CAS 2020/A/6892 Andrew Starykowicz v. United States Anti-Doping Agency

ARBITRAL AWARD

delivered by the

COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

Sole Arbitrator: Mr Luigi Fumagalli, Professor and Attorney-at-Law, Milan, Italy

between

ANDREW STARYKOWICZ, United States
Represented by Mr Howard L. Jacobs and Ms Linday S. Brandon, Attorneys-at-Law at the Law Offices of Howard L. Jacobs, Westlake Village, California, United States

as Appellant

and

UNITED STATES ANTI-DOPING AGENCY (USADA), United States
Represented by Mr William Bock III, General Counsel, and Mr Jeff Cook, Senior Director of Results Management and Investigations, Colorado Springs, Colorado, United States

as Respondent

I. THE PARTIES

1. Mr Andrew Starykowicz (the "Athlete" or the "Appellant") is a US professional athlete of international level, born on 14 April 1982, competing in triathlon events. The Athlete is subject to the Ironman® Anti-Doping Rules (the "Ironman ADR") adopted by the World Triathlon Corporation ("WTC") to implement the World Anti-Doping Code (the "WADC") as one of its signatories.

2. The United States Anti-Doping Agency ("USADA" or the "Respondent") is the independent anti-doping agency for Olympic-related sport in the United States. USADA has full authority to execute a comprehensive anti-doping program in the United States, encompassing testing, adjudication, education and research, and to develop programs, policies, and procedures in each of those areas. USADA has its seat in Colorado Springs, Colorado, United States, and is a signatory to the WADC.

II. FACTUAL SUMMARY

3. Below is a summary of the main relevant facts, as submitted by the Parties in their written pleadings and adduced at the hearing. Additional facts may be set out, where relevant, in connection with the legal discussion that follows. Although the Sole Arbitrator has considered all the facts, allegations, legal arguments and evidence submitted by the Parties in the present proceedings, he refers in this Award only to the submissions and evidence he considers necessary to explain his reasoning.

4. On or about 2 October 2019, the Athlete began to experience coughing and shortness of breath. The week before, his son had visited a hospital with similar symptoms and had been diagnosed with pneumonia.

5. On or about 8 October 2019, the Athlete began a course of antibiotics, without however seeing significant improvement in his condition.

6. On 12 October 2019, therefore, he was forced to withdraw from the Ironman World Championships in Kona, which was scheduled to take place on that day.

7. On 15 October 2019, the Athlete was examined by Dr Anita Shah, a pulmonologist in Chicago, who diagnosed him with possible viral pneumonitis and mucopurulent bronchitis (bronchospasm), with a possible viral etiology. Dr Shah prescribed the Athlete a Medrol (Methylprednisolone) pack (course of 5 days) and a one-month course for once daily use of a Breo Ellipta 200/25 (Fluticasone Furoate and Vilanterol inhalation powder) inhaler ("Breo"). Methylprednisolone and Fluticasone Furoate (Glucocorticoids) and Vilanterol (a Beta-2 Agonist) are included in the List of Prohibited Substances and Methods (the "Prohibited List") established by the World Anti-Doping Agency ("WADA") for 2019. Vilanterol is prohibited at all times; Methylprednisolone and Fluticasone Furoate are prohibited in-competition only, when administered by oral, intravenous, intramuscular or rectal routes.

8. On 15 October 2019, the Athlete first used Breo and Medrol.

9. On the same day, 15 October 2019, the Athlete filed with USADA an application for a Therapeutic Use Exemption ("TUE") for Breo (Vilanterol) and Medrol (Methylprednisolone). The TUE application, signed also by Dr Anita Shah, referred to a diagnosis of "*Mucopurulent chronic bronchitis*", and was for the administration of Breo inhaled "*once daily x 4 wks*", and of 4 mg tabs of Medrol administered orally "*daily x 5 days*".

10. On 21 October 20192, the Athlete received an email from USADA indicating that his TUE application was incomplete. In detail, the Athlete was invited to provide "*a statement from your physician explaining why the prohibited substance is necessary and why any permitted alternative is not appropriate or were not effective in treating the condition*".

11. On or about 23 October 2019, the Athlete submitted to USADA a declaration signed by Dr Anita Shah, as follows:

> "*I am treating Andrew Starykowicz for cough and SOB which has been ongoing for the last several weeks. His chest-x-ray is concerning for a viral pneumonitis. His lung exam has diffuse expiratory wheezing consistent with bronchospasm from his viral infection. Andrew is severely limited in his daily activity due to this bronchospasm. Bronchospasm and infectious cough requires anti-inflammatory and bronchodilator therapy for treatment. He has already completed a course of steroids for 5 days and requires the Breo which is an inhaled steroid and bronchodilator for 4 weeks. There is no other acceptable alternate therapy in the short term given his abnormal lung exam and symptoms. I am aware that Breo is on the list of banned medications for professional athletes however Mr. Starykowicz has a serious illness that was causing disability and requires a limited 4 week treatment with the above medications.*"

12. On 25 October 2019, the Athlete was informed by USADA that his TUE application had been forwarded to the TUE Committee of USADA (the "USADA TUEC") for review, and that until a final certificate of approval was received the Athlete did not have an active TUE.

13. On 2 November 2019, the Athlete competed at Ironman Florida, in Panama City, Florida, and underwent an in-competition doping control.

14. On 8 November 2019, the Athlete's TUE application for Methylprednisolone (Medrol) was approved.

15. On that same day, however, the Athlete was informed by USADA that his TUE application for Vilanterol (Breo) had been denied. The reasons for the denial (the "USADA TUEC Decision") were expressed as follows:

> "*1. The statements in the medical information provided do not unequivocally support a confirmed diagnosis of a chronic or acute medical condition where withholding Breo would cause the athlete to experience a significant impairment to his health. There was no evidence-based rationale given for the use of Breo as opposed to other medications. Additionally, the spirometry values indicated in the clinical note do not meet the WADA guidelines regarding an increase of at*

least 12% and 200mL in FEV1 following the use of an inhaled beta-2 agonist as the standard for the reversibility of an airway obstruction.

2. *The medical criteria were not met since in the absence of a confirmed diagnosis of a reversible airway obstruction, Breo (Vilanterol Trifenatate) use may provide a performance enhancement to the athlete beyond returning him to a normal state of health.*
3. *There are alternatives medications with a combination of a similar inhaled corticosteroid and similar long acting beta2 agonists such as Advair®, Symbicort®, Dulera®, there are not on the prohibited list. This is contrary to the documentation provided in which the treating provider states, "there is no other acceptable alternative therapy in the short term given his abnormal lung exam and symptoms".*

16. On 21 November 2019, Dr Anita Shah submitted a formal response to the USADA TUEC Decision, accompanied by an article regarding lung function testing, as follows:

"*... I saw Andrew in my pulmonary clinic with an acute illness. He presented with several days of cough, shortness of breath and chest pain. Lung exam revealed bilateral expiratory wheezing and scattered rhonchi which is suggestive of bronchoconstriction. Andrew's 3-year-old son presented to the emergency department with similar symptoms of cough and shortness of breath. Pneumonia was confirmed on his son's chest x-ray and his son was prescribed formoterol 110mcg inhaled twice daily, albuterol every six hours and as needed for shortness of breath and antibiotics (azithromycin and amoxicillin). Given that Andrew presented with identical symptoms to my office and had a chest x-ray suggestive of a pneumonitis, Andrew was treated with Augmentin, Medrol dose pack and Breo. Andrew presented with chest pain and an acute illness which is likely to cause suboptimal pulmonary function test results. I have attached the American Thoracic Society guidelines "ATS/ERS TASK FORCE: STANDARDISATION OF LUNG FUNCTION TESTING" which clearly outlines in table 1 "conditions that will lead to suboptimal results." "Chest or abdominal pain of any cause" is the first item listed in the table and that is the reason lung function testing was not performed on Andrew prior to treatment. As such there is no documentation of lung function reversibility.*

Given that Andrew presented with wheezing suggestive of bronchoconstriction, a beta-adrenergic agent was indicated. Vilanterol is a beta-adrenergic agonist and chemically similar to formoterol and salmeterol but it is inhaled only once daily increasing compliance among patients. Andrew only used Breo during his acute illness and did not use it outside the period of acute illness.

I was unaware that other agents were allowed based on the website as there is nothing listed identifying acceptable alternatives. I provided samples to Andrew to save the him a co-pay for an inhaler that was only going to be used in the short term. Thank you for your consideration."

17. On 5 December 2019, the Athlete was notified by WTC that the in-competition doping control 2 November 2019 had returned an adverse analytical finding for Vilanterol and that a provisional suspension had been imposed upon him pursuant to Article 7 of the Ironman ADR.

18. On the same day, 5 December 2019, the Athlete requested that the denial of a TUE for Vilanterol be reviewed.

19. On 12 December 2019, USADA confirmed the denial of the TUE application for Breo, stating *inter alia* (bold in the original; footnotes omitted, containing references to the "*Medical Information to Support the Decisions of TUECs – Asthma v. 6.1 (17 January 2019)*" and "*Medical Information to Support the Decisions of TUECs – Post Infectious Cough v. 3.2 (September 2017)*") that:

> "*the ... decision was made in consultation with USADA's Therapeutic Use Exemption Committee (TUEC). USADA and the independent TUEC panel concluded that your medical evidence does not support granting a TUE approval in accordance with the criteria set forth in the ... WADA International Standard for Therapeutic Use Exemptions (ISTUE). ...*
>
> ***a. The Prohibited Substance or Prohibited Method in question is needed to treat an acute chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.***
>
> *Article 4.1a was not met as the additional physician memorandum failed to adequately establish a clinical evidence-based rationale for treatment with Breo as opposed to other medication. While the athlete had a confirmed medical condition requirement treatment, the assessment that Breo was required over other medications was not unequivocally established. It was stated in the physician's memorandum that the primary reason for providing Breo was for compliance (once a day use) as well as economic (saving the athlete form a co-pay for a short-term inhaler). It also stated that the athlete's chest x-ray was "suggestive of a pneumonitis" and his symptoms were "likely to cause a suboptimal pulmonary function test (PFT) results." However, there was no PFT completed to conclusively establish the athlete suffered from reversible airway obstruction nor was the radiological evaluation able to confirm pneumonitis requiring treatment with Breo specifically. Furthermore, there was no evidence provided that the athlete had past or current medication compliance issues nor evidence that any other non-prohibited alternatives (formoterol and salmeterol) were not considered feasible as the athlete's son was given formoterol (110 mcg) for the same symptoms and was seen concurrently with the athlete. Thus, based on the information provided, it was assessed that the athlete would not have suffered a significant impairment to his health were the Breo withheld in lieu of treatment with a non-prohibited alternative.*
>
> ***b. The Therapeutic Use Exemption of the Prohibited Substance or Prohibited Method is highly unlikely to produce additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition.***
>
> *Article 4.1b was not met since the absence of a confirmed diagnosis of a medical condition requiring Breo, its use may provide a performance enhancement to the athlete beyond returning him to a normal state of health.*
>
> ***c. There is no reasonable therapeutic alternative to the use of the Prohibited Substance or Prohibited Method.***
>
> *Article 4.1c was not met as the additional medical information provided did not provide clinical evidence-based reasons to rule out the permitted alternatives to Breo. The treating provider stated that "I was unaware that other agents were allowed based on the website as there is nothing listed identifying acceptable alternative."; however, this is not entirely accurate as a search on Global DRO® would reveal there are suitable alternatives with similar inhaled corticosteroids and similar long acting beta 2 agonists (e.g. Advair® that has Salmeterol, Dulera® and Symbicort® that both have*

Formoterol) which are not prohibited as long as they are administered in typical dosages under the WADA threshold.

d. The necessity of the use of the prohibited substance or prohibited method is not a consequence, wholly or in part, of the prior use (without a TUE) of a substance or method which was prohibited at the time of such use.

Article 4.1.d is not applicable at this time."

20. On 13 December 2019, the WTC charged the Athlete with an anti-doping rule violation pursuant to Articles 2.1, 2.2 and 2.6 of the Ironman ADR.

21. On 20 December 2019, Dr Anita Shah directly addressed each of USADA's reasons for denying the Athlete's TUE application for Breo. This included, *inter alia*, the following:

"First, I would like to summarize my clinical impression at the time of my examination on October 15th, 2019.

Andrew initially presented urgently to my office with several weeks of respiratory symptoms including chest pressure, constant audible wheezing worsening at night, mucopurulent cough and bloody drainage from his sinuses.

On exam, his vitals showed evidence of impaired gas exchange and V/Q mismatch by a decreased pulse oximetry (96%) from his baseline. He appeared ill and uncomfortable.

There was diffuse wheezing with prolonged exhalation throughout both lungs fields. A chest X-ray showed no significant infiltrates.

My clinical impression was that Andrew was acutely ill and needed urgent treatment for the following:

1. *Acute / chronic bronchitis*
2. *Acute exacerbation of airways disease*
3. *Sinusitis*
4. *Viral Pneumonitis and possible pneumonia*

There were several concerns raised by USADA regarding my treatment decisions that I would like to address. First, there were concerns regarding section 4.1.a: ...

As a pulmonary and critical care physician with 10 years' experience, I felt an urgency in treating Andrew. He had been symptomatic for weeks and described a progressive and worsening course. I want to stress that he looked ill and uncomfortable in his breathing. Ancillary testing such as PFT's was unnecessary given his obvious wheezing and inappropriate as it could have exacerbated his symptoms. I felt any delay in initiating treatment would put Andrew's health at further risk.

The Chest X-ray showed an absence of infiltrates. This is consistent with Andrew's history and exam that was predominantly an acute "airway process" with wheezing, shortness of breath and chest discomfort.

I would also like to clarify that Andrew does not have a diagnosis of asthma. Wheezing is neither necessary nor sufficient to make a diagnosis of asthma. It is a clinical diagnosis that can be supported by reversible airflow on spirometry. A first episode of wheezing in the middle of an acute respiratory infection may be a harbinger of developing asthma as an adult, but more often than not is usually an isolated event. Whether Andrew will go on to show a pattern of severe airflow obstruction with future infections is to be seen. Andrew's presentation did not fit any of the labeled TUE exemption guidelines on the USADA website.

The use of once daily medication, when available, is standard of care for my practice

for treating acute and urgent illness. Waiting for a potential treatment failure due to compliance issues with a patient as sick as Andrew was not a clinical option. In my medical opinion it would have been substandard care and would have jeopardized Andrew's health. Advair Symbicort and Dulera are all twice-a-day inhalers and in my medical opinion were inappropriate options for this initial treatment of Andrew's acute airway inflammation and wheezing.

The use of Breo was not done in isolation. It was part of a comprehensive treatment strategy (antibiotics, short course of steroids) that reflected my concern for his clinical condition. ...

In response to your concerns under 4.1.b: ...

Again, my clinical impression was that of acute airflow obstruction most likely of viral origin. Andrew was short of breath in my office and was limited in walking even a short distance when testing ambulatory pulse oximetry. Without urgent treatment, I believe Andrew would have needed to be hospitalized and treated with continuous short acting bronchodilators.

In response to 4.1.c:

The document you reference in 4.1.c is the "Medical Information to support the decision of TUEC's-Asthma v 6.1 17 January 2019". Again, I want to reiterate that Andrew does not have a diagnosis of asthma. He was being treated for severe airflow obstruction. I know it may seem just semantics, but there are no evidence-based practice guidelines for how to approach a patient such as Andrew who comes in acutely ill with difficulty breathing for airflow obstruction without a diagnosis of asthma. He does not fall under the rubric of asthma exacerbation. There were no guidelines on the USADA website for Andrew's condition. His management was dictated by my clinical judgment and best practices for my patients. I directed Andrew with a treatment plan that included antibiotics, pulse steroids combined with once daily Breo use for a month. Andrew was clearly instructed that ANY worsening of his symptoms he should go the nearest emergency room as that would be the next step in his medical care. ...

... I feel that Andrew deserved the best medical care for his progressive and worsening medical condition. I do not believe his status as a professional athlete should put his health at increased risk. ..."

22. On 14 January 2020, USADA confirmed its denial of the TUE application for Breo, addressing, *inter alia*, Dr Shah's observation as follows:

"*All facts considered, while the athlete did have a confirmed diagnosis of mucopurulent bronchitis and possible viral pneumonitis, the decision to deny the TUE was primarily because a prohibited substance [vilanterol] was used when suitable permitted alternatives of equal efficacy were available but were not used, considered nor excluded by clinical evidence. The treating physician's rationale for the use of Breo centered upon the opinion that "the use of once daily medication, when available, is standard of care for my practice in treating acute and urgent illness." The difference in compliance between a once-daily drug (Breo®) versus a twice-daily drug (e.g. two permitted combination alternatives) is not a compelling reason to forgo the latter. Generalized statements and/or opinions advocating once daily medication prescription over twice-daily without clinical evidence to support it are not acceptable justification for the use of a prohibited substance.*

The athlete's physician also indicated that there was concern over the need to treat an "urgent" condition, which is stressed more than once in the documentation. Despite this, there was no mention of what would be considered a more appropriate therapy

(albuterol) that would impact the athlete's physical state immediately and that is indicated in truly urgent conditions requiring quick relief to treat or prevent bronchospasm. Breo® is not indicated for urgent, acute respiratory disorders but rather is used as a medication for long-term condition management. The clinical case asserted in the medical documents certainly does more to raise questions as to why a short-acting beta-2 agonist was not used rather that supporting the use of a prohibited long-acting beta-2 agonist.

While there are no specific WADA guidelines available for this particular diagnosis, it is perfectly reasonable to extrapolate from the WADA guideline on other respiratory diseases that are available. The initial explanation provided by the treating physician indicated that she was not aware that there were non-prohibited substances available (note dated 11-21-2019). Subsequent explanations provided indicate that she was practicing within her own standard of care (note dated 12-20-2019) and that the prohibited substance was needed for an "urgent" condition. In the professional opinion of the TUEC reviewers, the documentation provided does not support the use of Breo®. The submission of the ATS/ERS: Considerations for Lung Function Testing by the treating physician had no bearing on the overall decision of the TUEC. Despite the diagnosis of a confirmed medical condition, the additional information did no address how the athlete would experience a significant impairment to health if Breo® were withheld and thus, does not materially impact criteria 4.1a, 4.1b or 4.1c which were not unequivocally met.

In totality, weighing both the medical evidence provided and the scientific literature, the fact remains that the use of Breo® is prohibited at all times and therefore could provide performance enhancement beyond a return to a normal state of health, particularly for an elite athlete."

23. On 27 January 2020, the Athlete's counsel request from USADA a clarification of the handling of his TUE application, since it was unclear whether USADA had conducted the TUE review on behalf of the WTC only or also on behalf of the relevant International Federation, *i.e.* the International Triathlon Union ("ITU").

24. On 28 January 2020, USADA confirmed that it had not considered the Athlete's application on behalf of the ITU.

25. On 4 February 2020, therefore, a request for review of USADA's TUE denial was made to the WADA Therapeutic Use Exemption Committee (the "WADA TUEC") pursuant to Article 4.4 of the Ironman ADR.

26. On 6 March 2020, the WADA TUEC issued a decision (the "WADA TUEC Decision") concluding that:

"*the Athlete has not discharged his burden of proof that all four of the conditions listed in ISTUE Article 4.1 have been met on a balance of probabilities. Consequently, the WADA TUEC upholds the decision of the USADA TUEC.*"

27. The WADA TUEC Decision contained the following "*Analysis*" and "*Reasons*":

"***D. Analysis***

The 37-year old male professional athlete (triathlon and Ironman) experienced an

acute respiratory infection, probably of viral origin (maybe with an added bacterial infection) and the description of his condition and clinical signs suggests a component of bronchoconstriction related to this infection.

From the records, the Athlete had previous normal expiratory flows, no previous diagnosis of asthma and there was no measurement of lung function during the infectious episode. There is a possibility however that it was an asthma exacerbation in a probable mild asthmatic subject, but the diagnosis remained unproven.

In such an "acute" case of bronchoconstriction, considering probable diagnoses based on the Physician's description, a fast-acting bronchodilator and an anti-inflammatory treatment with an inhaled corticosteroid (ICS) or an oral (if the underlying airway obstruction was considered severe) glucocorticoid would be a standard treatment protocol.

The glucocorticoid treatment was correctly prescribed. However, the Physician gave the Athlete Breo Ellipta, a combination of ICS (fluticasone furoate) and vilanterol. The bronchodilator vilanterol is not considered a fast-acting "reliever" and it is also a prohibited drug as per the WADA List of Prohibited Substances and Methods. Either salbutamol or formoterol could have been prescribed, together with an inhaled glucocorticoid. Indeed, Breo Ellipta is not indicated for the relief of acute bronchospasm. The FDA approved monograph (USA) says: Important limitation: Not indicated for relief of acute bronchospasm.

In the documents submitted, the Athlete's Physician states that a sample of Breo Ellipta was offered to the Athlete to favor adherence to the treatment in an acute situation and to avoid the co-payment of the drug.

The argument that once-daily medication, when available, is the standard of care to treat acute and urgent illness, is not in keeping with current national and international guidelines. There are no specific guidelines for such acute events in athletes and the general consensus is that for the athlete population, current general guidelines apply, taking into account the prohibited agents (such as vilanterol and terbutaline, for example).

While it has been estimated that the cost to the patient for either a generic or brand named inhaler of vilanterol plus fluticasone would be between $5-$50, this cost should never influence a decision to use a prohibited substance.

The Physician, in this case, did not consider available permitted alternatives. In fact she stated that she was unaware that other agents were allowed.

The Athlete continued his therapy with a prohibited medication despite the TUE denial, and the Physician did not consider changing medication to a permitted beta-2 agonist.

In summary, the Athlete, suffering from an acute respiratory illness, sought urgent medical assistance from an appropriate medical specialist. His Physician chose to use a combined preparation of inhaled vilanterol and fluticasone as her standard protocol for the acute management of bronchospasm, in this case secondary to probable viral infection. It would appear that at this time the attending Physician was not aware that alternative permitted medication options were available. The TUE request was declined in a reasoned statement. The Athlete, a mature international competitor subject to anti-doping rules, accepted the decision of his Physician despite being informed that he was using a prohibited medication. Despite the availability of permitted alternative drugs, the Athlete continued to use the prohibited substance. Despite a request to the Physician for additional endorsement for the use of the prohibited substance, no convincing evidence was provided and indeed, the drug chosen is contraindicated for the treatment of acute bronchoconstriction. Subsequently the Athlete returned an AAF for the use of a prohibited beta-2 agonist in the absence of

a valid TUE.

E. Reasons

Pursuant to ISTUE Article 4.1, an athlete may be granted a TUE if they can demonstrate, on a balance of probabilities, that all of the conditions listed in ISTUE Article 4.1 have been met.

a) ISTUE Article 4.1(a)

On the basis of the Athlete's medical file, the WADA TUEC considers that it has been established that the Athlete suffers from an acute respiratory infection with bronchoconstriction. In coming to this conclusion, the WADA TUEC is of the view that the Athlete's medical file contains sufficient evidence to support the diagnosis of respiratory infection with secondary bronchoconstriction. Bronchoconstriction was not verified by standard measurements of respiratory function, but based on typical clinical signs. The diagnosis was made by a specialist respiratory physician.

The WADA TUEC considers that if a beta-2 agonist inhaler were withheld, the Athlete would experience a significant impairment to health. Indeed, if the Athlete were to stop using a beta-2 agonist, in combination with either inhaled or systemic glucocorticoids he would risk worsening of bronchoconstriction in this case provoked by a probable viral infection.

Therefore for the reasons mentioned above, the WADA TUEC considers that the Athlete has discharged his burden of proof in relation to ISTUE Article 4.1(a).

b) ISTUE Article 4.1(b)

In the WADA TUEC's opinion, and on the basis of the analysis discussed above, the Athlete has established that it is highly unlikely that he would benefit from any additional enhancement of their performance beyond what might be anticipated by a return to a normal state of health following the treatment of respiratory infection with bronchoconstriction.

The WADA TUEC comes to this conclusion on the basis that there is no evidence of performance enhancement by a one-month treatment with therapeutic doses of inhaled beta-2 agonists. Treatment of bronchoconstriction with therapeutic doses of a beta-2 agonist is essential in the restoration of normal pulmonary function.

For the reasons mentioned above, the WADA TUEC considers that the Athlete has discharged his burden of proof in relation to ISTUE Article 4.1(b).

c) ISTUE Article 4.1(c)

In the WADA TUEC's view, there are reasonable alternatives to the use of vilanterol to treat brochoconstriction. Indeed, vilanterol is contraindicated in acute bronchoconstriction whereas a fast-acting beta-2 agonist is the appropriate alternative based on clinical guidelines. Importantly, there are permitted fast-acting beta-2 agonists such as salbutamol (albuterol) and formoterol. These permitted alternatives are accepted first-line choices in the management of acute bronchoconstriction in situations demanding urgent intervention. The urgency of the situation was stressed by the attending Physician in her letter. The WADA TUEC considers that reasonable alternatives such as salbutamol and formoterol exist and that the Athlete should have used one of these appropriate medications instead of vilanterol, in association with the glucocorticoid therapy. The prohibited substance [vilanterol] was used when suitable permitted alternatives of equal efficacy were available but were not used, considered nor excluded by clinical evidence.

For the reasons mentioned above, the WADA TUEC considers that the Athlete has failed to discharge his burden of proof in relation to ISTUE Article 4.1(c).

Since the WADA TUEC does not consider that ISTUE Article 4.1(c) has been satisfied, there is no need for the WADA TUEC to provide any further analysis of ISTUE Article 4.1(d) in light of the fact that all of the criteria listed in ISTUE Article 4.1 must be satisfied in order to grant a TUE."

III. PROCEDURE BEFORE THE COURT OF ARBITRATION FOR SPORT

28. On 27 March 2020, the Athlete filed a statement of appeal with the Court of Arbitration for Sport ("CAS") against USADA and the WTC pursuant to Article R47 *et seq.* of the Code of Sports-related Arbitration (the "Code"), challenging the denial of his TUE application for Breo. The statement of appeal cited the WTC and USADA as Respondents and contained the indication that the Parties had agreed to designate Professor Luigi Fumagalli as Sole Arbitrator.

29. On 7 April 2020, the Athlete filed his appeal brief, together with a bundle of documents, the witness statement of Dr Anita Shah and the expert reports of Dr Jeremy Topin and of Dr Bhaven Shah.

30. On 8 May 2020, the CAS Court Office informed the Parties, on behalf of the President of the CAS Appeals Arbitration Division, that Prof. Luigi Fumagalli had been confirmed as Sole Arbitrator.

31. On 20 May 2020, WTC requested an order dismissing it from the proceedings. Counsel for WTC indicated that he had been authorized by counsel for the Athlete and for USADA to state that they did not have any objection to WTC's request. In the same letter, in any case, WTC declared that it agrees to recognize and be bound by the final award rendered in this CAS arbitration.

32. On 25 May 2020, the CAS Court Office, noting that no objection had been made to the WTC's request, confirmed that WTC was dismissed from this procedure. At the same time, the CAS Court Office advised the Parties that the Sole Arbitrator, at the Parties' request, decided to hold a hearing by video-conference on 24 June 2020.

33. On 29 May 2020, following agreed-upon extensions of time, the Respondent filed with the CAS Court Office its answer pursuant to Article R55 of the Code. The Respondent's answer attached, in addition to a group of documents, an expert report signed by Dr Kerlan Wolsey, as well as the designation as witnesses, in addition to Dr Wolsey, of Dr Matthew Fedoruk and of Mr Richard Mohr.

34. On 12 June 2020, the Respondent filed with the CAS Court Office an executed copy of a stipulation dated 10 June 2020 narrowing the disputed issues in this arbitration.

35. On 17 June 2020, the CAS Court Office, on behalf of the Sole Arbitrator, issued an order of procedure (the "Order of Procedure"), which was accepted and

countersigned by the Parties. The Order of Procedure confirmed, *inter alia*, the CAS jurisdiction to hear the appeal brought by the Athlete.

36. On 23 and 24 June 2020, the Appellant and Respondent, respectively, filed further exhibits in support of their written submissions.

37. A hearing was held by video conference on 24 June 2020 on the basis of the Parties' agreement and the notice given in the letter of the CAS Court Office dated 25 May 2020. The Sole Arbitrator was assisted at the hearing by Mr Brent J. Nowicki, Managing Counsel to the CAS.

38. The Sole Arbitrator was joined at the hearing by the following:

i. for the Appellant: by the Athlete in person, and by Mr Howard L. Jacobs and Ms Lindsay S. Brandon;

ii. for the Respondent: by Mr William Bock III, Mr Jeff Cook, Mr Ted Koehler, Ms Rachel Sayer-Tai, Ms Chelsea Busa, Mr Aaron Mojarras.

39. At the hearing, the Parties made submissions in support of their respective cases. The Sole Arbitrator heard the depositions on direct, cross and re-direct examination of Dr Jeremy Topin and Dr Kerlan Wolsey as experts, and of Dr Anita Shah, Dr Jill Starykowicz and the Appellant as witnesses. USADA renounced to the deposition of Dr Matthew Fedoruk and Mr Richard Mohr. The experts and the witnesses who had submitted a written report or statement confirmed its content. Dr Jeremy Topin and Dr Kerlan Wolsey were also given the opportunity to discuss their respective expert opinions by conferencing. In essence:[1]

- the experts stated their positions *inter alia* with respect to the administration of long-acting beta-agonists ("LABA") as opposed to the use of short-acting beta-agonists ("SABA") to treat the medical conditions of the Athlete, to the use of Vilanterol to treat Bronchospasm, to the characterization of the medical conditions of the Athlete as "acute" or "sub-acute", or as a "post-infectious cough";
- Dr Anita Shah testified regarding her background and expertise, her diagnosis and/or treatment of the Appellant and her reports that were submitted in connection with the Appellant's TUE applications;
- Dr Jill (Cwik) Starykowicz, the Appellant's wife as well as a pharmacist, testified as to the circumstances surrounding the Appellant's diagnosis and treatment for his respiratory illness, her knowledge of the TUE process, and her involvement in the applications for a TUE;
- the Appellant testified regarding his background and experience as an elite triathlete, the circumstances surrounding his respiratory infection and its treatment, his applications for a TUE, and his future competition schedule.

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1 The Sole Arbitrator emphasises that he considered the entirety of the declarations made at the hearing, even though no exhaustive summary of such declarations is set out in this Award.

40. At the conclusion of the hearing, the Parties confirmed that they had no objections in respect of their right to be heard and to be treated equally in the arbitration proceedings.

IV. THE POSITION OF THE PARTIES

41. The following outline of the Parties' positions is illustrative only and does not necessarily comprise every contention put forward by the Parties. The Sole Arbitrator, however, has carefully considered all the submissions made by the parties, even if there is no specific reference to those submissions in the following summary.

A. The Position of the Appellant

42. In his statement of appeal, the Appellant requested the CAS to rule as follows:

> "*1. That the appeal of Andrew Starykowicz is admissible.*
> *2. That the decision of the USADA TUE Committee be set aside.*
> *3. That Andrew Starykowicz is entitled to a TUE for the short-term use of Breo (fluticasone furoate and vilanterol inhalation powder) inhaler.*
> *4. That the TUE for the short-term use of Breo (fluticasone furoate and vilanterol inhalation powder) be granted from 25 October 2019, which was the effective date of the TUE which was granted for the use of methylprednisolone.*
> *5. That Respondents shall bear all costs of the proceedings, including a contribution toward Appellant's legal costs.*"

43. In the appeal brief, then, the Appellant slightly amended the relief requested and asked the CAS to rule as follows:

> "*1. That the appeal of Andrew Starykowicz is admissible.*
> *2. That the decision of USADA (and WADA) be set aside.*
> *3. That Andrew Starykowicz is entitled to a one-time TUE for the use of a Breo inhaler to treat an acute viral respiratory infection, with an effective date no later than 25 October 2019.*
> *4. That Respondents shall bear all costs of the proceedings including a contribution toward Appellant's legal costs.*"

44. In support of his position, the Appellant underlines that his case does not concern the commission of an anti-doping rule violation, but concerns the denial of a TUE for a product (a Breo inhaler disk) prescribed by his pulmonologist for a severe viral illness. USADA accepted the accuracy of the diagnosis; agreed that withholding the medication would have impaired his health; and agreed that the Vilanterol in the Breo inhaler, as used by the Athlete, would not have provided any performance enhancement. Therefore, the only question in this case is whether the Athlete could have treated his medical condition with another non-performance-enhancing beta-2 agonist that was not prohibited by WADA. The Athlete was prescribed Breo for a serious viral infection of the lungs, not asthma, yet both USADA and WADA based their TUE denials as though he was being treated for asthma. However, the Athlete needed and used

the Breo inhaler only for one purpose: to help him recover from his severe viral illness. In the Appellant's opinion, therefore, his TUE for Vilanterol should have been approved. The decisions issued by the USADA TUEC and the WADA TUEC that held otherwise should be set aside.

45. In more detail, the Athlete submits that all of the four criteria of Article 4.1 of the ISTUE for the issuance of the requested TUE for Vilanterol were satisfied.

46. Preliminarily, however, the Appellant remarks that the comment to Article 4.1 1 of the ISTUE clarifies that the WADA documents titled "*Medical Information to Support the Decisions of TUECs*" should be used to assist in the application of these criteria in relation to particular medical conditions. Yet, WADA does not provide medical information for every medical condition. According to the Appellant, where there is no WADA guideline for a particular medical condition, it would be inappropriate to simply apply a WADA guideline for a different condition merely because the medication prescribed is also used to treat that other condition. In this case, the fact that Breo is used to treat asthma does not make the WADA TUE Physician Guidelines on Asthma applicable to Dr Shah's treatment of the Appellant's severe viral illness, which was treated with Medrol and Breo.

47. With respect to the specific criteria relevant under the ISTUE, the Appellant submits the following:

    i. as to Article 4.1(a) of the ISTUE, the Appellant notes that USADA, despite its initial denial that Article 4.1(a) had been satisfied, finally conceded on 14 January 2020 that the Athlete "*did have a confirmed diagnosis of mucopurulent bronchitis and possible viral pneumonitis*". Then, the WADA TUEC Decision directly confirmed that the Athlete had discharged his burden of proof in relation to Article 4.1(a) of the ISTUE;

    ii. as to Article 4.1(b) of the ISTUE, the Appellant contends that, in its 14 January 2020 letter, USADA did not address the relevant issue of whether the Appellant's use of therapeutic doses of Breo for 4 weeks to treat his acute respiratory infection with bronchoconstriction would produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health. That issue was addressed then in the WADA TUEC Decision, which concluded that the Athlete had discharged his burden of proof in relation to ISTUE Article 4.1(b);

    iii. as to Article 4.1(c) of the ISTUE, the Appellant disputes the conclusions reached in the USADA TUEC Decision and in the WADA TUEC Decision, because, contrary to their indications, the only thing that the Athlete was required to establish (on a balance of probability) in order for his TUE for Breo to be approved was that there was no reasonable therapeutic alternative available to treat his condition. This requirement was met because:

        - Dr Shah never diagnosed the Athlete with asthma, and therefore there were no specific guidelines to extrapolate based upon the

WADA medical information;

- two independent experts, specialists in pulmonary disease, have confirmed that Dr Shah's treatment plan was consistent with best practices for a respiratory diagnosis of viral induced bronchoconstriction;
- the Athlete immediately consulted with USADA, which told him to go ahead and file a TUE request for his medications. At no point was he told that he should use alternative medications, despite the fact that the Athlete needed immediate medical treatment;
- as explained by Dr Jeremy Topin, the use of Breo to treat the Appellant's condition was not contraindicated, as asserted by USADA and WADA;
- the conclusion that Article 4.1(c) was not met on the basis that there were permitted SABAs (such as Salbutamol/Albuterol) available as therapeutic alternatives ignores several factors:
  - the Athlete was not diagnosed with, nor suffering from, asthma;
  - the Athlete consulted with USADA immediately after his appointment with Dr Shah, before he submitted his TUE application;
  - Breo was readily available for Dr Shah to prescribe and demonstrate use of to the Athlete. Furthermore, Breo was prescribed to ensure compliant use of the medication (Breo's one per day use inherently makes it a better option for patients);
  - the Athlete did in fact discuss the use of an Albuterol rescue inhaler with Dr Shah to supplement his use of Breo. As explained by Dr Shah, she did not prescribe the Athlete with an albuterol inhaler because he indicated that he already had inhalers at home that were prescribed for his son;
  - the Athlete researched the prescription options on the WADA website with Dr Shah, and further considered those options with his wife (who is herself a pharmacist) and decided to move forward with the use of Breo because it was the best option for his condition;
  - as explained by Dr Topin, a LABA with quick action onset combined with an inhaled Corticosteroid (such as in Breo) was a more appropriate treatment than Albuterol; Breo was a more appropriate treatment than Advair, because it is faster acting; and the once a day use of Breo made it a better treatment option than Symbicort, despite the fact that both USADA and WADA have discounted the importance of treatment compliance;

iv. as to Article 4.1(d) of the ISTUE, the Appellant notes the condition thereby posed was never addressed. In any case, there is no evidence that

the Appellant previously used any prohibited substance.

48. In summary, the Athlete met his burden of proving that he was entitled to a TUE for the short-term use of a Breo inhaler; and USADA erred in its repeated denial of that TUE. As a result, since the conditions established were satisfied, there is no discretion to be exercised and a TUE should be granted for Vilanterol, with an effective date no later than 25 October 2019, *i.e.* the date on which USADA approved the TUE for Methylprednisolone.

B. The Position of the Respondent

49. In its Answer, the Respondent submitted that:

i. *Appellant's appeal should be dismissed*;

ii. *Appellant should be required to pay all costs of this CAS proceeding*"; and

iii. *USADA should be awarded a contribution towards its legal fees and other expenses incurred in connection with the proceedings.*

50. In essence, the Respondent contends that the appeal should be dismissed because the Appellant is unable to establish that the decisions of the USADA TUEC and of the WADA TUEC to deny his application for a TUE for Breo (Vilanterol) were without basis. According to the Respondent, it is not sufficient for the Appellant to identify experts who state that his physician's choice to give him Breo (Vilanterol) was reasonable, or even that that product was the best choice under the circumstances of his case: the Appellant has the burden to prove that he satisfied each of the criteria necessary to obtain a TUE for Vilanterol, but failed to carry it. On the contrary, the evidence demonstrates that the decisions rendered by the WADA and USADA TUEC, whose members are top practitioners in the relevant field of medicine, were rational and supported by the medical evidence, and are entitled to substantial deference. Therefore, they should be confirmed.

51. In support of this contention, the Respondent first underlines three preliminary points:

i. most of the submissions advanced by the Appellant are irrelevant for the decision in this appeal based on denials by USADA and WADA for his TUE application. For instance, the Appellant's past testing background, his Twitter announcement concerning why he withdrew from the Ironman World Championships, his personal consultation of Global DRO, his personal observations and conclusions regarding what he believed was permissible and what he believed was not permissible, the advice the Appellant received from his wife regarding his use of medications, when the Appellant began using the Breo inhaler, his consultations with USADA about competing while using the Breo inhaler, his participation in the Ironman Florida competition while using the Breo inhaler, when he finished using the Breo inhaler, the Appellant's notification of his positive drug test from WTC, and when and why WTC charged the Appellant with

an ADRV, are all facts which may be relevant in an Appellant's later case involving his anti-doping rule violation on the question of his degree of fault. They are not relevant in this case challenging the decisions of the TUECs. Likewise, the reports of the Appellant's experts and the witness statement of the Appellant's treating physician contain a number of assertions about why the prescription of Breo (Vilanterol) was allegedly reasonable, such as that Appellant's physician had free samples readily available in her office, or that it might be more conducive to the Appellant's compliance than other drugs because Vilanterol needed to be used only once a day. These matters, which go to the reasonableness of the Appellant's conduct and that of his doctor, are also irrelevant to this TUE appeal. In this case, there are no issues regarding the Appellant's degree of fault, sanction length, and/or whether he committed an anti-doping rule violation: this case should be narrowly focused only upon whether the decisions of the WADA and USADA TUECs to deny the Appellant's application to use Vilanterol in sport should be upheld, and whether Appellant can prove he is entitled to a TUE;

ii. as recognized in the CAS jurisprudence (and principally in the awards in CAS 2004/A/717, *International Paralympic Committee v. Brockman & WADA*, and in CAS 2016/A/4772, *Dominguez v. FIA*), in light of the expert medical judgment that the TUEC embodies, on appeal the reasoned medical judgment of a TUEC is entitled to deference and the role of the CAS Panel is not that of substituting itself for the TUE Committee. Even though a CAS Panel has full power and authority in exercising its appellate jurisdiction to review both facts and law, that power is not undercut by an appellate standard that affords due weight to the expertise of the TUEC whose decision is challenged. As a result, USADA submits that, consistent with the *Brockman* and *Dominguez* cases, the Sole Arbitrator should give the medical judgments made by the WADA and USADA TUECs deference. In other words, the Sole Arbitrator should not merely substitute his judgment (or the judgment of other medical practitioners) for the decisions of the two TUECs which considered Appellant's TUE applications, so long as those decisions were reasonable. As the *Brockman* Panel stated, where the TUEC has made a reasonable medical judgment, TUEC's decision should not be supplanted by substituting the Panel's judgment (or that of an athlete's medical expert) where the athlete cannot establish that the TUEC's decision was inconsistent with law, arbitrary, an abuse of discretion, grossly disproportionate, irrational, or in bad faith;

iii. the Appellant challenged both the decisions of the USADA TUEC and of the WADA TUEC to deny his application for a TUE for Vilanterol. Therefore, the Appellant's appeal can only be upheld if both the decision of the WADA TUEC and the decision of the USADA TUEC are overturned. In addition, the Appellant must carry the burden of establishing that each element of Article 4.1 of the ISTUE has been established, regardless of whether or not his TUE application was previously denied on that basis.

52. The Respondent, then, explains why, in its opinion, the Appellant has failed to prove that he satisfied each of the criteria necessary to obtain a TUE for Breo (Vilanterol):

    i. the Appellant is unable to establish that he satisfies the condition under Article 4.1(a) of the ISTUE, *i.e.* that Breo (Vilanterol) was required to treat "*an acute ... medical condition*". Indeed, the USADA TUEC noted that Vilanterol "*is not indicated for urgent, acute respiratory disorders but rather is used as a medication for long-term condition management*", and therefore concluded that the Appellant's TUE application did not satisfy Article 4.1(a) ISTUE. Then, the USADA TUEC, while it acknowledged that the Appellant had been diagnosed with an acute health condition, pointed out that a SABA should have been used instead of Vilanterol (a LABA). The point is also confirmed by Dr Kerlan Wolsey in his expert report. The WADA TUEC Decision does not contradict the conclusions of the USADA TUEC or Dr Wolsey. Instead, the WADA TUEC merely stated that "*if a beta-2 agonist inhaler were withheld, the Athlete would experience a significant impairment to health.*" Thus, under Article 4.1(a) of the ISTUE, the WADA TUEC simply did not consider the distinction between a LABA, which was prohibited, and a SABA, which was not prohibited, and also happened to be the first-line, standard of care treatment for Appellant's condition;

    ii. the Appellant is unable to establish that he satisfies the condition under Article 4.1(c) of the ISTUE. In fact, there were one or more reasonable therapeutic alternatives to the use of Vilanterol, as found by both the USADA TUEC and the WADA TUEC, because SABAs, such as Albuterol or Formoterol, in combination with Methylprednisolone (for which Appellant's TUE was approved), were available to treat his condition. Dr Wolsey agrees with this conclusion. In response, Appellant's experts side-step the issue of whether reasonable alternative treatments existed, and do not directly address the relevant question, which is not what the best available medication was, but whether reasonable therapeutic alternatives existed, and whether the Appellant could have been treated with non-prohibited medications. In short, the USADA TUEC, WADA TUEC, and USADA's expert, Dr Wolsey, all agree on this fundamental point: the Appellant could have been properly treated with Methylprednisolone and one or more non-prohibited medications. This conclusion, on which apparently at least seven experts have agreed and as to which there is not clear disagreement from Appellant's experts, is sufficient alone to decide this case, mandating a determination that, pursuant to Article 4.1(c) ISTUE, the Appellant's request for a TUE was properly denied.

53. Initially, the Respondent submitted also that the Appellant is unable to establish that he satisfies the condition under Article 4.1(b) of the ISTUE. However, in its written stipulation dated 10 June 2020 (§ 34 above), USADA accepted the WADA TUEC Decision that Vilanterol is not performance enhancing for the purposes of Article 4.1(b) of the ISTUE. In its stipulation, USADA underlined

that its conclusion not to pursue issues in this regard was only intended to avoid complications and expenses related to additional experts, and was limited only to the present case.

V. JURISDICTION

54. Pursuant to Article 4.4.7.2 of the Ironman ADR:

> "*Any TUE decision by WTC (or by a National Anti-Doping Organization where it has considered the application on behalf of WTC) ... that is reviewed by WADA but is not reversed upon review, may be appealed by the Athlete and/or the Athlete's National Anti-Doping Organization exclusively to CAS, in accordance with Article 13.*"

55. Article 13.4 of the Ironman ADR then provides that:

> "*TUE decisions may be appealed exclusively as provided in Article 4.4.*"

56. Neither Party objected to CAS jurisdiction, and indeed confirmed such jurisdiction when signing the order of procedure. The Sole Arbitrator confirms, therefore, that the CAS has jurisdiction to decide the present dispute between the Parties.

VI. ADMISSIBILITY

57. Article R49 of the Code provides as follows:

> *In the absence of a time limit set in the statutes or regulations of the federation, association or sports-related body concerned, or in a previous agreement, the time limit for appeal shall be twenty-one days from the receipt of the decision appealed against. The Division President shall not initiate a procedure if the statement of appeal is, on its face, late and shall so notify the person who filed the document. When a procedure is initiated, a party may request the Division President or the President of the Panel, if a Panel has been already constituted, to terminate it if the statement of appeal is late. The Division President or the President of the Panel renders her/his decision after considering any submission made by the other parties.*

58. The Appellant received notification of the WADA TUEC Decision on 6 March 2020. Pursuant to the notification letter from WADA, and consistent with Articles 4.4.7.2 and 13.6.1 of the Ironman ADR, the Athlete had 21 days to file an appeal to CAS. Therefore, his statement of appeal, submitted on 27 March 2020, was timely.

59. In addition, the statement of appeal complies with the requirements of Article R48 of the Code.

60. Accordingly, the Sole Arbitrator considers that the appeal is admissible.

VII. SCOPE OF REVIEW

61. According to Article R57 of the Code, the Sole Arbitrator has full power to review the facts and the law of the case. Furthermore, the Sole Arbitrator may

issue a new decision which replaces the decision challenged, or may annul the decision and refer the case back to the previous instance.

VIII. APPLICABLE LAW

62. Pursuant to Article R58 of the Code, the Panel is required to decide the dispute:

> "*according to the applicable regulations and, subsidiarily, to the rules of law chosen by the parties or, in the absence of such a choice, according to the law of the country in which the federation, association or sports-related body which has issued the challenged decision is domiciled or according to the rules of law, the application of which the Panel deems appropriate. In the latter case, the Panel shall give reasons for its decision*".

63. The Sole Arbitrator notes that in this case the WTC and WADA rules and regulations have to be applied, the former constituting an implementation by reference of the latter in the WADA system. On the other hand, the Sole Arbitrator was not directed to the application of any domestic law.

64. The WTC and WADA rules and documents relevant in this arbitration, or to which the Parties have referred to in their submissions, are the following:

i. Article 4.4 ["*Therapeutic Use Exemptions*"] of the Ironman ADR:

> *4.4.2 All Athletes Using or intending to Use a Prohibited Substance or Prohibited Method must seek a TUE from their National Anti-Doping Organization or Regional Anti-Doping Organization as applicable in accordance with the policies of those organizations. Athletes in the IRONMAN Registered Testing Pool must obtain a TUE before using a Prohibited Substance or Prohibited Method as provided in the International Standard for Therapeutic Use Exemptions. If permitted by their National Anti-Doping Organizations or Regional Anti-Doping Organizations, all other Athletes may seek to obtain a TUE retroactively.*
>
> *4.4.7 Reviews and Appeals of TUE Decisions*
>
> *4.4.7.1 WADA shall review any decision by WTC not to recognize a TUE granted by the National Anti-Doping Organization that is referred to WADA by the Athlete or the Athlete's National Anti- Doping Organization. In addition, WADA shall review any decision by WTC to grant or recognize a TUE that is referred to WADA by the Athlete's National Anti-Doping Organization. WADA may review any other TUE decisions at any time, whether upon request by those affected or on its own initiative. If the TUE decision being reviewed meets the criteria set out in the International Standard for Therapeutic Use Exemptions, WADA will not interfere with it. If the TUE decision does not meet those criteria, WADA will reverse it.*
>
> *4.4.7.2 Any TUE decision by WTC (or by a National Anti-Doping Organization where it has considered the application on behalf of WTC) that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon review, may be appealed by the Athlete and/or the Athlete's National AntiDoping Organization exclusively to CAS, in accordance with Article 13.*

ii. Article 4 ["*Obtaining a TUE*"] of the ISTUE:

4.1 An Athlete may be granted a TUE if (and only if) he/she can show, by a balance of probability, that each of the following conditions is met:

a. The Prohibited Substance or Prohibited Method in question is needed to treat an acute or chronic medical condition, such that the Athlete would experience a significant impairment to health if the Prohibited Substance or Prohibited Method were to be withheld.

b. The Therapeutic Use of the Prohibited Substance or Prohibited Method is highly unlikely to produce any additional enhancement of performance beyond what might be anticipated by a return to the Athlete's normal state of health following the treatment of the acute or chronic medical condition.

c. There is no reasonable Therapeutic alternative to the Use of the Prohibited Substance or Prohibited Method.

d. The necessity for the Use of the Prohibited Substance or Prohibited Method is not a consequence, wholly or in part, of the prior Use (without a TUE) of a substance or method which was prohibited at the time of such Use.

IX. MERITS OF THE DISPUTE

65. The dispute submitted to the Sole Arbitrator concerns the denial of a TUE for the use by the Athlete of an otherwise prohibited substance, a Beta-2 Agonist, falling in Section S.3 of the Prohibited List in force, pursuant to the WADC and the Ironman ADR, at the time of the request (and nowadays). The WADA TUEC, acting on review of a decision of USADA, confirmed the denial of the TUE requested by the Appellant. The Appellant contends that he is entitled to such TUE, since all conditions prescribed by the relevant rules have been satisfied. USADA, on the other hand, seeks the confirmation of the denial of the Athlete's TUE application for Vilanterol.

66. The question of whether a TUE should be granted arose with respect to the medical prescription and use of Breo, a medicine combining an inhaled Corticosteroid (Fluticasone Furoate) and a LABA (Vilanterol) by the Athlete. Breo, according to the FDA Prescribing Information, is a long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease, and for once-daily treatment of asthma in patients aged 18 years or older. In more detail, a one-month course of Breo was prescribed to the Athlete by his treating physician for once daily use, together with a course of 5 days of Medrol, a medicine containing Methylprednisolone, which is a Glucocorticoid. As Methylprednisolone, administered orally, and Vilanterol are prohibited substances, they needed a TUE for their use. No TUE, on the other hand, was necessary for inhaled Fluticasone Furoate (a Glucocorticoid combined with Vilanterol in Breo). Methylprednisolone and Fluticasone Furoate are in fact prohibited (in-competition) only when administered by oral, intravenous, intramuscular or rectal routes.

67. The TUE was in essence denied by WADA because the WADA TUEC concluded that the condition set at Article 4.1(c) of the ISTUE had not been satisfied. Such WADA TUEC Decision was adopted on review of the USADA TUEC Decision, which had also found that the condition set at Article 4.1(a) of the ISTUE had not been met.

68. The satisfaction of those two criteria, *i.e.* of Article 4.1(a) and Article 4.1(c) of the ISTUE, is also the object of this arbitration. Indeed:

    i. the submissions initially advanced by USADA in its answer, denying the satisfaction of the condition set by Article 4.1(b) of the ISTUE, have been withdrawn in a written stipulation submitted by USADA on 12 June 2020 to narrow the disputed issues in this arbitration;

    ii. the presentation by USADA of contentions regarding the alleged non-fulfilment of the Article 4.1(a) condition did not require the filing by USADA of an appeal against the WADA TUEC Decision, which found that the Athlete had discharged the burden to prove the satisfaction of that condition. In fact, WADA confirmed and did not reverse upon review the denial of the TUE application submitted by the Athlete. As a result, the Sole Arbitrator finds it admissible for USADA to introduce in this procedure the relevant reasons to support its (and WADA's) decision to deny the application, and to oppose the Athlete's appeal;

    iii. as noted by the Comment to Article 4.4.7.2 of the Ironman ADR, in the event the decision rendered by the National Anti-Doping Organization (in the current case, USADA) is reviewed but not reversed by WADA, as in the present case, the decision being appealed is the decision of the National Anti-Doping Organization (in the current case, the USADA TUEC Decision). Therefore, all grounds (including the reference to Article 4.1(a) of the ISTUE) already offered by USADA in support of its decision to deny the TUE application could be submitted in the appeals proceedings brought against it.

69. The question before this Sole Arbitrator is, therefore, whether the prohibited substance in question (Vilanterol, as contained in Breo in combination with Fluticasone Furoate) was needed to treat an acute or chronic medical condition, such that the Athlete would experience a significant impairment to health if Breo was withheld (Article 4.1(a) of the ISTUE), and there was no reasonable therapeutic alternative to the use of Breo to treat the medical conditions of the Athlete (Article 4.1(c) of the ISTUE).

70. The examination of such issues involves the consideration of complex medical aspects, relating to the diagnosis of the health problems encountered by the Athlete and the identification of the relevant treatment. Those aspects have been considered by his physician, when she first visited him, and then provided the supporting documentation for the TUE application, by the qualified members of the USADA TUEC and of the WADA TUEC, and by the experts brought by the Parties (Dr Topin and Dr Wolsey) in this arbitration and heard at the hearing.

71. In such framework, the Sole Arbitrator, who enjoys a full power to review the facts and the law, can only base his decision on the Parties' submissions, as also substantiated by the relevant evidence and expert opinions, to determine whether the Athlete has satisfied the burden he bears to prove on balance that all the conditions for the grant of the TUE have been satisfied. In other words, the medical evaluations on file have to be assessed by the Sole Arbitrator in the exercise of his free appreciation of the available evidence and framed into a legal mechanism to reach a conclusion regarding the TUE application.

72. The Sole Arbitrator notes that the conditions set by Article 4.1(a) and by Article 4.1(c) of the ISTUE raise different questions: the first, implied by Article 4.1(a), regards the prohibited substance in itself, and requires an assessment of its impact on the medical conditions of the Athlete, of need of the substance to treat them and of the consequences of its withdrawal; the second, implied by Article 4.1(c), involves a comparison of the substance for which the TUE is sought with other substances, and chiefly with not prohibited substances, to verify the absence of reasonable therapeutic alternatives. Those aspects need not be conflated: a finding that a substance is a proper (if not the most proper) treatment of a disease (which would satisfy Article 4.1(a) of the ISTUE) does not rule out the existence of reasonable alternatives (which must be excluded for the purposes of Article 4.1(c) of the ISTUE).

73. On such basis, the Sole Arbitrator can agree with the Appellant and the WADA TUEC that the condition set by Article 4.1(a) of the ISTUE was met. At the same time, however, the Sole Arbitrator concludes, contrary to the Athlete's contention, that the condition set by Article 4.1(c) of the ISTUE was not satisfied, as held by the USADA TUEC Decision and confirmed by the WADA TUEC Decision.

74. Much discussion occurred at the hearing about the characterization of the Athlete's condition, at the time he was visited by Dr Anita Shah, as "acute" or "sub-acute". While at the hearing a consensus appeared to emerge as to their description as "sub-acute", the Sole Arbitrator notes that Dr Shah, an expert physician, with a remarkable CV, described, in a letter to USADA of 21 November 2019, the illness of the Athlete as "acute". Such reference was made also in a letter of 20 December 2019. In the same documents, Dr Shah referred to "*wheezing suggestive of bronchoconstriction*", possibly caused by viral infection, requiring the administration of a beta-andregenic-agent, such as Villanterol, prescribed to treat "*post-infectious cough*". Dr Wolsey, the USADA expert in this arbitration, and Dr Topin, the Athlete's expert, agreed in their expert report with the conclusion of "*respiratory infection with secondary bronchoconstriction*".

75. The Sole Arbitrator notes that Breo, according to the FDA Prescribing Information, is "*not indicated for relief of acute bronchospasm*". Such indication would appear to speak against the appropriateness to treat an "*acute illness*" involving symptoms "*suggestive of bronchoconstriction*", as the Athlete's medical conditions were initially described by his treating physician. The Sole Arbitrator, however, notes that at the hearing a further consensus

emerged that Breo is often used "off-label" to treat "*secondary bronchoconstriction*". In addition, Dr Wolsey conceded that the Athlete would have suffered significant impairment to his health if a beta-2 agonist was withdrawn. The objections advanced by Dr Wolsey in that context, that a SABA should have been prescribed instead of Vilanterol, appear more focussed on the existence of an alternative therapy, than to exclude the suitability of Breo to avoid a significant health impairment. In general term, the WADA TUEC's observation that, if the Athlete was withheld the use of a beta-2 agonist (be that a LABA or a SABA), in combination with either inhaled or systemic Glucocorticoids, he would have risked worsening of bronchoconstriction provoked by a probable viral infection, can be accepted.

76. Therefore, for the reasons mentioned above, the Sole Arbitrator considers that the Athlete has discharged his burden of proof in relation to Article 4.1(a) of the ISTUE.

77. As noted above, however, the circumstance that Breo was a viable (if not the most appropriate) treatment for the Athlete's conditions, consistent with best practices for a respiratory diagnosis of viral induced bronchoconstriction, does not imply that no reasonable alternatives existed, and subsequently, that the Athlete implicitly discharged his burden of proof also in relation to the condition set by Article 4.1(c) of the ISTUE.

78. In that regard, the Sole Arbitrator notes that the Athlete advanced a number of reasons in support of his contention that other therapeutic alternatives were not reasonable:

- Breo was readily available for Dr Shah to prescribe and demonstrate its use to the Athlete;
- the immediate availability of Breo, supplied by Dr Shah to the Athlete, allowed him to avoid a co-payment for the purchase;
- Breo is to be used once daily, and therefore better ensures compliance by the patient than other products requiring a twice-a-day administration;
- the Athlete researched the prescription options on the WADA website with Dr Shah, and further considered those options with his wife (who is herself a pharmacist), but found that these possible alternatives were also subject to use restrictions and therefore decided to move forward with the use of Breo because it was the best option for his conditions;
- Dr Shah did not prescribe the Athlete with an Albuterol rescue inhaler, because he indicated that he already had inhalers at home that were prescribed for his son;
- a LABA with quick action onset combined with an inhaled Corticosteroid (such as in Breo) was a more appropriate treatment than Albuterol; Breo was a more appropriate treatment than Advair, because it is faster acting; and the once-a-day use of Breo made it a better treatment option than Symbicort.

79. According to Article 4.1(c) of the ISTUE, the Athlete may be granted a TUE if (and only if) he can show, by a balance of probability, that there is no reasonable therapeutic alternative to the use of the prohibited substance in question. In other words, the Athlete is not required to show that no therapeutic alternatives exist, but only that the existing alternative therapies are not reasonable, taking into account *inter alia* the nature of the alternative substance to be used (*e.g.*, whether it is prohibited or not), and the respective therapeutic impact on the medical conditions to be treated. Additional elements, such as cost, availability, and easiness of use can be also considered.

80. As already noted, the Sole Arbitrator finds that the Athlete has not discharged the burden he had to prove, on balance, that the existing alternative therapies, as suggested by USADA, are not reasonable.

81. The main issue, as discussed in this arbitration, and explored at length at the hearing, concerns the use of a SABA, such as Albuterol/Salbutamol, or of not prohibited LABAs, such as Formoterol or Salmeterol, to treat the Athlete's medical conditions in alternative to Breo. Dr Wolsey, the USADA expert, submitted that a SABA was better indicated than a LABA (such as Vilanterol). Dr Topin, the expert for the Athlete, disputed such contention and explained that in his opinion a SABA (indicated for rescue purposes) was not a reasonable therapeutic alternative for the sub-acute condition of the Athlete.

82. The Sole Arbitrator notes that Albuterol/Salbutamol (Ventolin) is a SABA not prohibited up to a maximum 1,600 mcg over 24 hours, in divided doses not exceeding 800 over 12 hours from any dose. The FDA Prescribing Information reports that Ventolin is indicated also for treatment or prevention of bronchospasm. As a result, it does not appear to be an unreasonable alternative to Vilanterol.

83. If, however, the indications of Dr Topin are to be followed, and a LABA was to be used (primarily if combined with an inhaled Corticosteroid) as a more reasonable therapeutic option for the Athlete, the Sole Arbitrator notes that other products were available, also combining a not prohibited LABA with an inhaled Corticosteroid. For instance:

- Advair Diskus is an inhalation product combining a LABA (Salmeterol) and a Corticosteroid (Fluticasone Propionate), indicated for maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease. Salmeterol is not prohibited for a dose of up to 200 mcg over 24 hours;
- Symbicort is an also inhalation product combining Formoterol (a LABA) and Budesonide (a Corticosteroid), indicated mainly for asthma, but also for maintenance in patients with chronic obstructive pulmonary disease. Formoterol is not prohibited for a dose of up to 54 mcg over 24 hours;
- Foradil Aerolizer is an inhalation also containing Formoterol. It is not a combination with a Corticosteroid, but is indicated for maintenance treatment of bronchoconstrictions in patients with chronic obstructive

pulmonary disease.

84. The Sole Arbitrator, having considered the experts' submissions, finds that those products were not unreasonable alternatives in terms of therapeutic indications and effects, consistent with the anti-doping rules, to the use of Breo. Dr Topin indeed indicated that Breo was a more appropriate choice, given its much quicker onset of action compared to Advair. However, such indication does not imply that the use of Advair was not reasonable. At the hearing, Dr Topin also conceded that, in the absence of Breo, Advair would have been a good therapeutic option.

85. The Sole Arbitrator remarks that the other factual indications offered by the Appellant to support his indication that there were no reasonable alternatives to Breo do not lead to a contrary conclusion:

- the fact that Breo was readily available for Dr Shah to prescribe and to demonstrate its use to the Athlete does not imply that the Athlete could not have easy access to, for instance, Advair. In addition, the Athlete could take advantage, for a demonstration of a careful use, of the experience of his wife, a pharmacist;
- there is no indication that the cost of alternative products was unreasonable;
- the Athlete is a top-level competitor, was suffering from a "*severe illness*" (as indicated by his physician to USADA on 23 October 2019), and was wishing to recover to return to training and competition. Issues of compliance, which would have made Breo, to be used once daily, a better option for common patients compared to products requiring a twice-a-day administration, appear to be marginal in the Athlete's circumstances;
- a cursory research regarding alternative LABAs would have shown that the use restrictions for Albuterol/Salbutamol, Formoterol and Salmeterol allowed proper treatment consistent with the respect of the anti-doping rules;
- the availability at home of a rescue inhaler (to be used with Albuterol/Salbutamol), prescribed for his son, speaks more in favour of a prescription for its use, and not against it.
- The Athlete is highly experienced and did not dispute that he was fully aware of his anti-doping obligations. In this moment in time, however, the Athlete walked blindly with confidence that a TUE would be granted. Logic would have been to seek further guidance or proceed with an alternative LABA in the short term until further confirmation was obtained on the use of Breo.

86. In summary, the Athlete has not proved that the existing alternative therapies suggested by USADA were not reasonable

87. In the light of the foregoing, the Sole Arbitrator holds that the appeal has to be

dismissed and that the denial of the TUE application for Vilanterol confirmed.

X. COSTS

88. Article R64.4 CAS Code provides the following:

> "*At the end of the proceedings, the CAS Court Office shall determine the final amount of the cost of arbitration, which shall include:*
> - *the CAS Court Office fee,*
> - *the administrative costs of the CAS calculated in accordance with the CAS scale,*
> - *the costs and fees of the arbitrators,*
> - *the fees of the ad hoc clerk, if any, calculated in accordance with the CAS fee scale,*
> - *a contribution towards the expenses of the CAS, and*
> - *the costs of witnesses, experts and interpreters.*
>
> *The final account of the arbitration costs may either be included in the award or communicated separately to the parties. The advance of costs already paid by the parties are not reimbursed by the CAS with the exception of the portion which exceeds the total amount of the arbitration costs.*"

89. Article R64.5 CAS Code provides as follows:

> "*In the arbitral award, the Panel shall determine which party shall bear the arbitration costs or in which proportion the parties shall share them. As a general rule and without any specific request from the parties, the Panel has discretion to grant the prevailing party a contribution towards its legal fees and other expenses incurred in connection with the proceedings and, in particular, the costs of witnesses and interpreters. When granting such contribution, the Panel shall take into account the complexity and outcome of the proceedings, as well as the conduct and the financial resources of the parties.*"

90. Having considered the outcome of the arbitration, the Sole Arbitrator finds that the costs of the arbitration, in an amount that will be determined and notified to the Parties by the CAS Court Office, shall be borne in full by the Athlete.

91. Furthermore, pursuant to Article R64.5 CAS Code and in consideration of the complexity and outcome of the proceedings as well as the conduct and the financial resources of the Parties and the efficiency in which the procedure was held (both Parties agree to a video hearing), the Sole Arbitrator rules that both Parties shall bear their own legal fees and other expenses incurred in connection with the present arbitration proceedings.

ON THESE GROUNDS

The Court of Arbitration for Sport rules that:

1. The appeal filed by Mr Andrew Starykowicz against the United States Anti-Doping Agency with the Court of Arbitration for Sport on 27 March 2020 is dismissed.

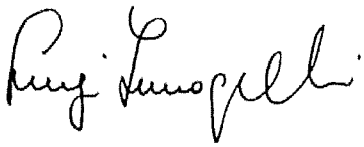
2. The costs of the arbitration, to be determined and served to the parties by the CAS Court Office, shall be borne by Mr Andrew Starykowicz.

3. Mr Andrew Starykowicz and the United States Anti-Doping Agency shall each bear their own legal and other expenses.

4. All other motions or prayers for relief are dismissed.

Lausanne, Switzerland
Dated: 5 August 2020

THE COURT OF ARBITRATION FOR SPORT



Luigi Fumagalli
Sole Arbitrator