person's establishing that he or she did not know or suspect, and could not reasonably have known or suspected even with the exercise of utmost caution, that he or she had Used or been administered the Prohibited Substance or Prohibited Method or otherwise violated an anti-doping rule. Except in the case of a Minor, for any violation of Rule 2.1, the Athlete must also establish how the Prohibited Substance entered his or her system.*
>
> ***No Significant Fault or Negligence:*** *The Athlete or other Person's establishing that his or her Fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the anti-doping rule violation. Except in the case of a Minor, for any violation of Rule 2.1, the Athlete must also establish how the Prohibited Substance entered his or her system.*
>
> *(underline added)*

World Anti-Doping Code and other WADA documents

202. Articles 2.1, 10.2 and 10.5 as well as Appendix 1 of the CADP are largely based on articles 2.1, 10.2 and 10.5 and Appendix 1 of WADA's World Anti-Doping Code.

203. WADA's Code is also complemented by the International Standards, which include WADA's *Prohibited List*.

204. *WADA's 2015 Prohibited List* includes the following provision regarding salbutamol:

> *S3. BETA-2 AGONISTS*
>
> *All beta-2 agonists, including all optical isomers, e.g. d- and l- where relevant, are prohibited.*
>
> *Except:*
> - *Inhaled salbutamol (maximum 1600 micrograms over 24 hours); […]*
>
> *[…]*

> *The presence in urine of salbutamol in excess of 1000 ng/mL or formoterol in excess of 40 ng/mL is presumed not to be an intended therapeutic use of the substance and will be considered as an Adverse Analytical Finding (AAF) unless the Athlete proves, through a controlled pharmacokinetic study, that the abnormal result was the consequence of the use of the therapeutic inhaled dose up to the maximum indicated above.*

205. In 2015, WADA also published version 5.1 of its information sheet entitled *Medical Information to Support the Decisions of TUECs - Asthma*. This document presents detailed information on asthma and includes the following statement:

> *"Since January 01, 2010, salbutamol and salmeterol, when taken by inhalation and in therapeutic doses, were removed from the Prohibited List. Hence, a TUE [Therapeutic Use Exemption] is no longer required. "*
>
> (Page 1 of the document)
>
> […]
>
> *"**Inhaled** salbutamol is no longer prohibited. However, the presence of salbutamol in the urine in excess of 1000 ng/mL is presumed not to be a therapeutic use of the substance and will be considered as an adverse analytical finding. The athlete would then need to document the details of his/her, medical condition and medication use. <u>The athlete may then be required to prove, by a controlled pharmacokinetic study (see annex 2) that the abnormal test result was the consequence of the use of a therapeutic dose (maximum 1600 micrograms over 24 hours) of inhaled salbutamol.</u> "*
>
> (underline added)

206. Annex 2 of this document describes the key guiding principles for a controlled excretion study (also called a *controlled pharmacokinetic study* or *follow-up analysis*).

<u>Canadian Sport Dispute Resolution Code (SDRCC Code)</u>

207. Subsection 7.12(a) of the SDRCC Code is important in this case because the Athlete is challenging the scientific validity of the method currently used to analyze the collected urine samples and to calculate the salbutamol

concentration in the urine of athletes, as required by WADA and applied by the CCES.

208. This article states:

> ***7.12 Methods of Establishing Facts and Presumptions***
>
> *Facts related to anti-doping rule violations may be established by any reliable means, including admissions. The following rules of proof shall be applicable for hearings before the Doping Dispute Panel pursuant to Rule 3.2 of the Anti-Doping Program:*
>
> *(a) Analytical methods or decision limits approved by WADA after consultation within the relevant scientific community and which have been the subject of peer review <u>are presumed to be scientifically valid</u>. Any Person seeking to rebut this presumption of scientific validity shall, as a condition precedent to any such challenge, first notify WADA of the challenge and the basis of the challenge. The CAS, on its own initiative may also inform WADA of any such challenge. At WADA's request, the CAS shall appoint an appropriate scientific expert to assist the Panel in its evaluation of the challenge. Within ten (10) days of WADA's receipt of such notice, and WADA's receipt of the CAS file, WADA shall also have the right to intervene as a Party, appear amicus curiae, or otherwise provide evidence in such proceeding.*
>
> (underline added)

209. It should be noted that article 3.2.1 of the CADP is virtually identical to subsection 7.12(a) of the SDRCC Code.

210. As stated above, the SDRCC consulted WADA on the interpretation of Subsection 7.12(a), specifically to clarify matters regarding the CAS notification to WADA in cases where scientific validity is challenged. WADA responded that the SDRCC was not required to issue a notice, in which case the undersigned considers that this matter need not be addressed any further.

VIII. <u>RELEVANT SCIENTIFIC LITERATURE</u>

211. During the hearing, certain doping-related and salbutamol-related studies

in the scientific literature were discussed.

212. Consequently, I find it important to set the context of the analysis by summarizing the scientific studies that were discussed in this case.

213. I will also briefly describe their interpretation by the expert witnesses.

Sporer Study[5]

214. The purpose of this study published in 2007 was to determine the effects of inhaled salbutamol on time-trial cyclists' performance and their urine concentrations of salbutamol.

215. Study participants were: (1) male; (2) either cyclists or triathletes; (3) nonasthmatic.

216. Participants inhaled various doses of salbutamol, as follows: placebo, 200 μg, 400 μg or 800 μg.

217. Results led the authors to observe that urine concentration of salbutamol increased with dosage and was highly variable, with the peak value observed being 831 ng/mL after a dose of 800 μg.

218. Shortly before stating their conclusions, the authors specified the following on page 156 of their report:

> "Currently, in international sport, any urine sample containing more than 1000 $ng \cdot mL^{-1}$ of SAL [inhaled salbutamol] is considered an adverse analytical finding by WADA. Even after four times the recommended therapeutic dose, none of the subjects in this study exceeded the limit. That said, several subjects did exceed values previously reported in the literature, both at rest and after exercise (23, 34). Additionally, Schweizer and colleagues (27) have reported an in-competition measurement of 8000 $ng \cdot mL^{-1}$ in a male athlete with a TUE [Therapeutic Use Exemption], and they were able to reproduce

[5] See footnote 2 for the full reference.

> this positive test in a non-exercising trial after a dose of 900 µg administered during 5 h.
>
> Although values exceeding the WADA limit are plausible, our data would suggest that they are not the norm, even after multiple doses. Recent changes by WADA, providing the opportunity for an athlete with a TUE that has exceeded this limit to prove that values were the result of therapeutic use of inhaled salbutamol, seem appropriate. ”
>
> (underline added)

219. The authors drew the following conclusions on page 149:

> “These findings suggest that inhaled SAL does not enhance time-trial performance, regardless of dose, and that urine cSAL [concentration of salbutamol in the urine] after exercise is related to dose, demonstrates high variability, and is partially related to hydration status.”
>
> (underline added)

220. According to the Athlete’s expert, this study corroborates the arguments presented in his expert testimony and report.

221. In his opinion, the Sporer study results show a dose-dependent effect on urine concentrations of inhaled salbutamol and that results vary considerably from one individual to the other.

222. In addition, authors state that this variability may be related to the dehydration status, which supports the hypothesis that the Athlete’s findings were influenced by her intense state of dehydration on the day of the competition.

223. Finally, Mr. Mouksassi reiterated that the study demonstrated that inhaled salbutamol did not enhance the performance of participants, regardless of the dose inhaled.

224. As for Prof. Ayotte, she emphasized the following excerpts of the Sporer study:

"Even after four times the recommended therapeutic dose [i.e. 800 µg], none of the subjects in this study exceeded the limit" (page 156).

"Urine concentrations of SAL after exercise at 1 h after inhalation increased with dose and were highly variable, although no subjects exceeded the WADA cutoff of 1000 ng·mL^{-1}" (page 153).

225. She also drew attention to Figure 5 on page 153 of the study, which I feel is relevant to reproduce below:

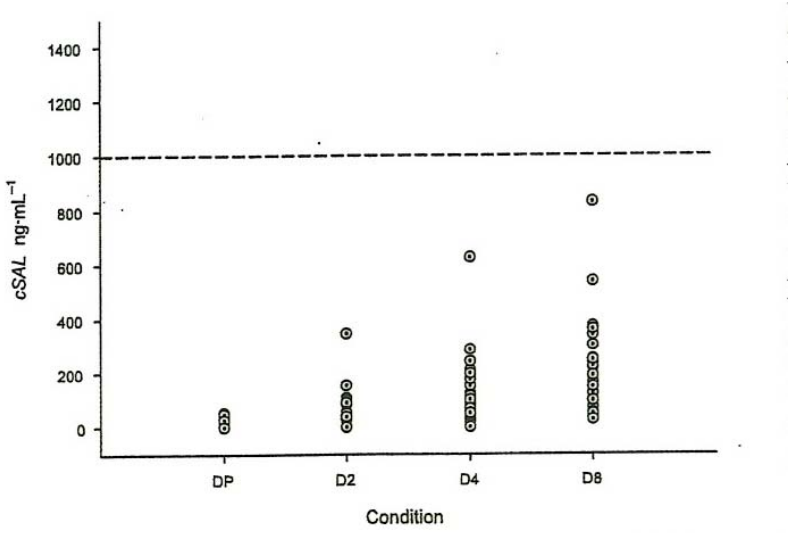


FIGURE 5—Urine concentrations of nonsulphated salbutamol (cSAL). The *dashed line* represents the doping control limit of 1000 ng·mL^{-1}. DP, placebo; D2, 200 µg; D4, 400 µg; D8, 800 µg.

226. According to Prof. Ayotte, the Sporer study findings confirm that:

(1) a 400 µm dose of salbutamol cannot be the cause of the Athlete's positive finding; and

(2) the method used for the controlled pharmacokinetic study is valid and required no modification because peak salbutamol concentrations are usually observed between 0 to 4 hours after inhalation.

Haase Study[6]

227. The purpose of this study published in 2015 was to investigate the influence of exercise and dehydration on the urine concentrations of salbutamol after inhalation of the maximal dose permitted (1600 μg) on the *2015 WADA Prohibited List*.

228. Thirteen (13) healthy males participated in the study.

229. Participants inhaled a single 1600 μg dose of salbutamol.

230. Urine concentrations of salbutamol were measured under three conditions: exercise (EX), exercise+dehydration (EXD), and at rest (R).

231. Urine samples of salbutamol were collected between 0 and 24h after salbutamol administration.

232. Adjustment of urine concentrations of salbutamol to a specific gravity of 1.020 was compared to data observed without adjustment.

233. Upon analysis of findings, the authors specified the following on page 5 of their report:

> "*Home samples collected 9 and 24 h after drug administration showed mean urine concentrations of ~200 and ~100 ng/mL, respectively, with no differences between conditions and USG adjustment".*

234. On page 6 of the report, the authors state:

> *"Although doping cases of salbutamol only were reported 11 times in 2013, it is important that athletes are not at risk of having a false positive doping control test result after inhalation within the current anti-doping regulations. As shown in Figure 2 of the present study, large inter-individual differences exist in the urine excretion of salbutamol, why some individuals may exceed the decision limit for salbutamol when 1600 μg is inhaled as a single dose. Timing of urine sample also has an impact on the concentration of salbutamol, with most of the AAFs [Adverse Analytical Findings] observed within the first 4 h of sampling (Figure 2).*

[6] See footnote #4 for the full reference.

Importantly, athletes that present an AAF of salbutamol in doping control are given the opportunity to prove that the AAF was due to therapeutic use through a pharmacokinetic study. "

(underline added)

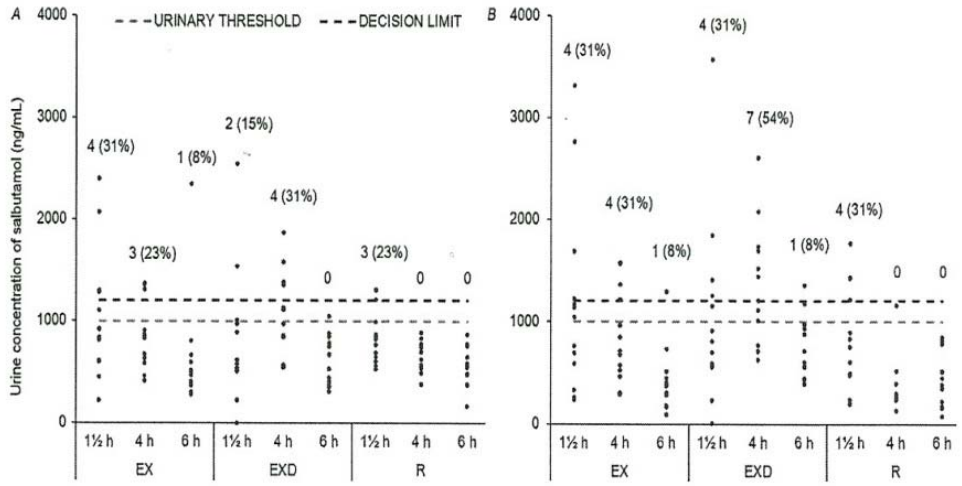


Figure 2. Individual urine concentrations of salbutamol after inhalation of 1600 µg salbutamol with (+)USG (A) and without (–)USG (B) adjustment of samples to a USG of 1.020 g/mL. Number of AAFs is shown for each sampling point during each condition with corresponding percentages (%) of AFFs at each sampling point. Urinary threshold (1000 ng/mL) and decision limit (1200 ng/mL) for salbutamol are based on the 2015 WADA prohibited list. EX: Exercise in hydrated state, EXD: Exercise in dehydrated state, R: Rest. Individual values are presented (n = 13).

235. In their conclusions, the authors wrote:

"In conclusion, the present study demonstrates that inhalation of that maximally allowed for salbutamol (1600 µg) on the WADA 2015 list of prohibited substances, can result in an AAF and that the risk of an AAF increases when exercise is performed with a limited fluid intake. The present findings could therefore be taken into consideration when evaluating doping cases of salbutamol. Although 1600 µg of inhaled salbutamol as a single dose exceeds that considered as normal therapeutic treatment, athletes using salbutamol should be made aware of this risk". (page 7)

(underline added)

236. According to Mr. Mouksassi, the Haase study confirms that exercise and dehydration greatly affect urine concentrations of salbutamol and increase the risk of exceeding the decision limit.

237. As for Prof. Ayotte, she refers to Figure 2 of the Haase study (shown

above) which clearly shows that a majority of adverse analytical findings occur during the first four (4) hours following inhalation.

238. Departing from Mr. Mouksassi's interpretation, Prof. Ayotte refers to the same Haase study in concluding that the use of salbutamol as described by the Athlete could not cause her to have tested positive in a doping test.

239. According to her, the only way to exceed the threshold is to inhale 1600 µg of salbutamol in a single dose. In this case, the Athlete testified to have only inhaled 400 µg of salbutamol on the morning of the competition.

Schweizer Study[7]

240. This study published in 2004 documents the case of a 22-year-old track and field athlete (400 m) who tested positive for salbutamol during the 2002 Swiss Championships.

241. Analysis of the athlete's sample showed a urine salbutamol concentration of approximately 8000 ng/mL.

242. The athlete was then subject to a suspension.

243. Afterwards, the athlete agreed to participate in a more detailed pharmacokinetic study.

244. The pharmacokinetic study was conducted under medical supervision two (2) months after the positive doping test and using the protocol described below:

[7] See footnote 3 for the full reference.

TABLE 1. Time Schedule of Salbutamol Excretion Study

Day	Time	Action	Remarks
1	All day	Athlete at home; no urine collected	No particular physical exercise
2	11:00	Arrival at the laboratory; first urine sample collected	Explanation of the study to the athlete
	12:00	Three inhalations of Ventolin	Regular urine collection
	12:15	Medical examination	
	16:00	Three inhalations of Ventolin	
	17:00	Three inhalations of Ventolin	
	19:45	Last sample collected in the laboratory	The athlete received vessels for the regular collection of urine at home
3	8:00	Intake of Symbicort	At home; no particular physical exercise; urine regularly collected and stored at 4°C
	12:00	Three inhalations of Ventolin	
	16:00	Three inhalations of Ventolin	
	17:00	Three inhalations of Ventolin	
	23:45	Last urine sample of the day collected	
4	6:00	Morning urine collected	End of study; urine samples are shipped to the laboratory by express mail

245. Interestingly, the last urine sample collected by the laboratory (i.e. under medical supervision) was taken at 7:45 p.m. on the second day. Afterwards, the athlete is home alone instead of under "controlled conditions".

246. Overall, twenty-three (23) urine samples were collected over a period of forty-three (43) hours.

247. The figure below which appears on page 314 of the report shows the athlete's urine concentrations of salbutamol during the study:

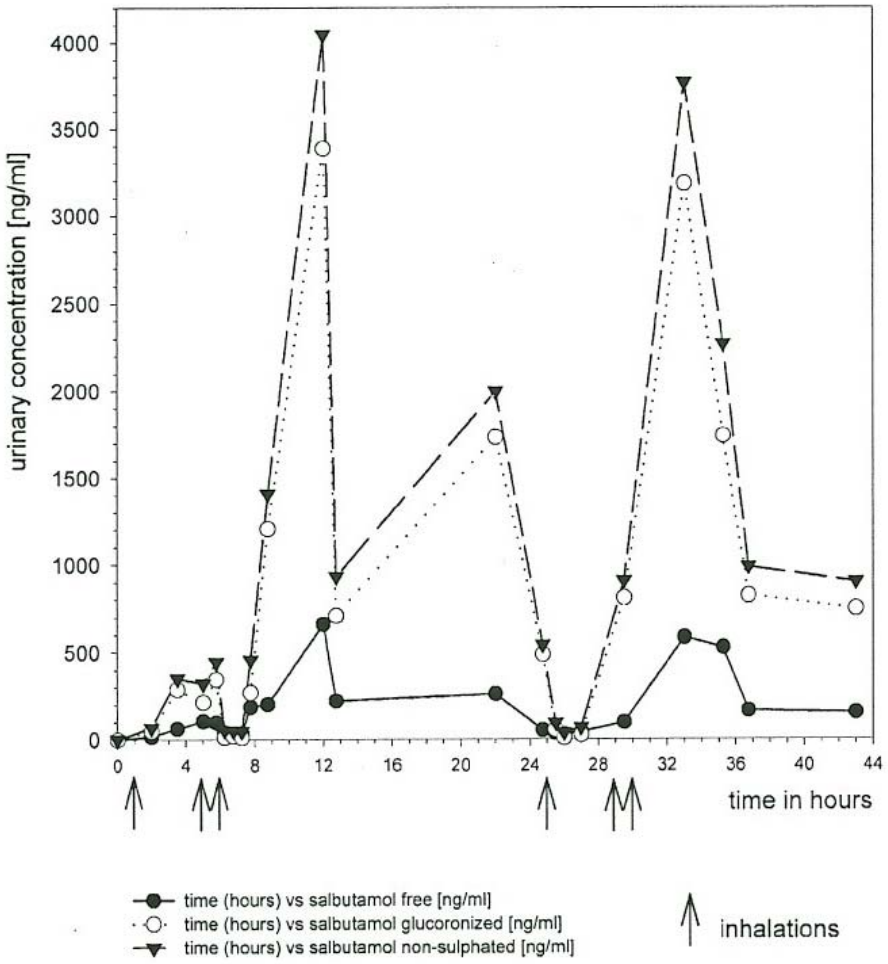


FIGURE 1. Urinary excretion of salbutamol.

248. Upon examining the graph, Mr. Mouksassi presented the following observations:

1) A concentration of free and glucoronized salbutamol can exceed 4000 ng/mL.

2) Measured urine concentrations vary considerably and can

increase sharply later during the day (around 10 p.m. on the graph), much later than the dosing period (around 5 p.m. on the graph as indicated by arrows).

3) The urine concentration profile over time is not monotone (it shows sharp peaks and valleys), making it impossible to interpret results of a pharmacokinetic study such as the one conducted with Ana Laura on June 25, 2015 where only four (4) samples were collected.

249. Mr. Mouksassi also noted that authors of the Schweizer study stated that they could not reproduce the exact state of dehydration of the athlete on the day of the competition.

250. He then compared this fact with the pharmacokinetic study to which the Athlete submitted. According to him, the study of June 25, 2015 did not correctly reproduce the actual state of dehydration of the Athlete on the day of the Canadian Championships.

251. According to Mr. Mouksassi, the Schweizer study shows that it is possible to exceed the decision limit of 1.2 µg/mL for salbutamol concentration by taking a dose of 800 µg the morning of the competition. He added that it is also possible to exceed 1.7 µg/mL with a dose of 400 µg.

252. Mr. Mouksassi reiterated the importance of the Schweizer study because it represents the only in-depth pharmacokinetic study in scientific literature that includes a large number of samples over a long period (i.e. 43 hours).

253. In his opinion, the pharmacokinetic study undergone by the Athlete was cursory because only four (4) samples were collected over a short period (6 hours).

254. As for Prof. Ayotte, she began her interpretation of the study by stating that scientifically a rule can only be established if the scientific results are reproduced twice. In this case, the Schweizer study was never reproduced.

255. Prof. Ayotte explained the necessity of weighing the relative importance of the study because it was not a controlled study. On this point, she refers to Figure 1 on page 313 of the study:

> *"19:45 – Last sample collected in the laboratory: the athlete received vessels for the regular collection of urine at home. At home, no particular physical exercise; urine regularly collected and stored at 4ºC."*

256. She noted that, oddly enough, the salbutamol peak in Figure 1 of the study appears only 8 hours into the study, which coincides with the moment when the athlete is home and medically unsupervised.

257. Therefore, Prof. Ayotte is of the opinion that the Schweizer study cannot be considered to demonstrate a person's *usual* reaction to salbutamol for the following reasons: it was not a controlled study and no other similar study has produced comparable results since 2004.

Jacobson Study[8]

258. The purpose of this study conducted in 1997 was to measure urinary concentrations of salbutamol in a large sample of asthmatic patients in order to determine if the urinary concentration was an indicator of overuse of the inhalator.

259. The study included one hundred and two (102) asthmatic patients who

[8] G. A. **Jacobson** BPharm(Hons), G. M. Peterson BPharm(Hons) PhD FSHP AFAIPM, and S. McLean MPharm PhD, *Investigation of urinary levels of salbutamol in asthmatic patients receiving inhaled therapy*, Journal of Clinical Pharmacy and Therapeutics (1997).

were not elite athletes.

260. The analytical findings from urine samples allowed researchers to determine that urine concentrations of salbutamol varied enormously between patients.

261. The authors drew the following conclusions on page 119:

> *"[…] Measuring urinary concentrations of salbutamol in spot samples provides only a relatively crude indication of the extent of use of inhaled salbutamol in the preceding 24h".*

262. This study, initially cited by the Athlete's expert, does not seem relevant to this case in my opinion.

263. At the most, it supports Mr. Mouksassi's hypothesis that urine concentrations of salbutamol can vary from one person to another.

Elers Study[9]

264. The purpose of this study conducted in 2012 was to collect pharmacokinetic data on inhaled salbutamol compared to oral salbutamol in elite athletes with asthma. The data collected would eventually help differentiate between therapeutic use and use for doping purposes.

265. The study included eighteen (18) subjects aged 18 to 33 years. Eight (8) subjects were elite athletes with asthma and ten (10) subjects were nonasthmatic.

266. Each participant was initially administered 0.8 mg of inhaled salbutamol. Fourteen (14) days later, each participant took 8 mg of oral salbutamol.

[9] Jimmi **Elers**, MD, PhD, Lars Pedersen, MD, PhD, John Henninge, MSc, Peter Hemmersbach, Prof Dr Kim Dalhoff, MD, DMSc and Vibeke Backer, MD, DMSc, *The Pharmacokinetic Profile of Inhaled and Oral salbutamol in Elite Athletes With Asthma and Nonasthmatic Subjects*, Clin J Sport Med, Volume 22, Number 2, March 2012.

267. When analyzing the results, the authors made the following observations:

> *"Maximum urine concentrations peaked in the period of 0 to 4 hours after the administration of inhaled and oral salbutamol in both groups. […] One sample exceeded the World Anti-Doping Agency threshold value of 1000 ng/mL with a urinary salbutamol concentration of 1057 ng/mL 4 hours after the inhalation, when no correction for urine specific gravity was done. When this sample was corrected for urine specific gravity, the result was 661 ng/mL".*
> (page 140)
>
> (underline added)

268. On page 5 of the report, the authors state:

> *"Urine samples collected after 24 or 48 hours would be interesting and could elucidate an important topic when evaluating doping cases, that is, time until complete elimination of the drug. Finally, extreme prolonged exercise could potentially alter metabolism and urinary pH. This might influence the analysis of salbutamol".*
>
> (underline added)

269. At the end of the article, the authors come to the following conclusions:

> *"Our results support the existing WADA limit of 1000 ng/mL to differentiate between therapeutic use and doping with salbutamol. However, our results indicate that urine salbutamol concentrations should be corrected for urine specific gravity.*
>
> (underline added)

270. This study supports the argument that WADA should apply a correction for specific gravity when analyzing salbutamol concentration in urine samples provided by athletes.

271. On the other hand, Prof. Ayotte stated that findings showing a salbutamol concentration of 1057 ng/mL would not be considered positive for doping because the decision limit is set at 1.2 µg/mL.

272. In fact, even if the threshold is 1000 ng/mL, a sample only becomes subject to adverse analytical finding starting at 1200 ng/mL.

IX. RELEVANT JURISPRUDENCE

273. Both parties submitted several authorities to support their arguments. For the sake of brevity, I will focus on existing jurisprudence that is most relevant to this case.

Filippo Volandri v. International Tennis Federation (ITF), Arbitration CAS 2009/A/1782

274. In this case, the Tribunal only imposed a reprimand to the athlete who slightly exceeded the maximum threshold of 1000 ng/mL for salbutamol.

275. Under paragraph 53, the Tribunal states:

> *53. The CAS Panel observes that Mr. Filippo Volandri was indeed at fault, as he has not been able to prove that the presence of salbutamol in his sample in excess of 1,000 ng/mL was the consequence "of the therapeutic use of inhaled salbutamol". However, the degree of his fault is minor as the threshold of 1,000 ng/mL was just exceeded. If, as ascertained by the ITF Tribunal itself, one puff corresponds to 100 mcg of salbutamol, the litigious excess represents less than a couple of puffs. […]*
>
> (underline added)

276. It is paramount that this decision be put into context. The athlete claimed that the salbutamol concentration in his body exceeded the allowed threshold because of an intense use of the inhaler. In fact, the athlete had an asthma attack the very morning of the competition.

277. In addition, in its analysis, the Tribunal considered the long procedural

delays to which the athlete was subjected and certain procedural irregularities:

> *54. However, in assessing the appropriate sanction, the CAS Panel also took the following factors into account. First, Mr. Filippo Volandri has never previously been found guilty of an antidoping rule violation. This, of itself, is of comparatively little weight: the same point can be made for any first-time offender. Secondly, however, and more importantly, the CAS Panel has been concerned that the procedures before the ITF were slow and suffered from inconsistencies, with the result that the Player was left in a state of uncertainty of over 8 months, which is very long in sporting matters. As a matter of fact, it is only on 13 November 2008 that the Player was formally charged with a doping offence. Before then, Mr. Filippo Volandri received information from the ITF which is to some extent contradictory and may also be confusing:[…]*
>
> (underline added)

278. The case at hand differs in that it does not involve a massive or exaggerated use of the inhaler by the Athlete. In addition, the control study was completed only a few weeks after the positive doping test, which gave the Athlete the opportunity to explain under what circumstances the inhaler was used.

CCES and Alicia Brown, SDRCC DAT 15-0006

279. It is always a strange feeling to cite one's own decisions, but the conclusions that were drawn in this case, in collaboration with my colleagues Yves Fortier and Robert Armstrong, are worth repeating.

280. In this case, the Doping Appeal Tribunal overruled the initial decision of the Doping Tribunal and suspended the athlete for a period of two (2) years.

281. The prohibited substance was Hydrochlorothiazide ("HCTZ").

282. Per this decision, the Tribunal ruled on the first criterion of the definition of "no significant fault or negligence" (Appendix 1 of the CADP), i.e. how did the prohibited substance enter the body of the athlete:

> *118. CCES argues that the test requires the Athlete to establish a single theory of ingestion whereas the Athlete submits that the test can be met by raising multiple possible explanations.*
>
> *119. For the reasons which follow, the Tribunal agrees with CCES.*
>
> *[…]*
>
> *122. In order to be entitled to a reduction of sanction, an athlete, under these Rules, must prove the following three cumulative requirements:*
>
> > *(i) how the Specified Substance entered his or her body;*
> >
> > *(ii) that such Specified Substance was not intended to enhance the athlete's sport performance or mask the Use of a performance-enhancing substance; and*
> >
> > *(iii) his or her degree of fault.*
>
> *123. It is evident that, in order for an athlete to meet the latter two requirements, he or she must establish a single source of ingestion of the Specified Substance. Otherwise, the adjudicator would never be able to assess accurately the athlete's degree of fault.*
>
> (underline added)

283. Based on the principle established in the Brown case, the burden of proof rests on the Athlete to demonstrate how the specified substance entered her body.

WADA v. *National Olympic Committee & Sports Confederation of Denmark & Dansk Holdspil-Union & Mr. Jesper Münsberg*, CAS 2008/A/1668

284. In this decision, the Tribunal suspended the athlete for a period of six (6) months.

285. The athlete's positive doping sample showed a salbutamol concentration of 2400 ng/mL.

286. Under paragraph 138 of this decision, the Tribunal states:

> *138. Thus, in order to benefit from the elimination or reduction of the sanction, the Player must fulfil two cumulative conditions, i.e. establish how the specified substance (in this case salbutamol) entered his body and establish the absence of intent to enhance his sporting performance.*
>
> (underline added)

287. In that case, the athlete was not disputing the presence of salbutamol at a concentration in excess of 1000 ng/mL in his urine sample.

288. In fact, the athlete submitted that a salbutamol concentration of 2400 ng/mL entered his body only through inhalation, using his inhaler.

289. Upon analysis of the first threshold, the Tribunal concluded:

> *147. The Panel therefore considers that on a balance of probability it is more likely than not that the Player did not take any salbutamol tablets but took quite a massive dose of inhaled salbutamol in successive series of puffs […] Accordingly, on the basis of the applicable standard of proof, it must be deemed established that the salbutamol entered the Player's body by inhalation of Ventolin.*
>
> (underline added)

290. Because the athlete established, on a balance of probabilities, how salbutamol entered his body at a concentration exceeding 1000 ng/mL, the Tribunal could then assess his degree of fault and determine whether a reduced sanction was possible in the circumstances.

DT 15-0238 – In the matter of an anti-doping rule violation by a Football Canada athlete asserted by the Canadian Centre for Ethics in Sport

291. This case was not brought before the SDRCC Doping Tribunal but was settled internally by the CCES. Since the analysis leading to the decision is not detailed, its scientific and legal value is not meaningful in guiding the Tribunal.

292. The decision was issued by Mr. Jeremy Luke, Director, Canadian Anti-Doping Program and Business Operations of the CCES.

293. The athlete is not named in the decision.

294. The athlete's urine sample collected on the day of the competition showed a salbutamol concentration in excess of 1000 ng/mL.

295. In rendering its decision, the CCES drew the following conclusions:

> (1) The athlete was not, at the time of testing, a national or international athlete as defined in the CADP;
>
> (2) The athlete was at all times using salbutamol for therapeutic purposes pursuant to a valid prescription properly obtained from his physician;
>
> (3) The athlete was using the medication salbutamol precisely as directed by his physician;
>
> (4) The athlete's urine sample was extremely concentrated (specific gravity measured at 1.035), and according to the expert opinion of the Director of the WADA-Accredited Laboratory in Montreal, the high specific gravity contributed significantly to the elevated finding for salbutamol in the athlete's urine sample;
>
> (5) The athlete is young with limited anti-doping education and awareness.

296. In light of these factors, the CCES ultimately determined that the sanction for this violation should be a reprimand.

297. Last by not least, because the athlete was a minor, he was not required to explain how the prohibited substance entered his body (as per the definition of "no significant fault or negligence" under Appendix 1 of the CADP).

298. Consequently, I cannot use this case to guide my analysis.

X. DISCUSSION

299. Doping cases that challenge scientific validity are not frequent but deserve a thorough analysis.

300. The Tribunal and Parties must be aware of the provisions of Article 3.2.1 of the CADP which state "*Analytical methods or decision limits approved by WADA after consultation within the relevant scientific community and which have been the subject of peer review are presumed to be scientifically valid*".

301. Consequently, the burden of proof rests entirely on the Athlete whose defence is to challenge the scientific validity of the test, and more importantly the burden is greater given that the Athlete must demonstrate, with supporting scientific studies and expert opinions, that the scientific literature, various WADA committees and expert(s) at the hearing have erred in determining the analytical methods or decision limits.

302. Furthermore, Article 3.1 states that the standard of proof requires more than simply raising reasonable doubt on scientific validity. The Athlete must satisfy the Tribunal that the scientific validity of analytical methods or decision limits are faulty on a balance of probabilities.

303. Firstly, both expert witnesses provided me with comprehensive information. Although they shared different views, a common occurrence in an adversary system, their testimony and explanations were clear, free of overly technical lingo and fundamental to providing a strong grasp of the stakes at hand.

304. With great respect for Mr. Mouksassi's experience as a clinician, with no prior doping knowledge, I found it obvious that Prof. Ayotte's experience helped better understand the subtleties of the conclusions in the scientific literature and doping tests, especially in the case of the Schweizer study.

305. Akin to Prof. Ayotte, I believe the Schweizer study cannot be considered revealing or conclusive in demonstrating how salbutamol is metabolized in an athlete's body. In fact, in that case, the athlete was subject to doping accusations, the study was not controlled and adverse findings began to appear when he was no longer under medical supervision. Finally, these results were never reproduced in a similar study.

306. I felt convinced that Prof. Ayotte's testimony was based on rock-solid knowledge of doping, which allowed her to draw the right conclusions on the determination of analytical methods and the decision limit. More specifically, the fact that Prof. Ayotte sat or sits on various WADA, IOC and international federation committees gave me the opportunity to weigh the serious nature of the work carried out by these groups, and there was no evidence that this work was done superficially or incorrectly where the determination of salbutamol analytical methods and decision limits are concerned.

307. In the absence of evidence to that effect, I conclude that the Athlete did not discharge herself of the burden of proof in challenging the scientific validity of the salbutamol threshold and decision limit.

308. To demonstrate no *significant fault or negligence*, Appendix 1 of the CADP requires that "...the athlete must also establish how the Prohibited Substance entered his or her system".

309. Salbutamol is a permitted substance but is considered a prohibited substance when an athlete's urine salbutamol concentration exceeds 1000 ng/mL. Consequently, the definition stated in Appendix 1 of the CADP means the Athlete cannot merely admit to the presence of the substance in her body. She is required to explain <u>how</u> the substance exceeded the threshold.

310. The principles emerging from the *Brown* decision whereby the degree of

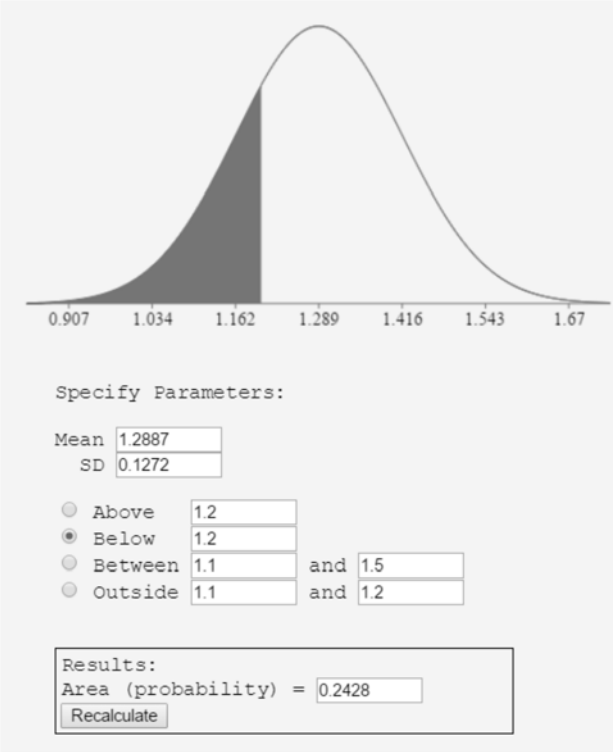
fault can only be analyzed if the athlete fully admits to ingesting the prohibited substance find particular resonance in a case where there is no precedent in doping arbitration jurisprudence.

311. It is my opinion that, since salbutamol becomes a prohibited substance solely when it exceeds a threshold of 1000 ng/mL, the Athlete cannot simply testify to inhaling 400 µg when she tested at 1.3 µg/mL, and could not reproduce this value during the pharmacokinetic study. The Athlete must also explain how the substance was found in her body at such a high level, when, scientifically, such level is inexplicable if relying solely on the Athlete's claims regarding inhalation.

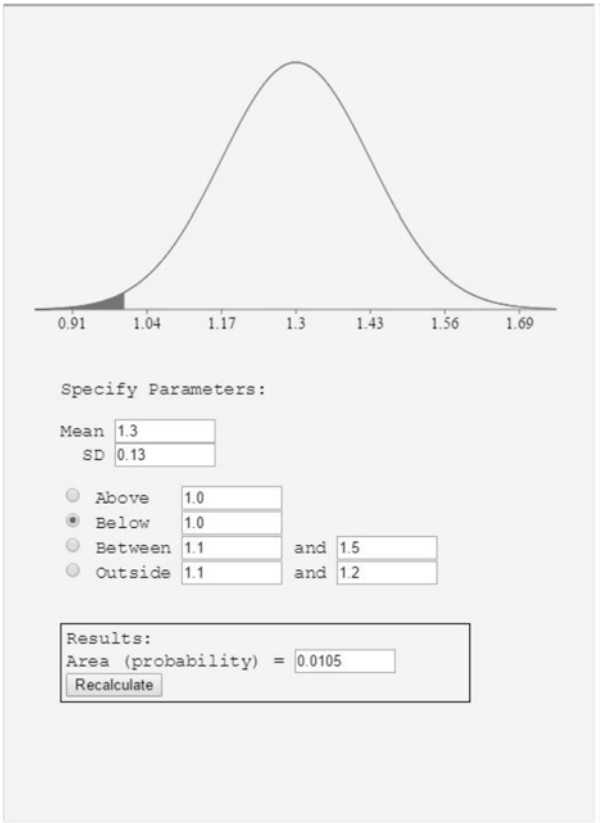
312. The contention that dehydration affects urine specific gravity, thereby causing the sample to test positive, did not convince me.

313. Firstly, the Athlete's 1.029 urine specific gravity is not considered abnormal in doping tests, contrary to Mr. Mouksassi's statement. Secondly, even when corrected for specific gravity, the result remained unusually high and was inconsistent with the doping findings. Finally, based on Prof. Ayotte's testimony, WADA's various committees clearly considered the matter of specific gravity for salbutamol and decided not to apply a correction factor to the analysis, establishing the threshold at 1000 ng/mL.

314. When analyzing WADA's established threshold and decision limit, Mr. Mouksassi's interpretation departed from that of Prof. Ayotte, but I agreed with the latter. In fact, I am satisfied that the 1.2 µg/mL decision limit already includes an error margin of ± 0.2 µg/mL. Mr. Mouksassi's opinion whereby he applies the error margin to the 1.3 µg/mL result, leading to a 24.28% chance that the average would fall below 1.2 µg/mL, is scientifically invalid where doping is concerned, because he focuses exclusively on the decision limit rather than on the threshold, while the threshold is what determines a violation of the World Anti-Doping Code.



Mr. Mouksassi's calculation is shown above.



Prof. Ayotte's calculation is shown above.

315. Prof. Ayotte's calculation is appropriate because the error margin is applied to the 1.0 µg/mL threshold instead of the 1.2 µg/mL limit. Using this calculation, the probability that the average falls below the 1.0 µg/mL threshold decreased to 1%.

316. I accept the 1% probability, which fully meets the balance of probabilities standard.

317. Consequently, in rejecting the Athlete's explanation, I conclude that the Athlete's admission is incomplete and fatally flawed under Article 10.5.1.1 and Appendix 1 of the CADP.

318. Therefore, I cannot assess the degree of fault. As a result, I am bound by the interpretation of the CADP which imposes a 2-year ineligibility period.

XI. DECISION

Ana Laura Portuondo-Isasi violated anti-doping rules under Rule 2.1 of the Canadian Anti-Doping Program.

It is not possible to reduce the ineligibility period under Rule 10.5.1.1 of the CADP for lack of a formal admission from the Athlete; she failed to explain how salbutamol reached such a high concentration in her body.

CONSEQUENTLY, Ana Laura Portuondo-Isasi is declared ineligible for a period of two (2) years, effective retroactively from May 17, 2015 until midnight on May 16, 2017.

I retain jurisdiction with respect of any issue which may arise concerning the interpretation or implementation of this decision.

Dated February 23, 2016 in Montreal.

_____

Patrice Brunet, arbitrator