CAS 2011/A/2566 Andrus Veerpalu v. International Ski Federation

ARBITRAL AWARD

delivered by the

COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President:	Mr. Romano Subiotto QC, Solicitor-Advocate, Brussels, Belgium and London, United Kingdom
Arbitrators:	Mr. Olli Rauste, Lawyer, Espoo, Finland
	Prof. Massimo Coccia, Avvocato, Rome, Italy
Ad-hoc Clerk:	Dr. Niklas Maydell, Attorney, New York

in the arbitration between

Andrus Veerpalu, Otepää, Estonia

Represented by Mr. Aivar Pilv, Mr. Ilmar-Erik Aavakivi, and Mr. Jaak Siim, Attorneys-at-law, Tallin, Estonia, and Dr. Lucien W. Valloni and Dr. Thilo Pachmann, Attorneys-at-law, Zurich, Switzerland

- Appellant -

and

International Ski Federation, Oberhofen am Thunersee, Switzerland

Represented by Dr. Stephan Netzle and Dr. Karsten Hofmann, Attorneys-at-law, Zurich, Switzerland

- Respondent -

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I. PARTIES

1. The Appellant, Andrus Veerpalu (the "Athlete"), resident of Otepää, Estonia, before his retirement on February 23, 2011, was a professional cross-country skier. Throughout the course of his 22-year career, Mr. Veerpalu won numerous professional competitions, including winning two Olympic gold medals.

2. The Respondent, the International Ski Federation, also known as *Fédération International de Ski* ("FIS", together with the Appellant, the "Parties"), is the principal international organization for all skiing sports, headquartered in Oberhofen am Thunersee in Switzerland. The FIS organizes several ski sport disciplines, for which it oversees World Cup competitions and World Championships.

II. BACKGROUND TO THE DISPUTE

A. Collection and Analysis of the Samples

3. On January 29, 2011, the Appellant was subject to an out-of-competition doping examination in Otepää, Estonia, performed by a Doping Control Officer ("DCO") of the World Anti-Doping Agency ("WADA"). Blood and urine samples were taken in a room in the Tehvandi Sports Centre in Otepää, Estonia.

4. Shortly thereafter, WADA's DCO filled out a report concerning the testing procedure conducted. This report outlined the DCO's observations surrounding the collection of the samples, including confirmation that the samples had been properly stored after collection (the "Mission Summary"). Upon WADA's request, the DCO also explained to Mr. Hamish Coffey of WADA by email the circumstances surrounding the taking of the sample. In this email, the DCO clarified the details of collection, including the type of storage used, the temperatures at which the samples were stored, and the persons present in the room prior to and during the collection of the samples.

5. The samples were then analyzed by the WADA-accredited Laboratory at the Deutsche Sporthochschule Köln in Germany (the "Laboratory") using human growth hormone ("hGH") Isoform Differential Immunoassays (the "Test"). The samples were received on January 31, 2011, the screening procedure took place on February 4, 2011, and the confirmation procedure took place on February 8, 2011 for Kit 1 and February 11, 2011 for Kit 2.[1]

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[1] The need for two kits is summarized in the WADA Guidelines for Application of hGH Isoform Differential Immunoassays (the "hGH Guidelines" or the "Guidelines") (version 1.0, June 2010, 4.1) as follows: *"In order to perform the test(s), two set kits ('1' and '2', supplied by CMZ-Assay GmbH, Germany), are used for the measurement of the hGH isoforms for each sample analysis. Either kit may be utilized for the Initial Testing Procedures, whereas both kit1 and kit2 shall be used for the Confirmation Procedures. Each kit contains one 'recombinant' and one 'pituitary' assay. In the 'recombinant' (recGH) assay, the coated capture antibody preferentially binds to*

6. The Test resulted in an adverse analytical finding ("AAF") of recombinant or exogenous human growth hormone ("recGH"). RecGH is a type of hGH that is listed on the banned substances of WADA and the use of which is a violation of Article 2.1 of the FIS Anti-Doping Rules ("FIS ADR"). This was reported to WADA on February 14, 2011.

7. On February 15, 2011, the FIS informed the Estonian Ski Association ("NSA EST") of the AAF in the original blood sample tested (the "A-sample"). FIS informed the NSA EST of the Appellant's right to promptly request the analysis of the confirmation blood sample (the "B-sample").

B. Athlete's Retirement and Opening of the B-sample

8. On February 17, 2011, the Secretary General of the FIS, Ms. Sarah Lewis, had a telephone call with Mr. Toomas Saavi, President of the NSA EST, to discuss the retirement of the Athlete from professional cross-country skiing and whether the opening of the B-sample could be postponed. The next day, on February 18, 2011, the Secretary General of the NSA EST, Mr. Jüri Järv, sent an email to Ms. Lewis summarizing this phone call. Mr. Järv wrote that the discussion had centered on the Appellant's retirement from professional cross-country skiing and whether the opening of the B-sample could be postponed until March 6, 2011. Ms. Lewis replied to Mr. Järv by email on the same day, February 18, 2011, stating that the B-sample opening would not take place before March 7, 2011.

9. The Appellant and the NSA EST announced the Appellant's retirement from professional cross-country skiing on February 23, 2011, the opening date of the Ski Championships in Oslo.

10. Between March 8, 2011 and March 24, 2011, there appears to have been some confusion regarding whether the Appellant did or did not admit use of the prohibited substance and whether he had or had not waived his right to have the B-sample opened. It began with an email from the FIS on March 8, 2011, alleging that the Appellant had admitted to the use of the prohibited substance and stating that the case would be handled by the FIS Doping Panel following the Athlete's withdrawal from the FIS Nordic World Ski Championships in Oslo. The NSA EST replied by letter on March 12, 2011, stating that it did not agree with the assumption of the FIS that the Appellant had accepted the result of the positive A-sample and, on that basis, declined to have the B-sample opened. The FIS replied on March 16, 2011, stating that the time limit for requesting the opening of the B-sample had expired, and that the Laboratory had been discharged from making arrangements for the opening of the B-sample because the NSA EST had informed the FIS on February 23, 2011, that the Athlete had

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the 22 kDa hGH present in the samples, whereas the 'pituitary' (pitGH) assay employs a capture antibody that recognizes a variety of pituitary-derived hGH isoforms. The respective assays are referred to as "rec1", "pit1", "rec2" and "pit2". The result of the test is expressed as the ratio of the concentration values recGH / pitGH for each particular kit."

admitted to hGH use. On March 21, 2011, Mr. Aivar Pilv introduced himself to the FIS as the Appellant's representative and restated the Athlete's wish to have the B-sample analyzed. On March 24, 2011, the FIS, while maintaining its position that the Appellant had not requested the B-sample analysis within the set deadline, nonetheless agreed to the Appellant's request to proceed with the B-sample analysis.

11. Following a number of requests from the Appellant for postponement, the opening and analysis of the B-sample took ultimately place on April 6, 2011. The Appellant was represented by Dr. Jüri Laasik, a biotechnology expert, who, as part of his witness protocol, confirmed that he had not witnessed any irregularities in the process of the opening and analysis of the B-sample.

12. On April 7, 2011, the FIS received the report from the Laboratory that an AAF of recGH had also been found in the Appellant's B-sample. The FIS announced that a hearing of its Doping Panel (the "FIS Doping Panel" or the "Doping Panel") would now be scheduled and invited the Appellant to attend. The Appellant informed the media of the AAF on April 8, 2011.

C. Pre-hearing Submissions and Questions

13. On April 13, 2011, the Appellant's representative requested the Laboratory Documentation Package of the A/B sample ("LDOC") from the FIS. This was forwarded to the Appellant and his representatives on April 15, 2011.

14. On April 14, 2011, the Appellant was informed that the hearing would take place in Ljubljana on Sunday June 5, 2011, and he was invited to submit any written observations on or before May 10, 2011.

15. On April 19, 2011, the Appellant requested and received copies of seven prior decisions of the FIS Doping Panel.

16. On May 2, 2011, the Appellant asked the FIS whether it or the Laboratory possessed any additional documents regarding the blood samples and, if so, for copies to be sent to the Appellant.

17. On May 3, 2011, the Appellant requested postponing the time limit for providing the written submissions until May 20, 2011. On the same day, the FIS confirmed that all relevant documents were contained in the LDOC and granted the postponement.

18. By letter of May 4, 2011, the Appellant submitted certain technical questions to the Laboratory regarding the LDOC and the Laboratory's quality standards.[2] The

[2] These questions were: "*1. What is the analytical rationality of using quality control samples in a completely different concentration range of the analyzed samples of athletes? 2. What is the concentration range of the samples with which the analytical uncertainty was calculated? 3. Why apparently no inter-assay quality control samples policy performance was applied? 4. Why the*

Appellant has asserted that these questions were again brought to the attention of the FIS on May 9 and 13, 2011. The Laboratory's answers, enclosed in a letter dated May 19, 2011, were forwarded to the Appellant's representative on May 21, 2011. In that reply, the Laboratory also noted a mistake in the LDOC and attached a corrected page 30.[3]

19. On May 20, 2011, the Appellant made his written submissions to the FIS Doping Panel together with 11 appendices, including the expert opinions of a number of scientists.

20. On May 27, 2011, the Appellant also informed the FIS Doping Panel that he, his representatives, and his witnesses would not travel to the hearing in Ljubljana but would attend the hearing by way of a telephone conference.

21. On June 3, 2011, the Appellant submitted a document from Dr. de Boer in response to the answers of the Laboratory, in which Dr. de Boer criticized the lack of "*solid and transparent answers to the questions asked.*"

D. The FIS Doping Panel Hearing and Decision

a) The FIS Doping Panel Hearing

22. The FIS Doping Panel hearing (the "FIS Doping Panel Hearing" or the "Doping Panel Hearing") took place on June 5, 2011, at the Grand Hotel in Ljubljana, Slovenia. Those present included the chairman of the Doping Panel, Mr. Patrick Smith, Doping Panel members, Mr. Sverre Seeberg and Mr. Roland Kumpost, Ms. Sarah Fussek of the FIS and Dr. Stephan Netzle, legal counsel for FIS. The Appellant, his legal counsel, and witnesses attended via telephone conference.

23. Following the hearing, the Appellant submitted a written "Summary of Explanations" dated June 5, 2011 to the FIS Doping Panel.

24. On June 27, 2011, the Doping Panel sent to the Appellant a statement from Dr. Osquel Barroso, Senior Manager of Science at the WADA, and requested that final comments be made on or before July 7, 2011. The Doping Panel also rejected a request from the Appellant for an extension.

25. The Appellant submitted his final comments on July 7, 2011, together with five attachments, including the opinions of Dr. de Boer and scientists from the University of Tartu, Prof. Dr. Sulev Köks and Dr. Anton Terasmaa (the "Tartu University Scientists").

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observed high coefficient of variation of the inter-assay performance of the external control samples is in contrast to the claimed analytical uncertainty of the performance of kit 2?"

[3] The Laboratory explained the mistake as follows: "*Due to a transcription error a different ratio (typo: rec ↔ pit) was printed on page 30, line 2 [of the LDOC], we apologize for this! Please find enclosed a corrected version of page 30 of the documentation package of sample A/B 431893, dated 15.04.2011.*"

b) The FIS Doping Panel Decision

26. On August 22, 2011, the Appellant received the FIS Doping Panel decision dated August 21, 2011. It is this decision that is the subject of the present appeal.

27. In its decision, the FIS Doping Panel held that the AAF of recGH in the Athlete's blood had been proven in violation of Article 2.1 of FIS ADR. At the outset, the Doping Panel noted that its task was to review whether the rules and regulations were complied with during the collection and analysis of the samples, but that it was not in a position to review a method of analysis introduced and approved by WADA and the WADA-accredited laboratories.

28. In a nutshell, the FIS Doping Panel went on to reject the Athlete's argument that the delay between the analyses of the A- and B-samples affected the accuracy of the Test. The Doping Panel instead accepted the submissions of WADA that any effects from the delay would have led to a false negative result, rather than a false positive. In relation to the collection and handling of the samples, the FIS Doping Panel found that the crucial question was whether the Laboratory found any irregularities in the samples that prevented it from carrying out the Test. As no such irregularities were noted, the Doping Panel rejected the Athlete's argument that the samples were no longer fit for testing at the time they had arrived at the Laboratory. The Appellant submitted that "*long and hard training*" prior to the collection of the samples could affect the results. However, the Doping Panel noted that the Athlete's experts did not contest that hGH levels would return to normal within two hours of exercise. As there were two hours and ten minutes between the training and blood sample collections, the Doping Panel held that the training could not have affected the results either.

29. The Doping Panel questioned whether the samples were actually collected under hypobaric conditions, as argued by the Appellant. The Appellant had alleged that the samples were collected in such high altitude conditions and that this had the potential to affect the results of an hGH test. The FIS Doping Panel ultimately left this issue open, but nevertheless stated that it was not convinced that such conditions would have had a decisive impact on the Test results. The FIS Doping Panel was satisfied that the Laboratory was WADA-accredited and that the LDOC contained all data required by WADA to constitute sufficient evidence for establishing an AAF. As to the possibility of the Athlete's genetic profile to affect the outcome of the analysis, the Doping Panel found that such an argument was unsubstantiated and was not supported by specific evidence. With regard to the labeling of the Test kits as "for scientific use only", the Doping Panel held, first, that Dr. Laasik had signed the witness protocol at the opening of the B-sample without any reservations; and second, that the Appellant's experts had not explained how the labeling of the Test kit could have affected the Test results.

30. The FIS Doping Panel imposed a sanction on the Appellant of a three-year period of ineligibility, effective from February 23, 2011, the date on which the Appellant announced his retirement. In calculating the sanction, the FIS Doping Panel

considered the Athlete's delay in requesting the opening of the B-sample "*disturbing*." According to the Panel, the delayed opening and analysis – which was only requested when the NSA EST was informed that the retirement of the Athlete would not save him from proceedings before the FIS Doping Panel – was "*deceptive or obstructing*." This caused the Doping Panel to find that it constituted an aggravating circumstance. The FIS Doping Panel also placed importance on the fact that recGH cannot be administered incidentally and that its administration requires sophisticated medical expertise on the part of a trained medical doctor. In light of these aggravating factors, namely the obstructive behavior and the concerted effort required to use hGH, the FIS Doping Panel increased the otherwise applicable sanction by one year, leading to the current three-year period of ineligibility.

III. PROCEEDINGS BEFORE THE COURT OF ARBITRATION FOR SPORT – PROCEDURAL ISSUES

A. Opening of the Appeal Case

31. On September 12, 2011, the Appellant submitted the Statement of Appeal to the Court of Arbitration for Sport (the "CAS" or the "Court") in Lausanne, Switzerland.

32. By letter of September 14, 2011, the CAS informed the Appellant and Respondent of the procedure for the matter.

33. On September 22, 2011, the Appellant submitted its Appeal Brief to the CAS, together with annexed exhibits list. The CAS acknowledged receipt of the Appeal Brief on September 23, 2011.

34. The Respondent submitted its request concerning how the case should continue procedurally on September 27, 2011. The Appellant replied to this letter on October 3, 2011, and objected to the Respondent's request that the Respondent should not have to answer the Appeal Brief while the request for production of documents made in the Appellant's Appeal Brief was still pending.

35. On October 4, 2011, the CAS sent a letter to the Parties notifying them of the formation of the CAS panel (the "Panel") appointed to decide the case. By letter of October 7, 2011, the Panel set out steps for the written procedure of this case. These included obtaining the Respondent's comments on the Appellant's request for documents, the Panel deciding which documents the Respondent should submit (the "FIS Documents"), the Respondent submitting the FIS Documents, the Appellant responding to the FIS Documents and, finally, the Respondent filing its response to both the Appeal Brief and the Appellant's reply to the FIS Documents (the "Appeal Response").

B. Arguments and the Panel's Findings Regarding the Request for Documents and the Respondent's Appeal Response

36. On October 17, 2011, the Appellant sent a reply to the Respondent's letter of October 7, 2011. In this letter, the Appellant commented on the allegations made by the Respondent regarding the document production request. A short explanation from the Tartu University Scientists relating to the disclosure request was also submitted.

37. The Respondent sent a letter on October 27, 2011, arguing that the continued submission by the Appellant of his views on procedural aspects was contrary to Article R56 of the CAS Code, which bars the amendment of legal arguments after the submission of the Appeal Brief. The Appellant disputed this claim in his letter of October 31, 2011, stating that the Respondent had not sufficiently fulfilled the Panel's request for the presentation of documents, on the grounds that it had not submitted the recording of the June 5, 2011 Doping Panel Hearing or all of the documentary evidence needed to validate the hGH isoform testing method.

38. The Respondent submitted the FIS Documents in stages by October 31, 2011. The Respondent forwarded the complete file relating to the FIS Doping Panel Hearing proceedings, accreditation documents, the witness statement of FIS Secretary General Sarah Lewis and the audio recording of the Doping Panel Hearing.

39. On November 8, 2011, the Appellant requested an extension for replying to the FIS Documents. This extension was granted on November 8, 2011. The Appellant sent the reply to the FIS Documents on November 17, 2011 ("Appellant Reply to FIS Documents"). In this reply, the Appellant requested the translations of all documents that had been submitted by the Respondent in German language.

40. The Respondent submitted the Appeal Response on December 19, 2011, together with a large number of exhibits.

41. In its Appeal Response, the Respondent relied on the longitudinal profile of the Appellant for the first time in the course of these proceedings. The Respondent referred to the Appellant's "*suspiciously high*" previous Test results and alleged that the Appellant had repeatedly used hGH in the past. By letters dated January 12, 2012 and February 9, 2012, the Appellant submitted that the Respondent's arguments on the longitudinal profile were new and that, as a result, the Panel had no jurisdiction to review the allegations relating to the Athlete's longitudinal profile as part of this appeal.

42. In its reply of March 2, 2012, the Respondent sought to dismiss these arguments. First, the Respondent submitted that both the CAS code and CAS jurisprudence permit new evidence to be relied upon in appeals to a CAS Panel. The Respondent submitted that the evidence regarding the Appellant's longitudinal

profile had been raised in order to rebut the Appellant's arguments regarding the effects of exercise and hypoxia. Specifically, the Respondent argued that the longitudinal profile offers information about the "*natural*" level of a substance in an individual. The Respondent explained that these results were not reported as Adverse Analytical Findings because at the time of their analysis the Test decision limits were under revision and the hGH Guidelines on the hGH Isoform Differential Immunoassays had not been officially published. Finally, the Respondent argued that the jurisprudence relied upon by the Appellant was "*missing the point*," submitting that it related to the bringing of a new motion, as opposed to new evidence. Second, the Respondent argued that the Athlete's longitudinal profile represented an aggravating circumstance for the assessment of the applicable sanction.

43. The Panel agrees that the Respondent has, in principle, the right to introduce new evidence to rebut arguments made by the Appellant in his Appeal Brief. The Panel notes that the basis of this Appeal is the Test result from the sample taken on January 29, 2011. Any reference to blood samples taken prior to this can merely be illustrative of how the Athlete has tested in the past. However, the Panel further notes that none of these prior test results were reported to the Athlete or the NSA EST as being an AAF, and although the Appellant raised this argument in his reply of November 2011, the Respondent has not made the relevant DCO reports and laboratory documents available to the Appellant. Given that the reliability and accuracy of those Test results cannot be verified, the Panel finds that it cannot admit the longitudinal profile in the proceedings before the CAS Court.

C. Arguments and the Panel's Findings Regarding Further Procedural Issues and the Independence of Professor Coccia

44. By letter of January 20, 2012, the Appellant contended that his reply was being restricted to "*only two of all the completely new issues raised in the Respondent's Answer*"; the Appellant argued that a new round of submissions was necessary to guarantee his right to be heard and requested the Panel to depart from CAS Article R56. The Appellant submitted that the Respondent's answer deviated substantially from the decision of the FIS Doping Panel and argued that either the Appellant should be allowed to respond without restrictions or the new facts and arguments should not be admissible. The Appellant argued that a full second round of submissions would restore procedural equilibrium between the parties.[4] The Appellant further argued that only witness statements relating to issues already fully substantiated in the appeal answer should be heard at the Oral Hearing. The Appellant also alleged a violation of his rights to a fair trial and to be heard under Article 6 of the European Convention of Human Rights ("ECHR").

[4] Appeal Brief at section 10.2.

45. On January 25, 2012, the Panel replied to the Appellant's letter of January 20, 2012. The Panel noted the Appellant's description of two "*new and surprising*" arguments raised by the Respondent, namely the two points on which the Panel invited the Appellant to comment in writing in its letter to the Parties of January 13, 2012.[5] Although under Article R56 of the CAS Code the Appellant did not have a right to comment on the Appeal Response, because the Panel agreed that new arguments had been raised, the Panel granted the Appellant 15 days within which to make written submissions in response to those two arguments and to the 15 pages of scientific material translated and submitted by the Respondent. Consequently, the Panel believes that the Appellant's right to be heard has been upheld and rejects the argument that a full new round of submissions was necessary.

46. The Appellant also submitted a letter on January 24, 2012, contesting the independence of the arbitrator appointed by the Respondent, Prof. Massimo Coccia, due to Prof. Coccia's alleged refusal to be appointed by an athlete facing a doping charge in 2007. The letter alleged that the Appellant's counsel, Dr. Valloni, tried to convince Prof. Coccia to act as arbitrator in another case on behalf of an athlete who was accused of having taken prohibited substances. On the grounds that Prof. Coccia declined that request, the Appellant claimed that the neutrality of Prof. Coccia was in question. Further, the Appellant argued that in order to assess Prof. Coccia's independence it was necessary for the Appellant to receive all unpublished CAS decisions in which Prof. Coccia acted as an arbitrator.

47. The Panel rejected the Appellant's allegations regarding the independence of Prof. Coccia. The reasons for this rejection were detailed in the Panel's letter to the Parties of February 3, 2012. In brief, first, Prof. Coccia refuted the content of the conversation as reported by the Appellant's representative, Mr. Valloni, and expressed his surprise at the incorrect reporting and improper disclosure by an attorney of a private conversation with another attorney. Second, none of the Panel members had a personal or professional relationship of any kind with Mr. Netzle, whom they merely knew as a former CAS arbitrator and with whom Prof. Coccia had only sat twice during his 15-year career as a CAS arbitrator. Third, several athletes had won their doping-related cases in front of CAS panels chaired by Mr. Coccia. Moreover, Prof. Coccia had been nominated by athletes on various occasions and had never previously been nominated by FIS.

48. On February 9, 2012, the Appellant submitted comments on the two topics indicated in the CAS letter of January 25, 2012, together with three exhibits. These were followed by copies of over forty scientific articles on human growth hormones.

49. On February 13, 2012, the Respondent requested that the deadline specified in the Panel's January 13, 2012 letter be extended to March 9, 2012 so that it could

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[5] This was previously stated in the letter of January 25, 2012, from the CAS to the parties.

reply to the Appellant's comments of February 9, 2012. By letter of February 14, 2012, the Appellant challenged the Respondent's requested extension. On February 16, 2012, the Panel granted the extension until March 3, 2012.

50. The Appellant wrote to the Panel again on February 16, 2012, reserving a right to challenge the independence of Prof. Massimo Coccia.

51. On April 10, 2012, the Appellant returned a signed copy of the Order of Procedure, and stated that this was not to be understood as a cure of what it alleged to be violations of the right to be heard under Article 6 of the ECHR and Article 29 of the Swiss Constitution. In the same letter, the Appellant reaffirmed its non-acceptance of Prof. Coccia as arbitrator.

52. In a letter dated April 11, 2012, the Appellant also noted that any expert witnesses presented to discuss issues that had not been substantiated in a party's witness statements should not be accepted under Article R55 of the CAS Code. On such a basis, the Appellant submitted that Dr. Zida Wu and Prof. Eryl Basset should not be heard by the Panel.

53. The Panel rejected the Appellant's argument in relation to the alleged breach of Article R55 of the CAS Code. Article R55 only requires a brief summary of possible expert witness statements; the Panel noted that even a cursory review of the Respondent's answer clearly indicated that the Respondent proposed to rely on eight witnesses, for all of whom a brief summary of the expected testimony had been included, and for six of whom a witness statement had been submitted. The Panel dismissed the Appellant's concerns about the remaining two witnesses for whom no statement had been submitted. Dr. Wu was said to have participated in the development of the Test together with two witnesses who had submitted a witness statement; it was to be expected that Dr. Wu's testimony would accord with that of those other two witnesses. As for Prof. Bassett, the Respondent had explained that Prof. Bassett would respond to questions relating to the statistical method used for the calculation of the decision limits. The Panel considered that Prof. Bassett's presence was useful for any questions raised by the Appellant or the Panel regarding this method. Consequently, the Panel found that Dr. Wu and Prof. Basset's expertise in the relevant scientific fields was sufficiently clear for the Appellant to understand why they were being called as expert witnesses, so that the Panel was satisfied that it had complied with Article R55 of the CAS Code.

D. Oral Hearing Dates

54. On March 1, 2012, the Panel suggested June 11-13, 2012 for the Hearing and invited the Appellant to accept the date by March 8, 2012 at the latest.

55. On March 8, 2012, the Appellant offered a qualified acceptance of the dates put forward by the Panel in its letter of March 1, 2012. The Appellant proposed a

two-day Hearing running from June 12-13, 2012, instead of the Panel's proposal to begin on June 11, 2012.

56. By letter of March, 14, 2012, the Respondent accepted the Appellant's proposal of a two-day Hearing. On March 16, 2012, the Panel agreed that the Hearing would be held on June 11-12, 2012, with June 13, 2012 as a reserve day. The Panel also requested, from both parties, a list of all persons who would attend the Hearing by May 11, 2012.

57. By letter of April 3, 2012, the Panel sent the parties the Order of Procedure for the Hearing and requested that the parties return a signed copy of the Order by April 10, 2012.

58. On April 4, 2012, the Respondent returned a signed copy of the Order of Procedure. The Respondent also enclosed a proposed timetable for the Hearing, for both the Panel and Appellant's attention, which included a list of participants, including expert and fact witnesses.

59. By letter of April 11, 2012, the Appellant alleged that the Respondent attempted, through its proposed timetable of April 4, 2012, to manipulate the outcome of the Hearing by inappropriately interfering with the Panel's duties. The Appellant invited the Panel to disregard the Respondent's proposed schedule or give it the option to produce its own proposal. The Appellant argued that if these requests were not accepted this would constitute a violation of the Appellant's right to a fair trial under Article 6 of the ECHR. The Panel rejects the Appellant's claim in this regard.

60. On April 30, 2012, the Panel sent the parties a draft schedule for the Hearing for their comments. The Respondent submitted its comments on May 7, 2012, and the Appellant on May 11, 2012. On May 30, 2012, the Panel communicated the adjusted schedule for the Hearing to the Parties.

E. The Oral Hearing and Post-Hearing Submissions

61. The Hearing took place on June 11-13, 2012, at the Court of Arbitration for Sport in Lausanne, Switzerland.

The following people attended:

Romano Subiotto, President of the Panel;

Olli Rauste, Appellant-Appointed Arbitrator;

Massimo Coccia, Respondent-Appointed Arbitrator;

Niklas Maydell, *Ad-hoc* Clerk;

Andrea Zimmermann, Counsel to CAS;

Thilo Pachmann, Appellant Counsel;

Aivar Pilv, Appellant Counsel;

Lucien Valloni, Appellant Counsel;

Ilmar-Erik Aavakivi, Appellant Counsel;

Stephan Netzle, Respondent Counsel;

Karsten Hofmann, Respondent Counsel;

Andrus Veerpalu, Athlete;

Sarah Lewis, FIS Secretary General, Witness;

Anton Terasmaa, Witness;

Martin Bidlingmaier, Witness;

Christian Strasburger, Witness;

Osquel Barroso, Witness;

Wilhelm Schänzer, Witness;

Eryl Bassett, Witness;

Douwe de Boer, Witness;

Sulev Köks, Witness;

Krista Fischer, Witness;

Jaak Mae, Witness;

Jüri Järv, Witness;

Ken Ho, Witness (via telephone); and

Karin Keerdo-Massa, Interpreter for Appellant.

62. The arguments raised by the parties during the Oral Hearing will, where relevant, be discussed in the corresponding sections on the merits below. Audio recordings of the Oral Hearing were provided to the Parties. Following the Hearing, the Panel agreed to accept, within two weeks of its conclusion, a maximum thirty-page post-hearing statement from each Party on all relevant arguments raised during the Hearing (the "Post-Hearing Brief").

63. The Appellant and Respondent submitted their respective Post-Hearing Briefs on June 29, 2012.

64. By letter of August 27, 2012, the Panel sent two questions on the parameters of the decision limits and the imposed multiplier of the standard deviation to the Respondent. The Respondent was invited to respond within ten days of receipt. The Appellant was then invited to respond ten days after the receipt of the Respondent's answer.

65. The Respondent submitted its answers to the Panel's questions on September 7, 2012. ("September 7, 2012 Answers to Panel Questions" or "Answers to First Set of Panel Questions").

66. By letter of September 13, 2012, the Appellant requested an extension of the time limit to submit comments on the Respondent's Answers to the First Set of Panel Questions until October 15, 2012, at which point the Appellant submitted its comments ("October 15, 2012 Comments on Respondent Answers" or "Comments on Respondent Answers to First Set of Panel Questions").

67. By letter of November 6, 2012, the Panel sent eight further questions regarding the decision limits of the hGH test to the Respondent with a ten-day answer deadline followed by another ten-day deadline for the Appellant's comments on those answers.

68. By letter of November 7, 2012, the Respondent requested an extension of the deadline until December 20, 2012 in order to respond to the Panel's latest questions. The Respondent stated that the ten-day timeframe was insufficient for them to answer the Panel's questions satisfactorily. The CAS requested, by letter of November 9, 2012, that the Appellant confirm the Respondent's extension to respond to the Panel's letter of November 6, 2012. The Panel also stated that the proceedings would be suspended pending the deadline decision. The Appellant, by letter of November 13, 2012, contested the extension and the suspension, citing the "*abnormally excessive*" deadline extension requested by the Respondent.

69. By fax of November 14, 2012, the CAS further explained the Panel's questions to the Parties and requested confirmation from the Respondent regarding its deadline request and whether it was still necessary. The Respondent, in its letter of November 16, 2012, agreed to a reduction of the time limit to December 12, 2012, citing that its initial extension request was made to allow the Court Office to proceed undisturbed by the holidays. The Respondent referred to the new requested extension as an "*absolute need*" in order for it to respond to the Panel's scientific questions sufficiently. The deadline for the Respondent's answer remained suspended until the Panel had decided the issue. By letter of November 19, 2012, the Panel informed the Parties of its decision to grant the Respondent the requested deadline of December 12, 2012. By letter of November 21, 2012, the Appellant criticized the extended deadline, stating that this "*confirms again the insufficient and poor validation*" of the hGH test.

70. The Respondent submitted its answers to the second set of Panel questions on December 12, 2012 ("December 12, 2012 Answers to Panel Questions" or "Answers to Second Set of Panel Questions").

71. By letter of December 13, 2012, the Court extended the deadline for the Appellant to file its observations on the December 12, 2012 Answers to Panel Questions until January 31, 2013.

72. The Appellant submitted its comments to the December 12, 2012 Answers to Panel Questions on January 31, 2013 ("January 31, 2013 Comments on Respondent Answers" or "Comments to Respondent Answers to Second Set of Panel Questions").

73. By letter of February 6, 2013, the Respondent submitted its comments on the Appellant's January 31, 2013 Comments on Respondent Answers ("February 6, 2013 Comments").

F. Jurisdiction, Applicable Law and Scope of Review

74. This Panel has jurisdiction to review the Appeal under Articles 8.1.9 and 13 of the FIS ADR and under paragraph 78 of the contested decision. In particular, Article 13.2.1 of the FIS ADR provides that:

"*In cases arising from competition in an International Event or in cases involving International-Level Athletes, the decision may be appealed exclusively to CAS in accordance with the provisions applicable before such court.*"

75. The Panel's jurisdiction is further based on Article R47 of the CAS Code which provides that:

"*An appeal against the decision of a federation, association or sports-related body may be filed with the CAS insofar as the statutes or regulations of the said body so provide or as the parties have concluded a specific arbitration agreement and insofar as the Appellant has exhausted the legal remedies available to him prior to the appeal, in accordance with the statutes or regulations of the said sports-related body.*"

76. In accordance with Article R58 of the CAS Code, the Panel shall decide the dispute according to the applicable regulations and 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.

77. The Rules and Regulations applicable in this case include:

- The FIS Anti-Doping Rules 2011 (the "FIS ADR");
- The WADA Prohibited List 2011;
- The WADA International Standards for Laboratories, Version 6.0, January 2009 (the "ISL");
- The WADA Guidelines "hGH Isoform Differential Immunoassays for anti-doping analyses", June 2010 (the "hGH Guidelines" or the "Guidelines");

- The WADA Technical Document – TD2009LDOC (Laboratory Documentation Packages) ("TD2009LDOC");

- The WADA Guideline for Laboratory Test Reports, August 2008; and

- The WADA Guidelines for Blood Sample Collection, Version 2.2, August 2010 (the "Collection Guidelines").

78. The FIS rules do not provide any guidance on the issue of whether the Panel may hear new arguments and evidence not previously raised at the FIS Doping Panel hearing. Therefore, the Panel shall have regard of its own rules and jurisprudence.

79. Article R57 of the CAS Code provides that the scope of review of the CAS is unlimited. The Panel notes that in order to exercise this full power of review, the CAS must be able to examine all facts and legal issues involved in the dispute, even if *de novo*.[6] This is in line with previous CAS jurisprudence.[7]

IV. THE MERITS

A. Structure of the Merits Section of this Award

80. The **Respondent** argues that the Appellant's anti-doping rule violation has been established by three different means: first, through the AAFs from the A- and B-samples; second, by the alleged admissions from the Appellant of hGH use; and third, from the Appellant's longitudinal profile, that is, the common range of his previous test results. As explained above at paragraph 43, the Panel did not admit the Respondent's third submission regarding the Athlete's longitudinal profile because the FIS failed to submit the relevant DCO reports and laboratory documentation for verification of such results.

81. The **Appellant** denies having violated the applicable doping rules, and submits that the AAF against him should not be relied upon by the Panel due to the unreliability of the Test. The Appellant argues that the Test is unreliable for essentially four reasons: first, the Test is defective and scientifically invalid, particularly because of unreliable decision limits; second, the Laboratory was not accredited to perform the Test; third, the Test was improperly applied and administered by the DCO and the Laboratory; and fourth, the Athlete's individual circumstances render any positive Test result meaningless. Moreover, the Appellant also denies having admitted to hGH use.

82. The **Panel** will address these issues in the following sequence:

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6 As a result, the Appellant's arguments regarding issues with the FIS Doping Panel hearing and the findings of the Doping Panel are not directly relevant to this appeal, as this Panel will in any event review all arguments raised at that hearing, in addition to further arguments now before it.

7 See, CAS 2009/A/1926 and CAS 2009/A/1782.

First, the Panel will establish the relevant standard of burden of proof applicable to the present proceedings.

Second, the Panel will discuss all issues relating to the way the Test was administered and its results reached with respect to the Athlete. This includes whether the Laboratory was accredited to perform the Test, whether the Test was carried out in violation of the ISL and other relevant WADA rules, and whether the Appellant's individual circumstances might have rendered the Test results invalid.

Third, the Panel will deal with all issues relating to the reliability of the Test. This includes all questions pertaining to whether the Test's design, method, and its underlying scientific assumptions are correct.

Fourth, the Panel will separately deal with whether the Test's decision limits have been scientifically correctly set. While this is conceptually speaking part of the third point, *i.e.*, the reliability of the Test, the Panel and in turn the Parties have attached particular importance to this issue in the course of the proceedings, which warrants a stand-alone discussion in this award.

Fifth, the Panel will address the question as to whether the Athlete's alleged anti-doping rule violation could be established by other means than the Test, in particular whether Appellant admitted to the use of hGH.

B. The Test

83. HGH is a hormone that is synthesized and secreted by cells in the anterior pituitary gland located at the base of the brain. It is naturally produced in humans and necessary for skeletal growth. However, hGH is also available artificially and is believed to be abused by athletes on a wide scale in order to increase performance. The hGH isoform Test has been developed as part of an effort to combat hGH doping in sports. The major challenge in developing a doping test for hGH is the fact that the level of total concentration of hGH in a human's blood will naturally vary substantially in the course of time. HGH is naturally released in a rhythmic, pulsatile manner, so that the total hGH concentration level may vary as much as 500-times between the pulses and the basal periods.[8] Normally there are around ten hGH pulses during any 24-hour period, so the total hGH concentration will differ significantly depending on the time of measurement. For this reason, developing a test based merely on the measurement of the total hGH concentration is, in practice, impossible. However, the administration of exogenous hGH changes the proportional shares of various hGH isoforms in a human's blood by increasing the proportional share of one hGH isoform compared to other isoforms. Accordingly, the Test has been designed to detect hGH administration by looking at the ratio between two types of isoforms of

[8] *See*, for example, Winer, Shaw and Baumann: Basal Plasma Growth Hormone Levels in Man 'New Evidence for Rhythmicity of Growth Hormone Secretion' (1990) Journal of Clinical Endocrinology and Metabolism 70(6), 1678-1686.

hGH. Even though the levels of total hGH concentration will vary substantially, it is assumed that the ratio between the relevant types of hGH isoforms measured by the Test will naturally remain relatively stable. The administration of exogenous hGH can thus be detected from an elevated ratio of the relevant hGH isoforms. The testing is done by using two distinct sets of reactive tubes coated with two different combinations of antibodies, which are referred to as Kit 1 and Kit 2 (or the "Kits"). The so-called decision limits determine the thresholds needed to assess whether an athlete's blood contains natural or doped levels of hGH.

84. The Test was first administered in practice during the 2004 Summer Olympic Games in Athens. It was subsequently used in the 2006 Winter Olympic Games in Turin. Following production and validation of the commercial kits on an improved technical platform, the new Kits were first used in the 2008 UEFA European Football Championship and the 2008 Summer Olympic Games in Beijing.

85. In 2010, WADA published its Guidelines on hGH Isoform Differential Immunoassays for Anti-doping Analyses. This document sets out a harmonized approach for the application of the Test in detecting hGH doping. It provides guidance on the pre-analytical sample preparation procedure, the performance of the Test and the interpretation of the Test results. Importantly, the Guidelines also contain the Test's decision limits. A laboratory must obtain certification from the relevant accreditation bodies to have this test for hGH included in a laboratory's scope of accreditation.

86. It is the Panel's understanding that an additional test for hGH abuse in professional sports (the "Biomarker Test") is currently being developed and validated by WADA. The Biomarker Test differs from the Isoform Test in that it detects unnatural increases in two markers (IGF-1 and P3NP) that are produced after the injection of hGH. One advantage of the Biomarker Test over the Isoform Test is its potential for detecting exogenous hGH for a longer period after injection: In contrast to the 72-hour collection requirement under the Isoform Test, the Biomarker Test can detect hGH up to 14 days after use. Dr. Larry Bowers, chief scientist for the US Anti-Doping Agency, has stated that although the Biomarker Test is not yet fully validated by WADA, it is nevertheless already fit for purpose in his opinion.[9]

C. Determination of a Potential Doping Violation through the Test

[9] Source: http://www.bbc.co.uk/news/science-environment-15167725, as accessed on March 5, 2013.

1. The Burden of Proof

a) The Appellant's Arguments

87. With regard to the reliability of the Test, the Appellant argues that according to Article 3.1 FIS ADR the burden of proof in this case generally lies with the Respondent:

"*FIS and its National Ski Associations shall have the burden of establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether FIS or its National Ski Association has established an anti-doping rule violation to the comfortable satisfaction of the hearing panel bearing in mind the seriousness of the allegation which is made. This standard of proof in all cases is greater than a mere balance of probability but less than proof beyond a reasonable doubt.*"

88. The Appellant relies on Article 3.1 to argue that it is for the Respondent to prove that the Test is reliable.[10] The Appellant further argues that the standard of proof is high, and cites in support Article 3.1 and sections 5.4.4.1.2 and 5.4.4.2.2 of the ISL.[11] With regard to section 5.4.4.1.2, the Appellant claims that it requires laboratories to prove the exogenous origin of prohibited substances directly.[12] The relevant part of ISL 5.4.4.1.2 provides as follows:

"*In the case of substances which are capable of being produced endogenously (for example testosterone, peptide hormones) and at any concentration (including below relevant thresholds), the Athlete's Sample will be deemed to contain a Prohibited Substance and the Laboratory will report an Adverse Analytical Finding if, based on any reliable analytical method (e.g. IRMS), the Laboratory can show that the Prohibited Substance is of exogenous origin.*"

89. For section 5.4.4.2.2, the Appellant relies on the statistical requirements for validation.[13] The relevant part of ISL 5.4.4.2.2 provides as follows:

"*The Confirmation Methods for Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-purpose include but are not limited to: Specificity. […] Intermediate Precision. […] Robustness. […]. Carryover. […] Matrix Interferences. […] Standards. […] Limit of Quantification (LOQ). […] Linearity. […]*"

90. The Appellant also argues that it cannot bear the burden of proof on the grounds that: i) the Appellant cannot influence the correctness and exhaustiveness of the documents compiled by the DCOs; ii) the Appellant's information requests were

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10 Appellant Post-Hearing Brief, ¶4.

11 Appellant Post-Hearing Brief, ¶¶5-7.

12 Appellant Post-Hearing Brief, ¶6.

13 Appellant Post-Hearing Brief, ¶7.

rejected or only formally answered by FIS; and (iii) the analytical criticism of the independent experts commissioned by the Appellant has been ignored.[14]

b) The Respondent's Arguments

91. The Respondent, on the contrary, maintains that the burden of proof, both regarding the reliability of the Test and its application to the Appellant, is determined by the question of whether the Laboratory is accredited to perform the Test.[15] The Respondent maintains that because the Laboratory is accredited for the hGH Isoform Test, the presumption of Article 3.2.1 FIS ADR applies, that is, that the Test has been conducted in accordance with the ISL and is therefore valid:

"*WADA-accredited laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The Athlete or other Person may rebut this presumption by establishing that a departure from the International Standard occurred which could reasonably have caused the Adverse Analytical Finding. […]*

Comment to Article 3.2.1: The burden is on the Athlete or other Person to establish, by a balance of probability, a departure from the International Standard that could reasonably have caused the Adverse Analytical Finding. If the Athlete or other Person does so, the burden shifts to FIS or its National Ski Association to prove to the comfortable satisfaction of the hearing panel that the departure did not cause the Adverse Analytical Finding."

92. The Respondent argues that because the WADA-accredited laboratory relied on a testing method which was "*fit for purpose*," it was for the Appellant to point to a particular departure or departures from the ISL that could have led to a false positive finding.[16] The Respondent maintains that only if the Appellant can show a departure from the ISL that could have caused the AAF is the presumption of reliability and validity reversed.

c) Analysis and Findings of the Panel

93. In the context of anti-doping violations, the burden of proof affects two distinct issues: first, the burden of proving the reliability of the testing method used and, secondly, whether the Test was administered to the samples in question in accordance with the testing method and the applicable rules determining the application of a test. These are considered in turn below.

94. **Reliability of the Test.** Article 3.1 of the FIS ADR and Article 3.1 of the WADA Code state that the "*FIS and its National Ski Associations shall have the burden of*

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14 Appeal Brief, at section 8.

15 Appeal Response, ¶47 *et seq*. and ¶122 *et seq*.; Respondent Post-Hearing Brief, ¶10 *et seq*..

16 Respondent Post-Hearing Brief, ¶10.

establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether the FIS or its National Ski Association has established an anti-doping rule violation to the comfortable satisfaction of the hearing panel bearing in mind the seriousness of the allegation which is made. This standard of proof in all cases is greater than a mere balance of probability but less than proof beyond a reasonable doubt. Where these Rules place the burden of proof upon the Athlete or other Person alleged to have committed an anti-doping rule violation to rebut a presumption or establish specified facts or circumstances, the standard of proof shall be by a balance of probability […]."[17]

95. In light of the foregoing and sections 5.4.4.1.2 and 5.4.4.2.2 of the ISL, this Panel holds that the *Respondent* bears the burden of proving to the Panel's comfortable satisfaction that the Test is reliable, including that it is scientifically sound. This is in line with previous CAS jurisprudence, namely that "*[m]ethods for the detection of prohibited substances need to be validated. Only methods which are scientifically 'fit for purpose' can be applied to analyze samples in the fight against doping.*"[18]

96. **Administration of the Test to the Appellant.** As for the administration of the Test, the FIS ADR and ISL state that WADA-accredited laboratories are presumed to have conducted procedures in accordance with the ISL.

97. As a preliminary point regarding accreditation, the Panel draws attention to CAS precedents stating that "*[a] CAS panel cannot place in question whether an ISO [International Organization for Standardization] accreditation was correctly attributed to a laboratory, because this would render the whole international standardization and certification system meaningless and because, notoriously, compliance with ISO accreditation requirements is regularly checked by external auditors.*"[19]

98. In order to rebut the presumption that WADA-accredited laboratories conducted procedures in accordance with the ISL, athletes must establish a departure from the ISL that could reasonably have caused the AAF, and that "*the occurrence of the circumstances on which the athlete relies is more probable than their non-occurrence or more probable than other possible explanations of the positive testing.*"[20] Therefore, the standard to rebut a presumption of ISL compliance is to show that there was an ISL violation and that it is more likely than not that this non-compliance led to a false positive.[21] If this is shown, the relevant respondent would then have to establish that the non-compliance did not cause the AAF.

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17 FIS ADR (Edition 2011), Article 3.1.

18 CAS 2010/A/2296, ¶¶146-147.

19 CAS 2010/A/2296, ¶146-147.

20 CAS 2008/A/1515, ¶115.

21 CAS 2011/A/2386, ¶225.

99. Therefore, given that the Test was performed by a WADA-accredited laboratory, the Appellant has to show that it is more likely than not that any deviation from the ISL could have caused a false positive finding. Only if the Appellant can establish this would the burden of proof shift to the Respondent.

100. Therefore, the Panel concludes that it must first judge whether the Test is reliable, and only then judge whether the Appellant has established a departure from the ISL that could have caused a false positive finding.

2. Laboratory Accreditation

101. The Appellant submits that the Cologne Laboratory, which analyzed its samples, was not validly accredited and that the Panel should therefore disregard the Appellant's AAF.

a) The Appellant's Arguments

102. **Change in test method and kits since accreditation.** The Appellant argues that the testing method and Kits have changed since the Laboratory's accreditation and, without re-accreditation, the Laboratory's accreditation was not valid at the time of the Test. According to the Appellant, although the accreditation documents presented by the Respondent verified a previous accreditation of the Test in 2008, the testing method was substantially changed in early 2009, with the introduction of new coatings of the Kits' tubes, so that the Laboratory had not been accredited for conducting the Test in its current form (*i.e.*, from early 2009). The Appellant also asserts that the renaming of the Test kits from "kits A and B" to "kits 1 and 2" would have required the re-accreditation of the Laboratory.

103. At the Oral Hearing, the Appellant also claimed that the certificates presented by the Respondent to prove the accreditation of the Test were insufficiently translated and did not provide clear information on whether the Laboratory had, in fact, been properly accredited.

104. **Dynamic approach and accreditation.** The Appellant argues that because of the dynamic approach, the process for determining the decision limits was still ongoing at the time of the Laboratory's accreditation. On this basis, the Appellant submits that the Laboratory's accreditation was invalid because the development of the Test had not yet been concluded at that time.[22]

b) The Respondent's Arguments

105. **Change in Test method and kits since accreditation.** Seeking to rebut the Appellant's argument on the invalidity of the Test, the Respondent points to the double accreditation procedure, referencing validation documents from both the WADA and the competent German accreditation body, the *Deutsche*

[22] October 15, 2012, Comments to Respondent Answers to Panel Questions, ¶15.

Akkreditierungsstelle GmbH ("DAkkS").[23] The Respondent explains that, as a pre-condition of the WADA accreditation process, the Laboratory needed to be certified by a national accreditation body to obtain the relevant accreditation - the ISO/IEC 17025 accreditation – which it did on March 25, 2009.[24] The Respondent argues that the purpose of the double accreditation procedure was to ensure that laboratories implementing accredited methods could be trusted. On May 17, 2010, the Laboratory applied for a new ISO/IEC 17025 accreditation with DAkkS, which was granted on January 5, 2011, and remains valid until March 24, 2014. This additional accreditation became necessary once the German accreditation system was centralized and consolidated into one national body, DAkkS, which began operating in January 2010.[25]

106. At the Oral Hearing, Prof. Schänzer and Dr. Barroso, giving testimony for the Respondent, explained the validation process to the Panel and confirmed that the same testing procedure had been used by the Laboratory since its initial accreditation. The Respondent submitted that the change in the Kits' antibody coating did not imply that the Test had changed. According to the Respondent, the Test method used in the present case was identical to the accredited method. In addition, the Respondent submitted that, even if the adjustment in the production process of the tubes leading to a different coating would have been regarded as a change of the testing method, the validity of the Laboratory's 2009 accreditation would not have been affected because, as stated in the Laboratory's first accreditation, it was "*allowed to modify as well as to further develop or create testing methods without prior information or approval*" of the relevant accreditation bodies.[26]

107. Additionally, the Respondent cites a CAS precedent which echoes the presumption in favor of the WADA-accredited laboratory stated in Article 3.2.1 of FIS ADR, namely *Floyd Landis*, in which the panel stated that it was not for them to review the accreditation and validation if a certain testing method was accredited with a certain laboratory. Instead, the laboratory benefited from the presumption that it conducted sample analysis in accordance with international standards and the Appellant needed to rebut this presumption by showing that a departure from the ISL occurred.[27]

108. The Respondent also asserts that CAS jurisprudence dictates that CAS Panels must rely on the accreditation of competent authorities and the Appellant's questioning of the Laboratory's accreditation was not supported by any jurisprudence or applicable rule.

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23 Appeal Response, ¶¶ 54-55.

24 Respondent Post-Hearing Brief, ¶15.

25 Respondent Post-Hearing Brief, ¶16.

26 Respondent Post-Hearing Brief, ¶19.

27 Appeal Response, ¶53.

109. In accordance with the above, the Respondent maintains that the Cologne Laboratory had been accredited for the Test at the time of the analysis of the Appellant's samples.

c) Analysis and Findings of the Panel

110. **Change in Test method and kits since accreditation.** The Panel acknowledges that not only must the Laboratory that conducts the analysis be accredited but the Test method used must also be validated and covered by the Laboratory's accreditation. Based on the documents produced by the Respondent, the Panel finds that there is no doubt that the Laboratory is WADA-accredited, and has been ISO-accredited for application of the Test by the German National Accreditation body, DAkkS, a full member of the International Laboratory Accreditation Cooperation ("ILAC") and signatory to the ILAC Mutual Recognition Agreement. In this regard the Panel notes that the accreditation of the Test for use by the Cologne Laboratory has been attested to by a WADA Director, by the quality manager at the Laboratory when the Test was carried out, who is now Chairman of the German National Anti-Doping Agency's Executive Board, and by two officials from DAkkS. Further, it is clear from both the German and English copies of the accreditation certificate that the Test is accredited for use in the Laboratory.

111. The Panel also sees no valid reasons to proceed on the assumption that the mere change of the coating of the testing tubes could have affected the functionality of the Test in such a magnitude that it could have been deemed to constitute a new testing method that would require re-accreditation. This technical modification had not changed the Laboratory's ability to properly analyze the Athlete's samples. The Panel further notes that even if the change of the coating was regarded as significant for the accreditation of the Test, the re-accreditation granted to the Cologne Laboratory by DAkkS on January 5, 2011 has in any event covered the Test in its altered form.

112. Therefore, the Panel finds that the Laboratory is properly accredited for the Test and that the Appellant has, on the balance of probability, failed to prove otherwise.

113. **Dynamic approach and accreditation.** The Panel is of the view that accreditation may still be granted even if there is a dynamic approach to decision limits, that is, even if such test thresholds are constantly being monitored and there is a possibility that they may change. Accreditation relates to the ability of a laboratory to perform test procedures and analysis correctly; decision limits are unrelated to such abilities, and are currently not evaluated in any accreditation procedures.

3. Alleged ISL Violations in the Performance of the Test

114. The Appellant alleges that his AAF should be disregarded because the following principles of ISL and other relevant WADA rules were violated during the performance of the Test: (i) the blood samples were not preserved properly in the five hours immediately following their collection; (ii) the time taken to transport the samples to the Laboratory was excessive; (iii) the delay in centrifuging the samples was too great; (iv) the Laboratory failed to comply with the relevant quality control ("QC") policy; and (v) the inter-assay variability (the Coefficient of Variation ("CV") of the measurement results of the Appellant's samples was excessive.

a) The Appellant's Arguments

115. **Temperature and handling of the samples in the first five hours after collection.** According to the Appellant, the blood samples were not handled properly during the first five hours following collection.[28] The Appellant relies on version 2.3 of the Collection Guidelines in relation to the sample collection, and points to section 7.6.1 which states that the DCO is responsible for ensuring that all samples are stored in a manner that protects their identity, integrity, and security whilst in the Blood Collection Facility.[29] The Appellant also points to section 7.6.3 of the Collection Guidelines and maintains that the blood samples must have been stored in a cool location at a temperature between two and twelve degrees Celsius.[30] The Appellant submits that under sections 7.6.1 and 7.6.3, the Respondent must prove that the conditions of storage were met. Although the Appellant acknowledges that the DCO stored the samples in a monitored cool box, the Appellant states that because the DCO did not record the temperature of that cool box it is both not possible to verify the temperature of the blood samples for at least the first five hours after collection, and that transportation at the correct temperature cannot be assumed.[31] Such information should have been included in the documentation showing that all necessary steps were taken to guarantee the reliability of the samples, and that a general statement from the DCO – that the entire process of taking the blood sample was correctly done – is insufficient proof that the blood sample was correctly handled in the first five hours.[32] Further, the Appellant points to Exhibit RE-38 and argues that the Test samples that are the subject of these proceedings are the only samples from all his previous tests which do not include any tag or documentation regarding cooling or transport.[33] This, the Appellant submits, demonstrates that the DCO "*obviously*

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28 Appeal Brief at section 3.3.1; Appellant Post-Hearing Brief, ¶¶84-85.

29 Appeal Brief at section 3.3.1.

30 Appeal Brief at section 3.3.1. Collection Guideline 7.6.3 provides as follows: "*The Blood Samples must be stored in a cool location, preferably in a refrigerator or cool box. Temperature should be maintained between 2 – 12 degrees Celsius.*"

31 Appeal Brief at section 3.3.1; Appellant Post-Hearing Brief, ¶85.

32 Appeal Brief at section 3.3.1; Appellant Post-Hearing Brief, ¶85.

33 Appellant Post-Hearing Brief, ¶84.

did not take care and check the temperature of the blood sample,"[34] and that the Respondent "*has not lived up to its burden of proof to document the entire chain of custody and to give Appellant the possibility to review the blood sample collection process.*"[35] The Appellant argues that the hGH isoform ratios change constantly if not cooled, and that, as a result, the alleged violation of the Collection Guidelines had an immediate impact on the AAF.[36]

116. Further, the lack of documentation of the temperature of the blood sample does not just constitute a substantial procedural error but the inadequacy of the procedure was of such significance that it was not possible to use the results of the laboratory analyses as objective and trustworthy evidence.[37]

117. **Transportation time.** The Appellant submits that the transportation time of the sample was excessive and not in accordance with the Collection Guidelines.[38] According to the A/B documentation package for the relevant samples, the samples arrived at the Laboratory approximately 42.5 hours after collection, and, according to the Appellant, this was a clear violation of section 7.7.5 of the Collection Guidelines, which states that the transport of blood samples should be made as soon as possible and preferably within 36 hours of collection.[39] Contrary to the submissions of the Respondent, the Appellant argues that the 36-hour figure is mandatory and not a recommendation.[40] Adopting a teleological interpretation of this section, the Appellant contends that samples should have been handed over to the Laboratory within a time span that secures their eligibility for testing.[41] The Appellant argues that the violations of the two conditions (sample preservation and timely transportation) preclude any assumptions as to the lack of adverse effect on the blood sample, and that any delay in transportation would lead to a change in the hGH isoforms.[42] Therefore, the Appellant submits that the samples are unreliable and were unsuitable for analysis.[43]

118. **Centrifugation of the blood samples.** The Appellant argues that the handling of the samples at the Laboratory violated section 6.2.2.5 of the ISL which states that

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34 Appellant Post-Hearing Brief, ¶85.

35 Appellant Post-Hearing Brief, ¶86.

36 Appellant Post-Hearing Brief, ¶87.

37 Appeal Brief at section 3.3.3.

38 Appeal Brief at section 3.3.2; Appellant Post-Hearing Brief, ¶¶88-90.

39 Appeal Brief at section 3.3.2. Collection Guideline 7.7.5 provides as follows: "*Transport of Blood sample(s) from site of collection to Laboratory should be made as soon as possible and preferably within 36 hours of collection.*"

40 Appellant Post-Hearing Brief, ¶88.

41 Appeal Brief at section 3.3.2.

42 Appeal Brief at section 3.3.2; Appellant Post-Hearing Brief, ¶89.

43 Appeal Brief at section 3.3.2.

samples should be centrifuged immediately after arrival at the Laboratory.[44] The Appellant argues that section 6.2.2.5 has to be read in conjunction with the maximum transportation time and the warning on the instruction manuals for the Kits that long delays (up to 60 hours) may have an impact on results,[45] which, the Appellant claims, demonstrates the need for immediate processing of samples. [46]

119. In this case, the samples were centrifuged 23 hours after their arrival at the Laboratory, 65 hours and 20 minutes after they were collected. The Appellant submits that their immediate centrifugation was even more important because the samples were not properly cooled during the first five hours after collection and the maximum transportation time for their transportation had been exceeded by 6.5 hours. The Appellant argues that the problem of the metabolic processes continuing, which was caused by incorrect post-collection handling and transportation, was compounded by the delay in centrifugation.[47] Consequently, the Appellant argues that the ISL was breached through delayed centrifugation, that the hGH ratios could have changed as a result, and that the delay has caused the AAF.[48]

120. **QC policy of the Laboratory.** The Appellant argues that the Respondent ought to have provided details of its internal QC policy, and that having failed to do so, it can be presumed that the applied QC policy departed from articles 5.4.7.3 and 5.4.4.3.2 ISL.[49] Further, the Appellant submits that without information on the QC policy, WADA has hindered the Appellant in defending itself.

121. **Excessive inter-assay variability of measurement results.** The Appellant submits that the inter-assay variability of his measurement results was too high to allow an assumption of an AAF. The Appellant argues that the difference between Kit 1 and Kit 2 in both samples and the difference between the measurement results of his A- and B-samples as measured with Kit 2 is extremely high, i.e., around 33 % (A- sample 3.07, B- sample 2.00). According to the

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44 Appeal Brief at section 3.3.3; Appellant Post-Hearing Brief, ¶¶91-94. The relevant part of ISL 6.2.2.5 provides as follows: "*Samples should be centrifuged immediately after Laboratory reception to obtain the serum or plasma fraction. When analyzed shortly after centrifugation (within 48 hours), Samples and/or Aliquots may be stored refrigerated at approximately 4 degrees Celsius until analysis.*"

45 The manuals state the following: "*Immediate processing (centrifugation) of the blood samples after the withdrawal of blood and clotting is recommended. Preliminary data suggest that a longer delay (up to 60 hours) might have little impact on assay results. However, any deviations in preanalytical conditions must be validated by the laboratory. Samples that will not be assayed within 60 hours after blood collection must be centrifuged and the supernatant must be stored at < -15C. Once thawed, the samples must be processed immediately and should not be left unused.*" Exhibit RE-41.1 p. 3.

46 Appeal Brief at section 3.3.3; Appellant Post-Hearing Brief, ¶¶92-93.

47 Appellant Post-Hearing Brief, ¶93.

48 Appellant Post-Hearing Brief, ¶94.

49 Appeal Brief, section 7.

Appellant, such a large variation is a significant indication of that "*something is technically or methodically wrong with the sample and/or the Test*" and on that basis submits that the Test result should be considered as negative.[50]

b) The Respondent's Arguments

122. **Temperature and handling of the samples in the first five hours after collection.** At the outset, the Respondent submits that the version of the Collection Guidelines applicable in this case is Version 2.2 of August 2010 and not Version 2.3 of August 2011, as suggested by the Appellant.[51] The Respondent rejects the Appellant's argument that the blood samples were improperly handled during the first five hours following collection. The Respondent submits that the facts – as established by the LDOC, the report of the DCO, and the testimony of Prof. Schänzer – demonstrate that the samples were always kept under sufficiently cool conditions.[52] The Respondent submits that pursuant to section 7.6.4 of the Collection Guidelines, the DCO must only document if the conditions of storage did not meet the temperature guidelines.[53] Consequently, the Respondent submits that compliance must be presumed in this case because no variation was reported by the DCO.[54] Further, the Respondent points to a section in the DCO's Mission Summary in which she states that "*the samples were stored as cooled as reasonably possible given the circumstances of this mission from the point of collection until the point of shipment*."[55] The Respondent also points to an email from the DCO to WADA, in which she explains that the samples' handling complied with section 7.6 of the Collection Guidelines.[56] Further, the Respondent submits that the samples were reviewed by the Laboratory upon receipt and that no irregularities were found.[57] Section 7.7.6 of the Collection Guidelines requires the Laboratory to document any irregularities upon receipt.[58]

123. **Transportation of the blood samples.** The Respondent submits that the samples were shipped on the same day as they were collected and thus fell within the

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50 Appeal Brief, section 2.2; Appellant Post-Hearing Brief, ¶¶65-68.

51 Note 125, Appeal Response.

52 Appeal Response, ¶114.

53 Collection Guideline 7.6.4 provides as follows: "*If the conditions for storage did not meet the guidelines for temperature in section 7.6, the DCO shall document this, and shall also contact the ADO immediately to inform them of the variation in temperature, and the length of time the samples were affected.*"

54 Appeal Response, ¶115.

55 Respondent Post-Hearing Brief, ¶64.

56 Respondent Post-Hearing Brief, ¶¶65-66.

57 Appeal Response, ¶¶114-115; Respondent Post-Hearing Brief, ¶67.

58 Collection Guideline 7.7.6 provides as follows: "*The Laboratory is required to document receipt and the subsequent chain of custody of samples. Samples are reviewed for evidence of tampering or damage, and stored in appropriate conditions until analysis in accordance with the ISL.*"

timeframe recommended by the Collection Guidelines, in that, first, the DCO must have dispatched the blood sample as soon as possible, on the same day and preferably within 36-48 hours of collection, as required under section 7.6.10,[59] and second, the samples were transported as soon as possible and within 36 hours of collection.[60] The Respondent also submits that the word "preferably" in the guidelines indicates that the 36 hours was not a mandatory limit, but instead a recommendation based on best practice.[61] In any event, the Respondent argues that even if the 36-hour limit was a mandatory requirement the Appellant would still be required to prove that this delay led to the AAF, and, the Respondent underlines, no such evidence has been submitted by the Appellant.[62] Further, the Respondent relies on the testimonies of Prof. Strasburger, Prof. Ho, and Dr. Barroso at the Hearing, who explained that any delays in the pre-analytical handling would, if at all, lead to dimerization or oligomerization of monomeric 22-kDa isoforms, but not to a "*decomposition*" of the pituary isoforms.[63] On this basis, the Respondent submits that the rec/pit ratio would only decrease from longer transportation times and could only result in a false negative rather than in a false positive test.

124. **Centrifugation of the blood samples.** The Respondent submits that the samples were stored under cooled conditions at the Laboratory until the A-sample was centrifuged and that the centrifugation took place within an acceptable time.[64] The Respondent argues that the samples were correctly handled in compliance with the ISL because they were stored at the correct temperature and were centrifuged the following morning, within the 24-hour time limit.[65] Further, the Respondent argues that if there were a delay in breach of the ISL, that the Appellant has not demonstrated how the delay caused the AAF.[66] The Respondent further argues that the Appellant's representative at the opening of the B-sample publicly acknowledged that the proceedings at the Laboratory were transparent and correct.

125. In light of the above, the Respondent maintains that no departure from the Guidelines occurred, and that there were no departures which could have caused the AAF.

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59 Appeal Response, ¶117; Respondent Post-Hearing Brief, ¶69. Collection Guideline 7.6.10 provides as follows: "*The DCO shall keep the samples under his/her control until they are passed to the courier. Blood Samples should be dispatched as soon as possible after collection to arrive at the Laboratory ideally on the same day, and preferably within 36-48 hours of collection.*"

60 Respondent Post-Hearing Brief, ¶70.

61 Respondent Post-Hearing Brief, ¶72.

62 Appeal Response, ¶117.

63 Respondent Post-Hearing Brief, ¶73.

64 Appeal Response, ¶114; Respondent Post-Hearing Brief, ¶¶77-80.

65 Respondent Post-Hearing Brief, ¶78.

66 Respondent Post-Hearing Brief, ¶81.

126. **QC policy of the Laboratory.** In response to the submissions of the Appellant that the Laboratory's QC policy can be presumed contrary to the ISL because the Respondent has not provided details of it, the Respondent argues that such a presumption should be rejected and points to the absence of a requirement in the ISL, the Guidelines or the Collection Guidelines for the Laboratory to submit any QC documentation or standard operating procedures ("SOP").[67]

127. Moreover, the Respondent argues that in any event the Laboratory had strict QC standards. Even though the Guidelines do not require, but only recommend that a laboratory implements internal quality control samples, the Laboratory only accepted samples if their ratios were less than 1.15 for negative controls and greater than 3.5 for positive controls. The Respondent submits that these requirements were met in the Appellant's case.[68]

128. **Excessive variability of measurement results.** The Respondent submits that the Appellant does not refer to any ISL which would have been violated, and that the ISL do not define a maximum difference between the A- and the B-samples or a maximum difference of ratios measured with separate kits.[69]

129. The Respondent further notes that while the ratios are the result of a calculation, the underlying concentrations of recGH and pitGH are within a very close range, and argues that the concentration differences between the A- and B-samples can be explained by the delay of almost two months between the two analyses, and the differences between the two kits resulting from their different composition of antibodies.[70] The Respondent also submits that the difference between the ratios of the A- and B-test with Kit 2 did not definitely cause the AAF.[71]

130. The Respondent has explained that the inter-assay CV concerns the acceptance value for the concentrations of samples, which, pursuant to section 5.1 of the Guidelines, is ±20% of the batch value. Both the control samples for each assay and the specific samples at issue should be within that 20% range of acceptance. On this basis, the Respondent argues that the Appellant has erred in its calculations on the inter-assay CV because the Appellant based its calculations on the ratios for the samples, not their concentrations. The Respondent submits that the values for the control samples are all within the 20% range.[72] The Respondent states that the Appellant's expert witness Dr. De Boer erroneously refers to the values of the ratios and not to the concentration values in this context.[73]

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67 Respondent Post-Hearing Brief, ¶87.

68 Respondent Post-Hearing Brief, ¶91.

69 Respondent Post-Hearing Brief, ¶83.

70 Respondent Post-Hearing Brief, ¶84.

71 Respondent Post-Hearing Brief, ¶¶82-85.

72 Respondent Post-Hearing Brief, ¶¶88-89.

73 Respondent Post-Hearing Brief, ¶89.

c) Analysis and Finding of the Panel

131. **Temperature and handling of the samples in the first five hours after collection.** According to Section 7.6 of the WADA Guidelines for Blood Sample Collection (Version 2.2, August 2010):[74]

"*The Blood Samples must be stored in a cool location, preferably in a refrigerator or cool box. Temperature should be maintained between 2-12 degrees Celsius.*

If the conditions of storage did not meet the guidelines for temperature in section 7.6, the DCO shall document this, and shall also contact the ADO immediately to inform them of the variation in temperature, and the length of time the samples were affected."

132. The Panel finds that it is unambiguously stated that the DCO must only report the exact temperature at which the samples are stored if there is a deviation from the guidelines. As the DCO did not report the exact temperature, it can be presumed, and the Panel finds, that this condition was complied with and that there was no deviation from the Collection Guidelines with regard to the preservation and handling of the samples in the five hours following their collection.

133. **Transportation time.** The Panel notes that the Collection Guidelines indicate two different preferred timeframes for arrival of the samples at the Laboratory. Section 7.6.10 denotes a preferred time of within 36-48 hours of collection, while Section 7.7.5 states a preferred time of 36 hours. The Appellant's samples arrived 42.5 hours after collection. From this, the Panel is comfortably satisfied that there was no actual breach of the Collection Guidelines. In any case, the word "preferably" does not denote an absolute and mandatory requirement. The samples were reviewed by the Laboratory upon arrival and no irregularities were found. On this basis, the Panel does not find a breach of the Collection Guidelines as regards transportation time.

134. **Centrifugation of the blood samples.** The Panel notes that there was some delay between the time of the samples' arrival at the Laboratory and their centrifugation. The samples were centrifuged 23 hours after their arrival at the Laboratory, and 65 hours and 20 minutes after they were collected. However, there is no mandatory requirement of immediate centrifugation in the ISL. ISL 6.2.2.5 stipulates that samples *should* be centrifuged immediately after Laboratory reception, but allows also their storing refrigerated at approximately 4 degrees Celsius provided that they are analyzed within 48 hours after centrifugation. The Appellant has thus not been able to establish any violation of the ISL or any other applicable rule.

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[74] The 2011 Version of these Guidelines was published in August 2011, which was after the relevant events. In any case, there appears to be no substantive difference between the two versions for our purposes.

The time limit of 60 hours in the Kits' instruction manuals is, according to its wording, only a recommendation. Pursuant to the expert witnesses heard at the Hearing, an excessive delay can only result in a lower ratio and false negative and not a false positive. Furthermore, it is unlikely that an additional delay of 5.5 hours after the recommended maximum delay in centrifugation time of 60 hours (i.e., less than 10 %) can have had any substantial effect on the result. Therefore, the Panel finds that this argument of the Appellant is without merit.

135. **QC policy of the Laboratory.** The Panel is convinced by the submissions of the Respondent that there is no ISL which requires that internal QC policies be provided to individuals such as the Appellant. On that basis, the Panel is not persuaded that a presumption against the application of ISL standards should be maintained where QC policies are not provided. Therefore, the Panel finds that there has been no breach of any ISL and no violation of the right of the Appellant to defend itself. The Panel rejects the Appellant's arguments on this point.

136. **Excessive inter-assay variability of measurement results.** The Panel finds that the Appellant has not been able to establish a violation of ISL or any other applicable rule in this respect. In general, the Appellant has failed to point to any rule requiring that the ratios obtained from an individual athlete's samples must not differ significantly from each other. With regard to differences between the ratios measured by different Kits (Kit 1 and Kit 2), the Panel concludes that by their very nature, Kit 1 and Kit 2 *should* give different results because different antibodies are employed by the two kits. With regard to differences between the Appellant's A- and B-samples, the Panel notes that the difference between the ratios of the Appellant's A- and B-samples as measured with Kit 2 is quite high (A- sample 3.07, B- sample 2.00). The Panel however notes that this difference has been partially caused by the quite low overall concentrations measured from the Appellant's samples, which would lead to significant differences in ratios even with only minor concentration changes in subsequent measurements.[75] In addition, the Panel considers that the difference between the Appellant's Kit 2 A- and B-samples has been partially caused also by the 57-day delay[76] between the two analyses. The Panel thus cannot see the difference as evidence of any irregularities in the samples or performance of the Test.

137. **Panel's conclusions on the alleged ISL violations.** In any event, the Panel finds that the Appellant has not demonstrated that any shortcomings or violations of the ISL in the pre-analytical handling, alleged or otherwise, could have led to a false positive finding. Although the Appellant argues that the alleged deviations from the ISL increased the chance of false positive results, the Appellant has not provided evidence to indicate that the particular departures at stake in these

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75 While the difference in ratios between the A and B samples has been 35 %, the difference in concentrations has been only 16 % for recGH (mean recGH has decreased from 0.43 to 0.36) and 28 % for pitGH (mean pitGH has increased from 0.14 to 0.18). Exhibit RE-12 p. 29 and p. 65.

76 The A sample analysis with Kit 2 was performed on February 8, 2011, and the B sample analysis with Kit 2 on April 6, 2011. Exhibit RE-12 p. 29 and p. 65.

proceedings could reasonably have led to an AAF. On the other hand, the Respondent has produced testimonies from three expert witnesses alleging that any effect, which the alleged departures may have had on the samples, would have been to the benefit of the Appellant. At the Hearing, Prof. Strasburger, Prof. Ho and Dr. Barroso provided convincing explanations that any delays in the pre-analytical handling would, if at all, lead to dimerization or oligomerization of monomeric 22 kDa isoforms but not to a "*decomposition*" of the pituitary isoforms. Consequently, the rec/pit ratio would decrease and could only result in a false negative result.[77] As a result, the Panel is satisfied that if affected, the samples were more likely to produce a false negative result than a false positive. Therefore, the Panel must reject the Appellant's submissions regarding the alleged non-compliance with the ISL.

4. The Appellant's Individual Circumstances

a) The Appellant's Arguments

138. **Impact of training and genetic predisposition.** It is the Appellant's case that the hGH level in his blood samples increased 150 times the baseline after exercise and, even after a two-hour recovery period, hGH levels had not normalized, instead remaining thirty times higher than the baseline.[78] According to the Appellant, the hGH level in athletes increases 50 to 250 times compared to baseline after three hours of exercise, an increase much higher than that expected according to the data in the scientific literature presented by the Respondent and what was claimed in Dr. Barroso's Witness Statement.[79] Further, the Appellant suggests that not only does strenuous exercise have a longer-lasting effect than described in the scientific literature, but also that the Appellant had more pronounced and longer-lasting hGH release because of a genetic peculiarity he possessed that resulted in the 22 kDa:20 kDa hGH ratio in his blood differing from the literature's reference population. The Appellant supports this claim by submitting that the screening Test results showed that the Appellant had the highest recGH values and the third highest pitGH values of all the persons tested.[80] In light of this, the Appellant submits that there was a physiological and genetic reason to have had an increased 22 kDa:pitGH ratio and, as such, the Test result was a false-positive.[81]

139. **Non-standardized conditions.** The Appellant claims that the Test is not robust against extreme physiological conditions such as intense physical training in high-

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77 Respondent Post-Hearing Brief, ¶73.

78 Appeal Brief at section 3.1.

79 Appeal Brief at section 3.1.

80 Appellant Post-Hearing Brief, ¶76.

81 Appeal Brief at section 3.1.

altitude conditions.[82] The Appellant argues that such conditions would increase the 22 kDa/20 kDa GH isoforms to the prejudice of the Athlete, and that the normalization of hGH levels would have taken a longer time so that the Athlete's hGH secretion would have increased.[83] The Appellant also argues that the Respondent only assumes that intense training does not alter the ratio between 22 kDa isoforms and other hGH isoforms.[84] To support the submission that the samples were collected following intense training and at high-altitude, the Appellant relies on his own witness statement and that of Jaak Mae, another athlete who was present in the Tehvandi Sports Centre where the blood sample collection took place. The Appellant cites the opinions of the Tartu University Scientists, according to whom those conditions could have led to the high 22 kDa/20kDa ratio.[85]

b) The Respondent's Arguments

140. **Impact of training and genetic predisposition.** The Respondent asserts that there is no data which would indicate if and to what extent the Appellant's organism reacts differently to intense training and why this would lead to a false positive result. The Respondent states that although there is much literature on the influence of exercise on hGH secretion, most of it focuses on laboratory exercise protocols for acute, short-term aerobic exercise, and are inapplicable for extended and high intensity exercise.[86] The Respondent relies on the testimony of Prof. Strasburger who explained that although stress could have caused a rise in hGH, rather than the exercise, this would only have affected the overall concentration of hGH, not the ratios between monomeric 22 kDa and other isoforms, contrary to the submissions of the Appellant.[87] Further, the Respondent argues that even if the ratio would slightly increase due to exercise, it would return to normal within 30 minutes following the exercise and would always remain well within the decision limits.[88] In any event, the Respondent notes that the concentration levels of hGH in the Athlete's samples were "rather low" so indicating that the exercise or hypoxia did not affect the Athlete's levels of hGH.[89]

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82 The Appellant clarified in its Post-Hearing Brief at ¶74 that the relevant conditions were not hypobaric, but hypoxic, that is, the Appellant claims the effect of low oxygen conditions rather than high pressure.

83 Appeal Brief at section 3.2.

84 Appellant Post-Hearing Brief, ¶39.

85 Appeal Brief at section 3.2.

86 Appeal Response, ¶104.

87 Respondent Post-Hearing Brief, ¶98.

88 Respondent Post-Hearing Brief, ¶33.

89 Respondent Post-Hearing Brief, ¶99.

141. The Respondent also argues that the 3.5 hours of strenuous exercise has not been proven, and that the testimony of Jaak Mae could not be relied upon because Mr. Mae did not train with the Appellant on that day.[90]

142. The Respondent also points out that the Appellant gave no specific information on why his genetic predisposition would be different to that of other athletes and how this could have led to a false positive.[91] On this point, the Respondent argues that the Appellant had failed to meet his burden of proof under Article 3.2 FIS ADR.

143. **Altitude-related issues.** The Respondent argues that even if the Appellant had been in high-altitude conditions prior to the blood sample collection, for which it claims there is no evidence, this could not have produced the claimed effect on the Appellant's hGH production.[92] For in the Respondent's view, it takes time for altitude conditions to have an effect on the human body.[93] Therefore, the Respondent submits that even if the Appellant had been using an altitude simulator two days prior to the taking of the blood sample in question (for which the Respondent submits it sees no proof), this could not have had the alleged effect on the Athlete's hGH level and ratios.[94] As above, the Respondent relies on the testimony of Prof. Strasburger to explain that stress could have caused a rise in hGH, rather than the high-altitude conditions, but that this would only have affected the concentration of hGH, not the ratios between monomeric 22 kDa and other isoforms, contrary to the submissions of the Appellant.[95]

144. Therefore, the Respondent argues that high-altitude conditions did not lead to any elevated 22 kDa/pitGH ratio and that the Appellant has not discharged its burden of proof under Article 3.2 FIS ADR.

c) Analysis and Findings of the Panel

145. **Impact of training and genetic predisposition.** The Appellant has not demonstrated to the satisfaction of this Panel that his prolonged intense training resulted in an elevated 22 kDa/pitGH ratio. Both the Respondent and the Appellant have submitted studies on the effects of exercise on the secretion of hGH. These studies indicate, contrary to the Appellant's submissions, that exercise-induced effects do not appear to continue to increase after 60 minutes of training, but may actually slightly decrease. Further, the Panel is convinced by the arguments of the Respondent, that even if exercise causes increased secretion of hGH, this would mainly affect the overall concentration of hGH, while the magnitude of the effects on the rec/pitGH ratio would remain limited and would

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90 Respondent Post-Hearing Brief, ¶95.

91 Appeal Response, ¶103.

92 Appeal Response, ¶111; Respondent Post-Hearing Brief, ¶98 and ¶100.

93 Appeal Response, ¶111.

94 Appeal Response, ¶111.

95 Respondent Post-Hearing Brief, ¶98.

not in any case explain the ratios detected in the Appellant's sample[96]. Furthermore, the Panel agrees with the Respondent's argument that the overall concentration levels of hGH in the Appellant's samples were relatively low, indicating that the exercise did not substantially affect the Appellant's levels of hGH any longer at the time of sample collection.

146. With regard to the Appellant's alleged genetic predisposition, the Appellant has failed to persuade the Panel that the Athlete in fact has any such a genetic peculiarity. This assertion was not supported by any scientific proof, an analysis of the Appellant's genetic makeup or other evidence of any kind, but is, in the opinion of this Panel, just an unfounded speculation on the part of the Appellant's experts. Therefore, the Panel cannot accept the argument that a genetic peculiarity of the Appellant was the cause, or a contributing cause, of the finding which is the subject of this appeal.

147. **Altitude-related issues.** The Panel agrees with the Respondent that even if the Appellant had been in high-altitude conditions prior to the blood sample collection, this could not have produced the claimed effect on the Appellant's rec/pitGH ratio. Even though training and staying in high altitude conditions may have an impact on overall hGH secretion,[97] there is no evidence that the magnitude of any possible effect to rec/pitGH ratio could sufficiently high as to explain the ratios detected from the Appellant's sample. The Panel is also not persuaded by the Appellant's unsubstantiated submission that such conditions would have a negative effect on the blood sample so as to result in a false-positive Test result.

148. Based on the above, the Appellant's arguments failed to convince the Panel that any relevant individual circumstances existed, and even if they did, the Appellant failed to demonstrate to the required standard of proof that such individual circumstances could have caused the AAF.

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96 The maximum exercise-induced increase in the rec/pitGH ratio discovered in the study of Wallace et al. from 8 non-doped athletes was 48% (from 0.54 to 0.80) after 30 minutes of exercise (*see* Wallace, Cuneo, Bidlingmaier, Lundberg, Carlsson Boguszewski, Hay, Boroujerdi, Cittadini, Dall, Rosén and Strasburger, 'Changes in non-22kDa Isoforms of Growth Hormone after Administration of 22-kDa Recombinant Human GH in Trained Adult Males' (2001) Journal of Clinical Endocrinology & Metabolism 86 ("Wallace et al"), 1731-1737, table 1 and figure 2. The antibodies employed and isoforms measured as the rec/pitGH ratio by Wallace et al. were not exactly the same as the rec/pitGH ratio measured by the Test, but Wallace et al nevertheless indicates that some elevation in the ratio may occur during exercise.

97 See, for example, Benso, Broglio, Aimaretti, Lucatello, Lanfranco, Ghigo and Grottoli 'Endocrine and metabolic responses to extreme altitude and physical exercise in climbers' (2007) European Journal of Endocrinology 157, 733-740; and Kon, Ikeda, Homma, Akimoto, Suzuki and Kawahara 'Effects of acute hypoxia on metabolic and hormonal responses to resistance exercise' (2009) Medicine & Science in Sports & Exercise 42, 1279-1285.

5. Reliability of the Test

a) The Appellant's Arguments[98]

149. The Appellant, in essence, contends that the WADA Test for hGH detection is unreliable, and as a result, is not suitable for the routine screening of doping use.[99] First, the Appellant claims that the Respondent has not (fully) made the scientific data upon which the Test is based publicly available and this renders impossible any independent review. Secondly, the Appellant argues that it is uncertain what the Test measures and how its conclusions can lead to the finding of exogenous substances in an athlete. Thirdly, the Appellant alleges that the Test is based on incorrect, underlying scientific assumptions. Fourthly, the Appellant claims that the A- and B-sample results point to systematic measurement errors that form part of the Test. Fifth, the Kits are labeled "For research use only." Lastly, the Appellant submits that the Test developers have a conflict of interests that undermines their objectivity and neutrality as expert witnesses in these proceedings. These submissions are now detailed in turn.

150. **Reviewing the validity of the Test from the Respondent's scientific data.** The Appellant argues that the Test is unreliable because the scientific data which would permit reviewing of the Test's validity has not been provided. The Appellant here relies on the Respondent's refusal to give the Appellant access to the Kits and the underlying data despite several attempts to contact those producing the Test.[100] The Appellant's scientific experts, Dr. de Boer and Prof. Köks, have both asked the producers of the Test and WADA for samples of the Kits, for data relating to the Kit components and for documents relating to the Test development. These requests were rejected by the Respondent and WADA.[101] On October 17, 2011 and October 25, 2011, the Respondent was asked by the Panel to produce all documents on which the Cologne Laboratory relied in order to validate the Test. Although the Respondent subsequently produced several documents, the Appellant remained unsatisfied, claiming that the documents did not enable it to scientifically review the validation of the Test.[102] Subsequently, the Appellant requested detailed data on the blood samples

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98 In this decision, the arguments made by the Appellant are taken from the Appeal Brief of September 22, 2011, the Appellant's Post-Hearing Brief of June 29, 2012, the Appellant's comments to the Respondent's Answers to the First Set of Panel Questions, and the Appellant's comments to the Respondent's Answers to the Second Set of Panel Questions. The evidence presented by the Appellant's experts in their various expert opinions is also referred to where appropriate. These expert opinions include: Dr. De Boer, June 3, 2011; Tartu University Scientists, July 7, 2011; Tartu University Scientists, September 21, 2011; Dr. De Boer, July 5, 2011; Dr. De Boer, May 15, 2011; and Tartu University Scientists, May 20, 2011, Dr. Krista Fischer and Prof. Sulev Kõks, October 14, 2012; and Dr. Krista Fischer, January 30, 2013.

99 Appeal Brief, at section 2.1.

100 Appellant Post-Hearing Brief, ¶¶9-10.

101 Appellant Post-Hearing Brief, ¶11.

102 Appellant Post-Hearing Brief, ¶¶14-15.

used to establish the decision limits, the positive and negative reference samples, the sensitivity and specificity of the Test, the chosen cut-off values used in the Test, the antibodies used to find both the 22 kDa isoforms, and the validation studies of the Laboratory.[103] Although the Appellant agrees that it is possible that the Test was correctly validated, the Appellant alleges that this is an assumption only, and that the Test cannot be relied upon until it has been reviewed.[104]

151. To support its argument on the inability to review the validation of the Test, the Appellant also cites the National Football League Players Association's ("NFLPA") efforts to obtain validation data from WADA.[105]

152. Similarly, the Appellant argues that the decision limits are unreliable because the underlying protocols behind the collection of sample data are not provided and that there is no evidence that the sample data is from the sources claimed.[106]

153. The Appellant further submits that by failing to provide the Kits or sufficient data to allow the Appellant to scientifically review the validation of the Test, the Respondent has not acted transparently and has violated the Appellant's right to be heard pursuant both to Articles 29 and 32 of the Swiss Constitution and Article 6 of the ECHR.[107]

154. **Uncertainty as to what the Test measures.** The Appellant seeks to rely on the opinions of the Tartu University Scientists to establish uncertainty as to what the Test measures. Two sets of their opinions, dated May 20, 2011 and September 21, 2011, have been submitted as evidence in this regard. The Tartu University Scientists claim that the Test only measures endogenous substances and cannot differentiate between exogenous and endogenous hGH, contrary to ISL section 5.4.4.1.2.[108]

155. **The Test's underlying assumptions are flawed**. The Appellant argues that the Test has not been properly validated and is unreliable because it is based on incorrect assumptions in relation to: (a) Intra- and Interpersonal Variability in hGH secretion; (b) the specificity of the antibodies employed; (c) the stability of

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103 Appeal Brief at section 2.4 and Appellant Post-Hearing Brief, ¶16.

104 Appellant Post-Hearing Brief, ¶15, ¶17.

105 Appeal Brief, section 2.7; Appellant Post-Hearing Brief, ¶20.

106 February 5, 2013 Comments on Respondent Answers, ¶47 and ¶85.

107 Appellant Post-Hearing Brief, ¶¶ 18-21.

108 Appeal Brief, section 2.5; Appellant Post-Hearing Brief, ¶2[mentioned in the context of a breach of Article 2.2 FIS ADR] and ¶38. Section 5.4.4.1.2 provides: "*... In the case of substances which are capable of being produced endogenously (for example testosterone, peptide hormones) and at any concentration (including below relevant thresholds), the Athlete's sample will be deemed to contain a prohibited substance and the Laboratory will report on Adverse Analytical Finding if, based on any reliable analytical method (e.g. IRMS), the Laboratory can show that the prohibited is of exogenous origin.*"

the ratios between rec and pit hGH; (d) other influences on ratios; and (e) the potential for athletes to change the Test results.

High Intra- and Interpersonal Variability in hGH secretion. The Appellant points to the views of experts at the Hearing to highlight the high variability in hGH secretion depending on, for example, the athleticism of an individual.[109] The Appellant argues that the Test is unreliable because it does not account for the fact that hGH secretion varies significantly between individuals and between the same individual at different occasions.[110]

Lack of specificity of the antibodies employed by the Test. The Appellant rejects the Respondent's assumption that the antibodies that detect the various hGH isoforms operate in the same way in the blood stream as in the pituitary gland.[111] The Appellant argues that the antibodies are insufficiently specific and recognize proteins other than hGH, and that this leads to an overinclusive hormone reading.[112] The Appellant gives the AK58 antibody as an example, and alleges that it is not specific to recGH, as claimed by WADA, but that it cross-reacts fully with clip 2 protein and partially with clip 1 protein.[113] The Appellant submits that the western blots provided by the Respondent cannot be relied upon to prove the specificity of the antibodies because the blots provided did not use human serum.[114] The Appellant also rejects the evidence of Dr. Barroso in this regard, and claims that Exhibit RW 4 indicates that the pitGH assay measures a wide range of proteins.[115] Finally, the Appellant argues that the Test is unreliable because there is no data on the specificity of each antibody separately.[116]

Unstable ratio between rec and pit hGH. First, the Appellant claims that the secretion of hGH, both the amount of 22 kDA isoforms and its ratio to different hGH isoforms, changes constantly, even during the course of a normal day.[117] On this basis, the Appellant submits that the Respondent's assumption that the ratio usually stays within certain limits has no scientific confirmation and is incorrect.[118]

Further, the Appellant argues that the association between recPH and pitGh is nonlinear, that is, the ratio between the recGH and pitGH is not constant as the

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109 Appellant Post-Hearing Brief, ¶30.

110 Appellant Post-Hearing Brief, ¶31.

111 Appellant Post-Hearing Brief, ¶36.

112 Appellant Brief at 1.1; Appellant Post-Hearing Brief, ¶36.

113 Appeal Brief at section 1.1.

114 Appellant Post-Hearing Brief, ¶37.

115 Appellant Post-Hearing Brief, ¶37, in particular, notes 33 and 34.

116 Appellant Post-Hearing Brief, ¶38.

117 Appellant Post-Hearing Brief, ¶32; Comments to Respondent Answers to First Set of Panel Questions, ¶¶34-38.

118 Appellant Post-Hearing Brief, ¶¶32-33.

pitGH levels vary.[119] The Appellant submits that the existence of outlier results, in both directions, suggests that there are factors aside from recGH which create variability within the ratio.[120] On this basis, the Appellant argues that the sample data cannot be fitted to a parametric distribution in respect of recGH/pitGH ratios because this data is neither independent nor identically distributed.[121]

In addition, the Appellant argues that the Respondent assumed that the exogenous recGH 22 kDa isoforms do not form any dimers in the blood and are therefore detectable.[122] The Appellant points to statements made by Prof. Köks that were, according to Prof. Köks, acknowledged by Prof. Strasburger at the Oral Hearing. The Appellant submits that monomers can form dimers and oligomers, and vice versa, and that, as a result, exogenous hGH consistently changes its form in the blood, thus rendering the hGH ratio of the exogenous isoforms unstable.[123]

Other distortive influences on the ratios. The Appellant submits that the Respondent assumes, incorrectly and without scientific confirmation, that strenuous training before testing, hypoxic conditions or the transportation conditions for the blood samples do not alter the ratio between the 22 kDa isoforms and other hGH isoforms.[124] Indeed, the Appellant argues that the increased pulses arising from strenuous exercise or hypoxic conditions would change these ratios, and that transportation conditions, particularly the time between collection and analysis, would unpredictably alter the ratios in the samples.[125]

The potential for athletes to change the Test's results. The Appellant argues that the Respondent incorrectly assumes that recGH consists only of 22 kDa isoforms and that through the injection of 22 kDa isoforms the non-22 kDa concentrations are reduced.[126] The Appellant relies on Dr. Strasburger's testimony at the Hearing to submit that the Test is ineffective because there are other forms of recGH and hGH isoforms which athletes could obtain and inject.[127]

156. **The inter-assay variability of the A- and B-samples points to systematic measurement errors that form part of the Test.** The Tartu University

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119 Comments to Respondent Answers to First Set of Panel Questions, ¶¶35-36; January 31, 2013 Comments on Respondent Answers, ¶35.

120 January 31, 2013 Comments on Respondent Answers, ¶35.

121 January 31, 2013 Comments on Respondent Answers, ¶36.

122 Appellant Post-Hearing Brief, ¶35.

123 Appellant Post-Hearing Brief, ¶35.

124 Appellant Post-Hearing Brief, ¶¶39-40.

125 Appellant Post-Hearing Brief, ¶¶40-41.

126 Appellant Post-Hearing Brief, ¶42.

127 Appellant Post-Hearing Brief, ¶42.

Scientists state that there is a difference of 33% between the results of the A- and B-sample, which, they claim, exceeds the difference limit (interassay variability) of 20% listed in the hGH Guidelines for the Test.[128] In particular, the Appellant queries why the samples collected from the same person at the same inspection yield such different results.[129] The Appellant argues that this difference could only be attributed to a methodical, technical, or measurement error, and thus indicates a serious problem with the Samples and/or Test.[130] The Appellant further argues that not only should the behavior of the Test be validated, but that the variability between the A- and B-sample Test measurements should also be validated so that there is a validated, fixed limit to that variability.[131]

157. **The Kits are labeled "For research use only."** As the Kits are labeled "For research use only – not for use in diagnostic procedures" the Appellant argues that this indicates "*poor or complete lack of validation.*"[132] In this regard the Appellant argues that there is no technical document for the Test, and that this provides a clear indication that the Test is not validated.[133] In addition, the Appellant cites Prof. Köks to support its further submission that, in accordance with the European Commission's "Guidelines on Medical Devices", medical devices labeled "for research use only" may not be used for the examination of blood with the purpose of providing information on physiological state of a human being. On this basis, the Appellant submits that the Kits are both unreliable and have been used contrary to EU Law.[134]

158. **Alleged conflict of interest.** The Appellant submits that the reliability of the Test must be questioned because the developers of the Test method are also the producers of the Kits.[135] In this regard, the Appellant relies on the fact that the developers of the Test, who were also the Respondent's principal expert witnesses during the Oral Hearing, have a direct and significant financial interest in the Test's success. The Appellant argues that should the Panel rule against the Test's validity, the developers would stand to lose financially due to substantial, future lost profits. Further, the Appellant highlights that this Test is sold only to WADA, which gives scientific grants to the scientists in question. The Appellant also underlines that WADA has invested heavily in the development of the Test, which provides a further incentive to WADA to keep it "alive" at any cost. This, the Appellant argues, creates a conflict of interest where the objectivity and

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128 Appeal Brief at section 2.2; Appellant Post-Hearing Brief, ¶¶65-68.

129 Appellant Post-Hearing Brief, ¶¶65-69.

130 Appeal Brief at section 2.2 and Dr. Köks's testimony at the Hearing, as cited in Appellant Post-Hearing Brief, ¶68.

131 Appeal Brief at section 2.2.

132 Appeal Brief at section 2.3 and Appellant Post-Hearing Brief, ¶72.

133 Appeal Brief at section 2.3.

134 Appellant Post-Hearing Brief, ¶¶71-73.

135 *See* Appeal Brief at section 6; October 15, 2012 Comments on Respondent Answers, ¶43; and Appellant Post-Hearing Brief, ¶17.

neutrality of both the development and implementation of the Test cannot be presumed, thus rendering it unreliable.

b) The Respondent's Arguments

159. Contrary to Appellant's arguments, the Respondent submits that the Test is reliable and properly validated. First, the Respondent rejects the Appellant's claim that the scientific data on which the Test is based should have been made publically available. Secondly, the Respondent argues that it is not uncertain what the Test measures. Thirdly, the Respondent submits that the Test is based on correct assumptions. Fourthly, the Respondent claims that the Test results do not point to systematic measurement errors that form part of the Test. Fifth, the Respondent submits that it is irrelevant that the Kits are labeled "For research use only". Lastly, the Respondent argues that the Test developers have no conflict of interests that would call into question their reliability as expert witnesses. These arguments are detailed below.

160. **Validity of the Test established by the Respondent's scientific data.** As a preliminary point, the Respondent submits that there is no ISL or any other provision that requires, as a precondition of a test's validation, that the details of anti-doping tests be published or that the hGH kits be made available to interested parties.[136] The Respondent further argues that the functioning of the Test was published by Dr. Bidlingmaier and others in a leading, peer-reviewed journal in the article 'High-sensitivity chemiluminescence immunoassays for detection of human growth hormone doping in sports' (2009) Clinical Chemistry 55, 445-453 ("Bidlingmaier et al") and that this constitutes sufficient review.[137]

161. The Respondent expresses sympathy for the Appellant's scientific interest in learning more about the Kits, but submits that WADA, seeking to balance the relevant interests at stake, chose to have the Test reviewed by independent experts and WADA-accredited laboratories and its stability reviewed through open, blind and double blind samples.[138]

162. The Respondent maintains that there is a good reason for not selling the Kits outside of WADA-accredited laboratories. The Respondent argues that the Kits' anti-doping purpose would be undermined if they were available to all laboratories, because this would facilitate doctors and athletes seeking to "*beat the system*" by trying to reverse-engineer the Test in an effort to develop new doping methods capable of remaining undetected by it.[139]

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136 Respondent Post-Hearing Brief, ¶58.

137 Respondent Post-Hearing Brief, ¶26 and ¶60.

138 Respondent Post-Hearing Brief, ¶59.

139 Respondent Post-Hearing Brief, ¶62.

163. The Respondent also claims that the Appellant's references to the NFLPA are irrelevant in the context of this case.[140]

164. Finally, the Respondent underlines that it has comprehensively and in detail responded to the Panel's questions on the Test, including on its decision limits.[141]

165. **No uncertainty as to what the Test measures.** The Respondent states that the Test has been described in great detail both in the WADA hGH Guidelines and the Bidlingmaier et al publication.[142] Further, the Respondent submits that at the Hearing the Parties agreed on what the Test actually measures, namely the concentrations of two sorts of hGH isoforms: Monomeric 22 kDa hGH on the one hand and a combination of other isoforms of hGH (dimeric and high molecular weight hGH forms) on the other.[143] The Parties agreed that if the ratio between the concentrations of monomeric 22 kDa isoform, which is predominantly present after injection of hGH, and other defined, mainly pituitary, isoforms exceeds the Test's defined decision limits, the result would lead to an AAF.[144]

166. Regarding the Appellant's reference to section 5.4.4.1.2 ISL and the alleged need for the Test to show "*directly*" that the prohibited substance is of exogenous origin, the Respondent rejects that submission, claiming that nothing in the ISL prohibits the identification of prohibited substances with the help of ratios and levels. Instead, the Respondent maintains that this is a well-established and widely used method to identify doping with substances produced by the human body.[145]

167. The Respondent also rejects the Appellant's assertion that no true positive samples have emerged in situations where individuals have used exogenous hGH. The Respondent seeks to rely on several examples, including positive findings which were often corroborated by con**c**essions in sports such as swimming, rugby, American football, and baseball.[146]

168. **Correct assumptions on which the Test is based.**

Intra and interpersonal variability in hGH secretion. In the course of its submissions, the Respondent relies on the distinction between the absolute concentrations of hGH, which are subject to change, and its composition, which is a mixture of isoforms present in constant relative proportions.[147] It follows from

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140 Appeal Response, ¶94.

141 February 6, 2013 Comments.

142 Respondent Post-Hearing Brief, ¶26.

143 Respondent Post-Hearing Brief, ¶27.

144 Respondent Post-Hearing Brief, ¶27.

145 Respondent Post-Hearing Brief, ¶29.

146 Appeal Response, ¶87.

147 Appeal Response, ¶66; Respondent Post-Hearing Brief, ¶31.

these submissions, according to the Respondent, that even if there is high intra and interpersonal variability in hGH secretion, this variability would not affect the functioning of the Test because the rec/pit ratio between the concentrations of monomeric 22 kDA would not change.

Specificity of the antibodies employed by the Test. With regard to the Appellant's claim that the antibodies in the Test are overinclusive, the Respondent first argues that these claims are purely speculative and that these arguments do not call the reliability of the Test into question because section 6.2.4.2.1.2 ISL does not require antibodies which are completely different, that is, without any overlap, for every assay.[148] Second, the Respondent argues that the antibodies are sufficiently specific and relies on Prof. Strasburger's testimony at the Hearing during which it was underlined that the selection of antibodies was the result of multiple investigations of cross-reactions and was conducted in cooperation with other scientists in other laboratories.[149] Third, the Respondent points to the fact that the specificity of the antibodies used in the Test was also a key component of the Bidlingmaier et al paper, which was published in a leading, peer-reviewed journal.[150]

Stability of the ratio between rec and pit hGH. As above, the Respondent argues that the Test is based, correctly, on the following two principles: first, that the normal composition of hGH in blood is a mixture of different isoforms that are present at constant relative proportions; and that, second, rec hGH is only comprised of the monomeric 22 kDa molecular form and that its administration alters the natural ratios established between the 22 kDa isoform and non-22 kDa isoforms.[151] To submit that the Test is correctly based on these principles, the Respondent relies on the work of Dr. Gerhard Baumann, set out in 'Growth hormone doping in sports: a critical review of use and detection strategies' (2012) Endocr Rev 33(2), 155-86, and 'Growth hormone isoforms' (2009) Growth Hormone & IGF Research 19, 333-340,[152] the work of Wallace et al, in 'Changes in non-22-kilodalton)(kDa) isoforms of growth hormone (GH) after administration of 22-kDa recombinant human GH in trained adult males' (2001) J

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148 Respondent Post-Hearing Brief, ¶38. ISL 6.2.4.2.1.2 provides in relevant parts: *"Immunoassays applied for the Initial Testing Procedures and Confirmation Procedures shall use antibodies recognizing different epitopes of the macromolecule analyzed, unless a properly validated purification or separation method is incorporated into the confirmation method to eliminate the potential for cross-reactivity prior to the application of "A" confirmation immunoassay. In assays which include multiple antibodies (such as sandwich immunoassays), only one of the antibodies (either capture or detection) used in the immunoassays applied for the Initial Testing Procedures and Confirmation Procedures must differ for antigenic epitope specificity. The other antibody may be used in both immunoassays."* It is common ground in this proceeding that hGH immunoassays are sandwich immunoassays employing multiple antibodies.

149 Respondent Post-Hearing Brief, ¶39.

150 Respondent Post-Hearing Brief, ¶39.

151 Appeal Response, ¶66; Respondent Post-Hearing Brief, ¶31-36.

152 Respondent Post-Hearing Brief, ¶32

Clin Endocrinal Metab 86, 1731-1737,[153] and the testimony of Prof. Strasburger at the Hearing.[154] The Respondent submits that there is no evidence of a statistically relevant change in the ratio between recGH and pitGH; the ratios can form the basis of the Test without undermining its validity or reliability.[155] According to the Respondent, the absolute concentrations of hGH may be subject to change for other reasons, but the ratio of the isoforms that is the basis of the Test remains stable.[156]

The Respondent also rejects the Appellant's submission that dimers could disintegrate into monomers and so alter the isoform ratios.[157] The Respondent highlights that the Appellant's expert, Prof. Köks, relied on "outdated" articles that did not support his hypothesis.[158] The Respondent relies on the testimony of Prof. Ho at the Oral Hearing to argue against the "two-way street" proposition advanced by Prof. Köks at the hearing.[159]

No other influences on the ratios. As above, the Respondent argues that influences such as exercise will not substantially alter the ratio of the hGH isoforms and submits that the Appellant erred in relying on an older study on a different topic which had been subsequently revised.[160] While the Respondent accepts that in the study by Wallace et al.[161] "a slight increase" of the ratio between 22 kDA isoform and 20 kDA isoform was witnessed, such an increase was, according to the Respondent, "very minor (from 0.6 to 0.75)".[162] Finally, the Respondent argues that in situations where hGH secretion is stimulated, whether by exercise or hypoxia, even minor changes in the ratio return to normal ranges soon after the stimulation due to the fact that other isoforms become predominant because of their longer half-lives, so that the ratios relevant to this Test remain unaffected.[163]

169. **No interassay variability pointing to systematic measurement errors that form part of the Test.** According to the Respondent, arguments regarding the percentage differences between the A- and B-sample results concern the Laboratory's execution of the Test, and not, as the Appellant alleges, the

153 Appeal Response, ¶66.

154 Respondent Post-Hearing Brief, ¶¶32-33.

155 Respondent Post-Hearing Brief, ¶33.

156 Respondent Post-Hearing Brief, ¶31.

157 Respondent Post-Hearing Brief, ¶¶34-36.

158 Respondent Post-Hearing Brief, ¶¶34-35.

159 Respondent Post-Hearing Brief, ¶36.

160 Respondent Post-Hearing Brief, ¶32-33.

161 Wallace et al, pp. 1731-1737.

162 Respondent Post-Hearing Brief, ¶33.

163 Respondent Post-Hearing Brief, ¶33.

reliability of the Test itself.[164] The Respondent further submits that the Appellant's argument regarding the difference in percentages between the A- and B-sample results is unclear because the Appellant has not specified which difference is at issue.[165] To clarify the argument, the Respondent submits that the requirement that the variation should not have been greater than 20% referred, in fact, to the inter-assay variation of the absolute concentrations of the pitGH and recGH, not to the inter-assay variation of the ratios.[166] The Respondent further submits that the 20% limit does not relate to the variation between an individual athlete's samples, but to the control samples of each kit, compared with the acceptance values of each batch of kits which are defined by the producer of the kits.[167] The Respondent submits that the 20% limit in this context was not exceeded[168] and states that the factual basis for Appellant's allegation is incorrect, as the concentrations of the control samples were well within 20% of the inter-assay cross-variability, and that all ratios of the internal control samples met the respective acceptance criteria.[169]

170. **The Kits' labels "For research use only" are irrelevant.** The Respondent explains, without further specifying why this would also apply to the Kits at hand, that these labels can be found on all immunoassay tests produced for and distributed on the US market except those which have received US-FDA approval for clinical use.[170] Manufacturers are required to label these kits as "For research use only" if the particular kit is not approved by the US-FDA for use on patients. The Kits were never intended for clinical use and therefore do not have US-FDA approval. The Respondent argues that although this labeling means that the Test is not approved by the FDA for use on patients, this would not bring the Test's validity or the reliability into question outside of a clinical context. Indeed, the Respondent points to ISL 5.3.6.1 which states that "*..kits labeled "Research Only" may be utilized for the purposes of Doping Control as long as they are validated by the [l]aboratory.*"[171]

171. **No conflict of interest.** The Respondent submits that it is wrong to conclude that the experts who developed the Test are in any way biased. The Respondent argues that the production of the Kits by the scientists who developed the Test

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164 Appeal Response, ¶77.

165 Appeal Response, ¶78.

166 Appeal Response, ¶78; Respondent Post-Hearing Brief, ¶89. The Panel notes that there has been some inconsistency in the Respondent's submissions on this topic. In the Appeal Response the Respondent speaks about *intra-assay* variation, while in the Post-Hearing Brief *inter-assay* variation is discussed. The Panel assumes that *inter-assay* variation was the intended meaning in both submissions.

167 Respondent Post-Hearing Brief, ¶89.

168 Appeal Response, ¶78; *see also,* Respondent Post-Hearing Brief, ¶89.

169 Respondent Post-Hearing Brief, ¶¶88-89.

170 Appeal Response, ¶81; Respondent Post-Hearing Brief, ¶92.

171 Appellant Post-Hearing Brief, ¶93.

was borne out of necessity because the only producer of such testing kits withdrew from the market.[172]

c) Analysis and Findings of the Panel

172. The Panel will now turn to each of the issues raised by Appellant and answered by the Respondent.

173. **Reviewing the validity of the Test from the Respondent's scientific data.** The Appellant argues that the Respondent must forward the relevant documents to allow the Appellant to analyze whether the Test was properly validated and is reliable. However, the Panel accepts the conclusions from Prof. Ho's testimony through which he emphasized that the Test's performance and robustness have been positively commented in Bidlingmaier et al.[173] The Panel emphasizes that the essential elements of the functionality of the Test have been publicly disclosed in this article, and the article has been peer-reviewed before its publication. Moreover, the Panel recognizes the balance of interest chosen by WADA to fight the reverse-engineering of the Test by auditing the Test using independent experts and WADA-accredited laboratories to affirm its methodology. The Panel further notes that also because there is no requirement for the publication of such underlying data for WADA-accredited tests there can be no breach of the Appellant's right to be heard. Hence, the Appellant's arguments on these points are rejected.

174. The Panel agrees with the Respondent that reference to the NFLPA's ongoing dispute regarding the implementation of the Test is irrelevant to the question of the Test's validity and reliability. The Panel further notes that the NFLPA dispute formed part of a wider National Football League/NFLPA discussion concerning their most recent collective bargaining agreement. The factual background and points of contention in that case are not relevant to this case.

175. **Alleged uncertainty as to what is measured by the Test.** Following a thorough discussion at the Oral Hearing as to what the Test measures, the Panel agrees with the Respondent's statement that "[t]*he hGH Isoform Test measures the concentrations of two sorts of hGH isoforms, namely the monomeric 22 kDa hGH on the one hand and certain other isoforms of hGH (dimeric and high molecular weight hGH forms) on the other hand. If the rec/pit ratio between the concentrations of monomeric 22 kDa (which is predominantly recombinant after injection of hGH) and the other defined isoforms (which are predominantly pituary) exceeds the defined* [decision limit] *the result constitutes an* [Adverse Analytical Finding]."[174] In other words, the Test measures the ratio of monomeric

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172 Appeal Response, ¶127.

173 *See* also Nguyen, et. al, 'Within-Subject Variability and Analytic Imprecision of Insulin-Like Growth Factor Axis and Collagen Markers: Implications for Clinical Diagnosis and Doping Tests' (2008) Clinical Chemistry 54,1268-76.

174 Respondent Post-Hearing Brief, ¶27.

22 kDa isoforms to other types of isoforms. The Panel is also convinced by the evidence of the Respondent that artificially inserted hGH only comes in the 22 kDa form, while human blood naturally contains a relatively constant relative proportion of 22 kDa isoforms to other isoforms, so that the Test measures whether the balance between these isoforms is at natural or artificially enhanced levels.

176. Based on the Respondent's submissions and explanations at the Hearing, the Panel is convinced that any concerns regarding the argument that the Test only measures endogenous hGH and not exogenous hGH have been dispelled by the Respondent's expert witnesses, who explained the process by which the Test does not measure the absolute concentration of hGH in circulation but instead measures changes in the hGH molecular isoform composition for detecting whether artificial hGH has been taken. Through the paired chemiluminescent immunoassay approach, two assay pairs employ antibodies that recognize monomeric 22 kDa hGH and other pituitary-derived isoforms, respectively. A second set of paired immunoassays are also used, employing different specific antibodies, to confirm the results. This testing method, based on relative proportions of isoforms in human blood, is in accordance with the WADA rules and the Appellant has not demonstrated the contrary with a sufficient probability for the Panel to rule otherwise. This Panel notes that the arguments of the Appellant and his witnesses regarding this point lack clarity and specificity. The Panel therefore rejects the Appellant's assertion that it would be uncertain what the Test actually measures.

177. **The assumptions on which the Test is based.** The Panel rejects the Appellant's arguments in this regard for the following reasons:

Specificity of the antibodies employed by the Test. The Panel is convinced by Prof. Strasburger's testimony at the Hearing, during which he explained both the antibodies' specificity and the process through which they were chosen for the purpose of the Test and by the fact that the specificity of the over 200 monoclonal antibodies developed for the Test was at the center of Bidlingmaier at al.[175] The Panel is further reassured by the fact, as explained by the Respondent, that ISL 6.2.4.2.1.2 does not require the antibodies employed in different assays to be totally different in the sense that there could be no overlapping at all in their catching area on the surface of the macromolecule analyzed. Some overlapping between the different antibodies can be tolerated, provided that they mostly catch on the different sides of a macromolecule. This basic requirement is fulfilled with regard to the antibodies employed in the hGH assays as was illustrated during the Hearing. Therefore, it is the Panel's view that the Test does not lead to over-inclusive results as a result of cross-reactivity of the antibodies. The Panel finds that the Test's reliability cannot be called into question on this basis.

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175 Respondent Post-Hearing Brief, ¶¶37-39.

The stability of the ratio between rec and pit hGH. Concerning the Appellant's claim that the secretion of hGH, both in absolute and relative terms to different isoforms, changes constantly over the course of a normal day, it is the Panel's view that the Respondent successfully rebutted Prof. Köks's assertion at the Oral Hearing that the ratio between monomeric 22 kDa isoforms and the other tested isoforms was substantially unstable. The Respondent referred to recent publications while the Appellant relied on older, less related, papers.[176] The Panel agrees with the Respondent's admission that some elevation of the ratio may occur during exercise and other strenuous situations, but the magnitude of any such possible elevation is not as big as to generally undermine the underlying assumptions of the Test. The Panel considers that any serious allegations on possible effects of such conditions on an elevated ratio detected from an individual can be addressed on a case-by-case basis where necessary. This, to the Panel, sufficiently dispels any concerns regarding the risk of substantial isoform fluctuation.

In addition, the Panel rejects the conclusions drawn by the Appellant on the degree of alleged inconstancy of the recGH/pitGH ratio.[177] Similarly, the Panel is not convinced by the Appellant's submission that the sample data cannot be modeled parametrically. The Appellant has not provided sufficient evidence on how other factors could affect the ratio between the recGH and pitGH.

Therefore, the Panel rejects the Appellant's arguments on the inconstancy of the ratio between recGH and pitGH and thus the Appellant's claim that the lack of constancy of the ratios cannot be relied upon as a key principle underlying the Test's functioning.

As for the Appellant's argument on the negative impact on the antibodies' reliability by the alleged disaggregation of oligomers and dimers, Prof. Ho convincingly rejected the Appellant's claim, which was based on articles published between the years 1975 and 1977, that oligomers and dimers cannot disaggregate to form monomers again: "*There is no phenomenon known in physical chemistry that allows hormones to dimerize or oligomerize in plasma to deaggregate to form monomers again.*"[178] Given the testimony of the Respondent's experts and the lack of recent publications or evidence supporting the Appellant's claims, the Panel is confident that the Appellant erred when claiming that non-monomeric 22 kDa isoform dimers could easily disintegrate to monomers. Therefore, the Panel rejects the claim that this alleged chemical occurrence could undermine the principles underlying the Test.

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176 The Respondent mainly referred to two recent articles of G. Baumann: 'Growth hormone doping in sports: a critical review of use and detection strategies' (2012) Endocrine Reviews 33, 155-86 and 'Growth hormone isoforms' (2009) Growth Hormone & IGF Research 19, 333-40.

177 Comments to Respondent Answers to First Set of Panel Questions, ¶¶34-38.

178 Respondent Post-Hearing Brief, ¶¶34-36.

Intra- and Inter-Personal variability of hGH secretion. As set out above, the Panel accepts the Respondent's submissions that although the absolute concentrations of hGH are subject to change throughout the course of a day, the mixture of isoforms of which it is comprised are present in relatively stable relative proportions.[179] Therefore, the Panel rejects the Appellant's arguments in relation to intra and interpersonal variability: even if there is high intra- and/or inter-personal variability in hGH secretion, this variability would not affect the functioning of the Test because the Test relies on variations in the rec/pitGH ratio, not on the level of absolute concentration of monomeric 22 kDA.

Other influences on hGH ratio. Similarly, the Panel is not convinced by the Appellant's arguments that influences such as exercise or altitude will alter the ratio of the hGH isoforms to such an extent that the underlying assumptions of the hGH Test could not be relied upon.

Potential for athletes to change results. The Panel rejects the Appellant's arguments that the Test is unreliable because athletes could interfere with the Test results by injecting other isoforms of recGH or hGH. As explained above, the Panel is convinced by the evidence of the Respondent that artificially-inserted hGH only comes in the 22 kDa form, so that there is no current possibility for athletes to alter the Test outcome by such means.

178. **Variability between the A- and B-samples allegedly pointing to systematic measurement errors that form part of the Test.** The Appellant submits that, in the present case, the difference between the result of the A- and B-Samples indicates a serious problem with the Test and/or the samples more generally. On this basis the Appellant argues that the Test is unreliable and/or that the Athlete's AAF should be disregarded. The Respondent argues that the factual and regulatory bases for that allegation are wrong, claiming that the concentrations of the control samples were well within 20% of the inter-assay cross-variability and that all ratios of the internal control samples met the respective acceptance criteria.[180] The Panel agrees with the Respondent that the Appellant's arguments in this regard lack clarity. As a result, the Panel has difficulty assessing whether the conclusions reached by the Appellant are in fact correct on a balance of probability. Moreover, and in relation to the Appellant's submission that the AAF should be disregarded, the Appellant merely states that such a conclusion voids the Athlete's AAF without explaining how the percentage difference would have reasonably led to a false positive result. Therefore, the Appellant has not met the necessary standard of proof and the Panel must reject these arguments.

179. **The Kits are labeled "For research only."** The Panel cannot see how the labeling "for research use only" could affect the Test's validity. In the Panel's view, the Respondent has provided sufficient explanations for this label, while the

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179 Appeal Response, ¶66; Respondent Post-Hearing Brief, ¶31.

180 Respondent Post-Hearing Brief ¶¶88-89.

Appellant failed to demonstrate the impact of this formality on the AAF. Consequently, the Panel rejects the Appellant's arguments in this regard.

180. With regard to the Appellant's submission that the Test is being used contrary to EU Law, the Panel considers that even if this were the case, the Appellant has not provided the necessary causal link as to why a finding of use contrary to EU Law would demonstrate the unreliability or incorrect validation of the Test. Therefore, the Panel equally rejects the Respondent's submissions on the labeling of the Kits.

181. Finally, the Panel considers it irrelevant to the Test's reliability that WADA has not produced a specific technical document for it. The Panel recognizes that technical documents are only published by WADA from time to time, when specific technical recommendations are required to address particular operational areas of the accredited laboratories; the absence of a technical document suggests that WADA is satisfied with the way accredited laboratories are performing the Test. The Appellant's argument on this point is rejected.

182. **Alleged conflict of interest.** The Panel has no reason to assume that the producers of the Kits and the Respondent's expert witnesses would have allowed any potential conflicts of interest to affect their professionalism and veracity in the course of the present proceedings. The Panel finds it highly unlikely that the Kits' producers would jeopardize their professional reputations by producing unreliable testing kits or concealing any shortcomings the Test may have.[181] Additionally, the Kits are ISO-certified, which buttresses the Panel's satisfaction in this regard.

183. **Panel's Conclusion on the reliability of the Test.** In light of the above, the Panel finds that the Appellant has failed to substantiate his claim that the Test is unreliable. Contrary to the Appellant's views, the Respondent has made available sufficient information (both in writing as well as orally during the Hearing) for this Panel to review the reliability of the Test. The Respondent has shown to the comfortable satisfaction of this Panel that the hGH Test is a reliable testing method for hGH abuse in professional sports that is based on scientifically correct assumptions and methods. Furthermore, the Panel agrees with the Respondent that even if the Appellant had established a minor flaw in the reliability and validation of the Test (*quod non*), the Appellant did in any event not show to the required standard of proof that this could have caused the AAF (as a false positive finding). It follows that the Appellant's arguments on the Reliability of the Test are rejected in their entirety (subject to the section on the Test's decision limits below).

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181 Similar conclusions were reached by the CAS Panel in CAS 2007/A/1394 ¶55.

6. The Test's Decision Limits

a) Introduction

184. The issue of whether the Test's decision limits have been correctly established by WADA is at the core of these proceedings. In essence, the decision limits determine whether the recGH/pitGH ratios in Kit 1 and Kit 2 qualify as an AAF. Kit 1 and Kit 2 have separate decision limits because they are coated with two distinct sets of antibodies: a rec/pit ratio exceeding 1.81 for Kit 1 and 1.68 for Kit 2 constitutes an AAF.[182] The Appellant's A-sample yielded rec/pit ratios for Kit 1 and Kit 2 of 2.62 and 3.07, respectively, while the B-sample showed ratios of 2.73 and 2.00 respectively.[183] According to the hGH Guidelines, an AAF requires that ratios for the athlete's A-sample exceed the decision limits for both Kit 1 and Kit 2. According to the WADA Code, this AAF will constitute proof of an anti-doping rule violation if the athlete waives analysis of the B-Sample and the B-sample is not analyzed; or, where the Athlete's B-sample is analyzed (as occurred in the case at hand), the rec-pit GH ratios in the B-sample must also exceed the decision limits for Kits 1 and 2 in order to constitute an anti-doping rule violation.

185. In essence, the Appellant argues that the decision limits are, for a variety of reasons, flawed and thus render the Test invalid, or, at least would, if determined correctly, be set at higher levels that would exceed the Appellant's Test results and would therefore render Appellant's Test results negative (at least with respect to Kit 2, which would suffice to render the overall result negative).

186. The Respondent, on the contrary, asserts that while minor inconsistencies when explaining the calculation of the decision limits to this Panel have occurred (*e.g.*, the misguided assumption that lognormal as opposed to gamma distribution was used for all the datasets relied upon when establishing the decision limits), none of these would result in higher decision limits. Rather, the decision limits were determined in accordance with generally accepted scientific procedures and were ultimately set at the conservative end of the possible spectrum to exclude, to the extent possible, false positive findings. The Respondent submits that the Appellant's results undoubtedly fall within the parameters of an AAF.

187. The Respondent explains that the decision limits were, before their publication in the hGH Guidelines and entry into force in June 2010, determined by WADA from two studies, one initial study and one verification study, and then, after publication, further confirmed by another verification study. Hence, the Panel will first outline its understanding of the relevant facts of each of these three studies before turning to the Appellant's and Respondent's arguments.

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182 The hGH Guidelines, p. 9.

183 There has been some discussion on whether the ratio of 2.00 reported by the Laboratory has in fact been accurate, or whether this figure has been subject to inappropriate rounding, leading to the exact ratio being 1.96. The Panel does not deem it necessary to rule on this point since it is irrelevant for the outcome of the case.

b) The studies from which the decision limits in dispute have been calculated

188. The decision limits in dispute were determined on the basis of the data (*i.e.*, athletes' blood samples) obtained in the 2009 IAAF/NADA Study (the "Initial Study"). The decision limits calculated on the basis of the Initial Study are the ones pursuant to which the Appellant's sample was considered to constitute an AAF. The two subsequent 2009-2010 and 2010-2011 Verification Studies (the "Verification Studies", or "First Verification Study" or "Second Verification Study," respectively) provided WADA with additional datasets that, according to the Respondent, confirmed that the decision limits established in the Initial Study were correctly set (and that they were at the conservative end). The limits therefore remained unchanged. Indeed, the Respondent has explained that the purpose of the Verification Studies was to check whether the decision limits calculated from the Initial Study were reliable in light of subsequent anti-doping data.

189. **The Initial Study (2009).** The Respondent explains that the samples for this study came from the IAAF World Championships in 2009 and from the German National Anti-doping Agency. The Respondent further submitted that the number of samples totaled 300, comprised of samples from 140 Caucasian males, 58 Caucasian females, 57 African males and 45 African females.[184] Only samples with a hGH concentration (whether recGH or pitGH) of $\geq$ 0.05 ng/mL were included.[185] This meant in practice that the total amount of relevant samples ("relevant" meaning that the sample fulfilled the concentration requirements) was 109 Caucasian males for Kit 1, 117 Caucasian males for Kit 2, 45 African males for Kit 1 and 48 African males for Kit 2.[186] The Respondent explained that in this Initial Study the combination of data from males and females "was arguable", and the two ethnic groups (Caucasians, Africans) could not be combined into one single distribution since the African group tended to yield higher ratios.[187] According to the Respondent, although the datasets produced from these samples could fit both the lognormal and gamma distributions, WADA selected the lognormal distribution to calculate the decision limits because doing so resulted in a higher cut-off value at the 99.99% point, leading to higher decision limits (hence more conservative ones).[188] Similarly, for each of the Kits WADA selected the highest decision limit value that had been established from either the Caucasian or African datasets.[189] This led to the values for the African group being implemented also for Caucasians. No samples fulfilling the concentration

184 Respondent Post-Hearing Brief, ¶42.

185 December 12, 2012 Answers to Panel Questions, ¶7.

186 Exhibit RE-52.

187 Respondent Post-Hearing Brief, ¶43.

188 December 12, 2012 Answers to Panel Questions, ¶¶8-9.

189 December 12, 2012 Answers to Panel Questions, ¶10.

requirements were excluded from this study.[190] These decision limits have since remained unchanged and are the subject of this appeal.

190. **The 2009-2010 Verification Study.** The Respondent explained that the data used in this study came from samples analyzed from January 2009 to March 2010 in nine WADA-accredited laboratories[191]. In this study, the minimum concentration requirement of recGH was raised to ≥1.0ng/mL,[192] and the additional relevant samples consisted of 711 male samples (both Caucasian and African) for Kit 1 and 38 for Kit 2.[193] With regard to the 38 samples for Kit 2, the Respondent explains that they fell into a narrow range except for one extreme "outlier" value.[194] Consequently, as the Respondent further explains, WADA sought to reduce the effect of the outlier on the dataset in order to make the process less "speculative" by analyzing the 2009-2010 dataset together with the dataset from the Initial Study.[195] The Respondent explains that the combined sample data from the Initial Study and the First Verification Study, which had values of recGH ≥ 0.1ng/mL and pitGH ≥0.5ng/mL, was 801 males for Kit 1 and 142 males for Kit 2.[196] According to the Respondent, at this point WADA found that there were no consistent differences between data relating to the genders and ethnicities, and decided to combine the datasets from the two sexes and from the two ethnic groups (Caucasians, Africans) before analyzing which distribution model would fit best.[197] The Respondent explains that the gamma distribution model fitted this combined dataset well, whereas the lognormal distribution did not.[198]

191. In addition, the Respondent explains that it has subsequently re-examined the data for this study in response to the Second Set of Panel Questions, by only analyzing data for male samples, one including the "outlier" value and the other excluding it.[199] The Respondent explains that a gamma distribution was still found to fit both sets of data best and that the lognormal distribution was not an acceptable fit.

192. According to the Respondent, the First Verification Study confirmed the results of the Initial Study, so that there was no evidence that the decision limits established for the Kits were too low and "*could reasonably be regarded as conservative*."

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190 September 7, 2012 Answers to Panel Questions, ¶7 at note 5.

191 September 7, 2012 Answers to Panel Questions, ¶14 and December 12, 2012 Answers to Panel Questions, ¶12 at note 10.

192 September 7, 2012 Answers to Panel Questions, ¶15.

193 December 12, 2012 Answers to Panel Questions, ¶12.

194 December 12, 2012 Answers to Panel Questions, ¶13.

195 December 12, 2012 Answers to Panel Questions, ¶¶13-14.

196 December 12, 2012 Answers to Panel Questions, ¶12 at note 10.

197 December 12, 2012 Answers to Panel Questions, ¶15. In fact, the samples in this Verification Study were no longer classified according to ethnic groups, so WADA did not have any other choice than to combine Caucasians with Africans in this Verification Study.

198 December 12, 2012 Answers to Panel Questions, ¶15.

199 December 12, 2012 Answers to Panel Questions, ¶¶17-18.

Therefore, WADA decided not to change the decision limits as calculated from the Initial Study and published these values in the hGH Guidelines in June 2010.[200]

193. **The 2010-2011 Verification Study.** This time, the data used came from 21 WADA-accredited laboratories,[201] with analyses conducted from January 2010 to February 2011 in respect of 1994 samples for Kit 1 (1297 for males and 697 for females) and 514 relevant samples for Kit 2 (352 for males and 162 for females).[202] The Respondent explains that WADA excluded from this dataset seven samples which were either "suspicious" or confirmed being affected by the application of recGH, or arrived at the laboratory in a critical condition.[203] From the Respondent's submissions, it appears that the datasets used to fit the distribution model were those for males of all ethnicities.[204] As with the First Verification Study, the Respondent found that a lognormal distribution did not fit this dataset, but that a gamma distribution was acceptable.[205] The Respondent explains that the estimated decision limits from this dataset were lower than those published in the hGH Guidelines, and that this provided confirmation that the decision limits in the Guidelines were highly unlikely to disadvantage any clean athletes.[206]

194. What follows summarizes the Parties' positions on the issue of the decision limits as expressed in their oral and written submissions, including the Respondent's Answers to the First and Second Set of Panel Questions, and the Appellant's Comments on Respondent's Answers to the Panel Questions.

c) The Appellant's Arguments

195. In essence, the Appellant submits that the decision limits are flawed or at least overinclusive. The values for Kit 1 and Kit 2 are set too low and could lead to an AAF even if the athlete did not use artificially-produced hGH, in other words, the established decision limits could produce false positive results. Based on its own assessment of what the correct value of the decision limits should be, the

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200 December 12, 2012 Answers to Panel Questions, ¶20.

201 September 7, 2012 Answers to Panel Questions, ¶17. At note 13 the Respondent explains that although two further WADA-accredited laboratories were invited to provide data, data from one laboratory arrived late but confirmed the results from the 21 other laboratories, and the other laboratory had not received any doping test results but had validated the hGH Isoform Test and provided the respective validation data which also confirmed the Decision limits.

202 December 12, 2012 Answers to Panel Questions, ¶¶45-46, in which the Respondent sets out the correct figure, contrary to figures given in its September 7, 2012 Answers to Panel Questions and in its Post-Hearing Brief at ¶49.

203 September 7, 2012 Answers to Panel Questions, ¶39-40 and Exhibit RE-52.

204 December 12, 2012 Answers to Panel Questions, ¶22 and Exhibit RE-60.

205 December 12, 2012 Answers to Panel Questions, ¶22.

206 September 7, 2012 Answers to Panel Questions, ¶19.

Appellant argues that his AAF should be disregarded because the Appellant's B-sample ratio for Kit 2 would have been below those recalculated levels.[207]

196. In support of this contention, the Appellant has raised numerous arguments in several submissions that are summarized below. They are summarized according to whether they relate to the composition of the samples in the datasets or the calculations performed to determine the decision limits.

197. **The exclusion of certain samples from the datasets used to estimate the decision limits was scientifically incorrect.**

Diverging concentration requirements between Initial and Verification Studies. The Appellant states that the Verification Studies were incorrectly used to corroborate the decision limits because the Initial Study was based on samples with different concentration levels than those applied in the Verification Studies. Hence, different samples have been excluded in the Initial Study as compared to the Verification Studies, which, according to the Appellant, renders it inadmissible to rely on the Verification Studies to verify the decision limits of the Initial Study. For the Initial Study, concentration levels for recGH and pitGH of $\geq$0.05 ng/mL have been employed, while for the Verification Studies concentration levels were set at pitGH $\geq$0.05 ng/mL and recGH $\geq$ 0.1ng/mL.[208] In the Appellant's view, "*by changing the detection thresholds the detection limits would have to be set again*."[209]

The exclusion of suspicious data. The Appellant argues that the Verification Studies were incorrectly performed because they deliberately excluded extreme values from the dataset on the grounds that they were 'outliers' or suspicious results.[210] In particular, WADA erred in excluding 'true' positives from the second Verification Study. The Appellant argues that WADA could not have known whether the results were, in fact, true positives or whether they were just at the high end of negative values.[211] On the same basis, the Appellant argues that all of the Appellant's samples should have been included in the Verification Studies.[212]

198. **The calculations to determine the decision limits were performed incorrectly.**

The recGH/pitGH ratio cannot be modeled parametrically. The Appellant argues that no parametric distribution at all could be fitted to the recGH/pitGH data. Relying on the evidence of Dr. Fischer, the Appellant submits that the

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207 Appellant Comments on Respondent Answer to Panel Questions, ¶¶41-42.

208 October 15, 2012 Comments to Respondent Answers to Panel Questions, ¶¶21-23.

209 October 15, 2012 Comments to Respondent Answers to Panel Questions, ¶¶21-23.

210 Appellant Post-Hearing Brief, ¶52; February 4, 2013 Comments on Respondent Answers, ¶43 and ¶101.

211 January 31, 2013 Comments to Respondent Answers, ¶68.

212 January 31, 2013 Comments to Respondent Answers, ¶84.

association between recGH and pitGH is nonlinear and thus cannot be modeled because the ratio cannot be constant as the pitGH varies. The Appellant also points to 'outliers' to argue that other factors, such as the sporting activity undertaken, ethnicity, or high altitude training, could equally affect the ratio and hence render a parametrically modulation inappropriate.[213]

Inappropriate distribution models chosen. Even if one were to assume that the recGH/pitGH could be modeled parametrically (which it cannot according to the Appellant), the Appellant suggests that the purpose of the Verification Studies was to determine whether the assumptions made in the Initial Study were correct.[214] Consequently, according to the Appellant, the Verification Studies proved that the assumption of lognormal distribution for the data was incorrect and that any new assumptions on distribution model would need to have been verified.[215] Further, the Appellant argues that it is not possible to determine and verify the decision limits once with the lognormal distribution and once with the gamma distribution.[216]

The Appellant also argues that the gamma distribution could not be used to model the data from the Verification Study. The Appellant relies on testimony of the Respondent's experts, who suggested that the gamma distribution was found to be a poor fit at the lower end of the dataset, but was an acceptable fit at the upper end, and argues that the gamma fit was, on this basis, inappropriate because distribution models should fit the sample fully.[217]

In addition, the Appellant argues that there are other distributions that could have been chosen and which may have fit the Verification Study datasets.[218] The Appellant also submits that the Respondent has failed to provide sufficient evidence, and cites the underlying doping control protocols as an example, on the decision not to distinguish between ethnicities in the Verification Studies and on the conditions of the athletes at the time that samples were taken.[219]

Lack of reliance on true positives. The Appellant argues that the decision limits have not been properly validated because there have been no or insufficient true positive findings which can be used to confirm them.[220] The Appellant submits that the 12 positive findings discussed by Respondent in support of the robustness of the decision limits cannot be relied upon as true positives, either because the admissions of use may have been made by athletes seeking to gain a reduction in

213 January 31, 2013 Comments to Respondent Answers, ¶35.

214 January 31, 2013 Comments to Respondent Answers, ¶14.

215 January 31, 2013 Comments to Respondent Answers, ¶14 and ¶34.

216 January 31, 2013 Comments on Respondent Answers, ¶92.

217 January 31, 2013 Comments to Respondent Answers, ¶¶62-63.

218 January 31, 2013 Comments on Respondent Answers, ¶32.

219 January 31, 2013 Comments on Respondent Answers, ¶45 and ¶68.

220 October 15, 2012 Comments to Respondent Answers to Panel Questions, ¶¶32-33.

their ban, because the athletes lacked the means to challenge the finding, or because the guilt of the athletes has not yet been proven, and, indeed, that one of the four AAFs relied on by the Respondent has been acquitted of the alleged violation.[221] The Appellant argues that the only true positive finding amongst the 12 came from a user who admitted to taking hGH for therapeutic reasons.[222] Further, the Appellant submits that these positive findings "*are in any case no valid way to validate whether the hGH-Test leads to true positive findings or not*."[223]

Insufficient sample sizes in the Initial and Verification Studies to reach the specificity of 99.99%. The Appellant submits that the decision limits are too low because the number of samples in the Initial Study led to an incorrect estimation of the 99.99% value (Respondent claims that the Test has a specificity of 99.99%).[224] The Appellant argues that the sample size of 140 made it impossible to estimate the distribution accurately because it was too small to provide a useful indication of the extreme values that would occur in the dataset, so that the specificity of the Test "*lacks any scientific reasoning*."[225] In support of this argument the Appellant relies on the opinions of Dr. Fischer, Dr. Barroso, and Prof. Bassett, who explained at the Oral Hearing that a sample of 140 would be too small to estimate the values at the top end of the dataset.[226] In addition, the Appellant argues that the concentration requirements reduced the number of samples which could be used in the study, so that the real sample number for Kit 1 was about 106 Caucasian males, rather than 140 (Appellant appears silent on the sample size of Kit 2 on this specific point).[227] Consequently, the Respondent argues that the sample numbers were too small to provide a good basis on which to estimate the distribution of the data and thus the decision limits.[228]

d) <u>The Respondent's Arguments</u>

199. The Respondent rebuts, in essence, all of Appellant's claims and has maintained throughout the proceedings that the decision limits have been correctly calculated and guarantee a 99.99% specificity of the Test. According to the Respondent, the decision limits do not lead to too many false positives but are in fact conservative that tend to result in false negatives. The decision limits had been purposefully set at high levels in order to protect clean athletes.

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221 Appellant Post-Hearing Brief, ¶54.

222 Appellant Post-Hearing Brief, ¶54.

223 October 15, 2012 Comments to Respondent Answers to Panel Questions, ¶¶32-33.

224 Appellant Post-Hearing Brief, ¶¶44-45.

225 Appellant Post-Hearing Brief, ¶45.

226 Appellant Post-Hearing Brief, ¶45.

227 October 15, 2012 Comments on Respondent Answers to Panel Questions, ¶¶24-26.

228 October 15, 2012 Comments on Respondent Answers to Panel Questions, ¶26; January 31, 2013 Comments on Respondent Answers, ¶29.

200. **Exclusion of certain data from the datasets used to estimate the decision limits was scientifically correct.**

The sample concentration requirements. Contrary to the assertions of the Appellant, Respondent explained that when the data from the Initial Study was combined with subsequent data in the Verification Studies, only samples from the Initial Study dataset that satisfied the requirements of pit $\geq$0.05ng/mL and rec $\geq$0.1ng/mL were included.[229] There were thus no diverging concentration requirements in the combined data.

The exclusion of suspicious data. With regard to extreme "outlier" results, the Respondent submits that it did include extreme results in the First Verification Study. The Respondent further submits that even when such results are included in the First Verification Study dataset, the resulting estimated decision limit remains below the decision limits calculated from the Initial Study.[230] The Respondent explained that it excluded samples from the Verification Studies that it considered were likely affected by the application of recGH, which is a scientifically correct thing to do. Samples were excluded on the grounds that they were very high and atypical, and/or that the relevant athletes had admitted to hGH use, had a therapeutic use exemption for hGH use, or had not contested their positive A-sample test.[231]

201. **Calculations to determine the decision limits were performed correctly.**

The recGH/pitGH ratio can be modeled parametrically. The Respondent maintains that the association between recGH and pitGH can be modeled parametrically and that for the Initial Study both the lognormal and the gamma distributions were found to fit the datasets, and that for the Verification Studies the gamma distribution was found to fit the larger datasets well.[232]

The right distribution models were chosen. The Respondent initially indicated in its submissions and at the Hearing that the lognormal distribution was used to model the data for the Initial and Verification Studies. In his witness statement of December 7, 2010, Dr. Barroso took the opportunity to correct certain calculations made by the Appellant that related to the decision limits. In doing so, Dr. Barroso stated that "…*log-normal is the appropriate distribution. WADA can reassure the Appellant that this was the distribution used in calculations leading to the published Decision Limits*", that "*the calculations were indeed based on the log-Normal distribution of the ratios*" and that "*WADA can again confirm that the Decision Limits are based on accurate calculations using the normal distribution of log-transformed values of the ratios*".[233] The use of the lognormal distribution

229 September 7, 2012 Answers to Panel Questions , ¶15.

230 December 12, 2012 Answers to Panel Questions, ¶¶17-19.

231 September 7, 2012 Answers to Panel Questions , ¶¶39-40.

232 December 12, 2012 Answers to Panel Questions, ¶37.

233 Exhibit RW-4, p.8, at note 3.

was also confirmed by Dr. Bassett at the Hearing, when he stated that the large number of samples available from WADA labs, rather than just the Initial Study's 140 samples were also fitted to such a distribution model.

In its Post-Hearing Brief and its response to the Panel's first set of questions, the Respondent only explained that the Initial Study was fitted to a lognormal distribution.[234] The Respondent did not explain how the data for the Verification Studies was modeled.

Subsequently, in its Response to the Second Set of Panel Questions, the Respondent changed its submissions on this: the Respondent now asserted that WADA used the lognormal distribution for the Initial Study only, and that the gamma distribution was used for the Verification Studies because the lognormal distribution did not fit sufficiently well for the Verification Studies.[235] Only at this point did the Respondent explain that both the gamma and lognormal distribution had been found to fit the data for the Initial Study, but that the lognormal distribution was chosen because it resulted in a higher 99.99% point.[236] As for the First Verification Study, the Respondent argues that the p-value for the gamma distribution was 0.53, whereas the p-value for the lognormal distribution was 0.04;[237] and for the Second Verification Study, that the p-value for the lognormal distribution was $p < 0.01$ and thus unacceptable, but that the p-value of 0.243 for the gamma distribution indicated a good fit.[238]

The Respondent argues that "*WADA always examined the fit of several different distributions to the datasets, and only those distributions that were statistically proven to be an acceptable fit were further considered.*"[239] The Respondent has not provided evidence or further information on the other distributions considered.

Finally, the Respondent submits that different datasets produced with the same analytical tool may be fitted to different parametric distributions.[240]

Reliance on true positives. First, the Respondent argues that it would be unethical (and impracticable) to "dope" elite athletes with hGH in order to receive true positive samples from different sports.[241] Second, the Respondent submits that corroboration through true positive samples is "*definitely not a requirement*

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234 Respondent Post-Hearing Brief, ¶44-47, and September 7, 2012 Answers to Panel Questions , ¶¶8-12.

235 December 12, 2012 Answers to Panel Questions, ¶8, ¶15 and ¶22.

236 December 12, 2012 Answers to Panel Questions, ¶¶8-9.

237 December 12, 2012 Answers to Panel Questions, ¶15.

238 December 12, 2012 Answers to Panel Questions, ¶22.

239 December 12, 2012 Answers to Panel Questions, ¶37.

240 December 12, 2012 Answers to Panel Questions, ¶37.

241 Respondent Post-Hearing Brief, ¶ 55(2).

for the validity of a testing method" and that the Appellant has not been able to point to any FIS ADR or WADA provision to the contrary.[242] The Respondent further submits that the Appellant's arguments are wrong, and relies on the fact that out of more than 10,000 Tests there have been 12 AAFs, of which, the Respondent submits, at least eight are likely to be true positive findings. The Respondent bases this submission on the argument that: (i) Four of these athletes admitted to hGH usage; (ii) one athlete was in possession of a therapeutic use exemption for hGH; (iii) further three athletes accepted the positive finding without any protest or appeal; and (iv) four of the remaining AAFs are currently still going through the results management process.[243]

Sufficient sample sizes in the Initial and Verification Studies. In contrast to the Appellant's figure of 140, the Respondent argues that it used a sample number of 300 in the initial study (comprised of 58 female Caucasians, 140 male Caucasians, 45 females of African origin, and 57 males of African origin).[244] In response to the criticisms by the Appellant of the initial sample size, the Respondent argues that a dynamic approach – that is, one in which a small initial sample is verified by further tests – is acceptable for establishing anti-doping tests.[245] The Respondent submits that the fight against doping requires expeditious proceedings to detect new substances to ensure a level playing field, and that new detection methods must necessarily be introduced on the basis of a relatively small number of data and further refined based on the results of actual doping tests.[246] The Respondent points to the testimony of Dr. Fischer, the Appellant's expert, to support the acceptability of a dynamic approach.[247] The Respondent also submits that any uncertainty resulting from an initially small sample size has been reduced by the Second Verification Study, which involved 3356 samples in respect of Kit 1 and 981 samples in respect of Kit 2.[248]

e) *Analysis and Findings of the Panel*

202. The Panel recalls that the burden is on the Respondent to show that an anti-doping violation has occurred by means of a test that is scientifically reliable. Such a burden applies to all aspects of the Test, including the determination of the decision limits.

203. In the Panel's view, the Respondent has, on balance, failed to establish to the comfortable satisfaction of the Panel that the decision limits were correctly determined and that they would lead to the claimed specificity of 99.99%.

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242 Appeal Response, ¶87.

243 Respondent Post-Hearing Brief, ¶51 and ¶53.

244 Respondent Post-Hearing Brief, ¶42.

245 Respondent Post-Hearing Brief, ¶11 and ¶48.

246 Respondent Post-Hearing Brief, ¶11.

247 Respondent Post-Hearing Brief, ¶55(2).

248 Respondent Post-Hearing Brief, ¶49(2).

Despite the Respondent's ample opportunities to convince the Panel on the correctness of the decision limits including in the post-Hearing brief as well as in response to the two subsequent rounds of Panel Questions, the Panel cannot exclude to its comfortable satisfaction that the decision limits are overinclusive and could lead to an excessive amount of false positive results (beyond the claimed specificity of 99.99%). Although the Panel has found that the Test itself is undoubtedly reliable (as explained in Section 5 ('The Reliability of the Test')), the Panel finds that the following factors prevent it from concluding that the decision limits are equally reliable: (1) The inappropriate exclusion of certain sample data from the dataset; (2) the small sample sizes; and (3) the data provided on the distribution models used. These factors will be considered in more detail below.

204. **The inappropriate exclusion of certain sample data from the dataset.** The Panel cannot determine with a sufficient degree of certainty which samples have been excluded in the Initial Study and the Verification Studies and for which reasons. This renders it impossible for the Panel to reverse engineer the Test's decision limits. In particular, on this basis, the Panel cannot conclude that all of the results excluded from the datasets were legitimately excluded because the Respondent has provided insufficient information in this regard. For instance, the Panel is not in a position, based on the Respondent's submissions, to determine which samples have been excluded for constituting 'suspicious data' and whether correctly so. For the purposes of any further studies for determining decision limits for prohibited substances that can be produced endogenously, the Panel recommends that any exclusion of samples from the reference population data be separately documented with reasoning.

205. **The insufficient sample size.** The Panel accepts that a dynamic approach to testing may be desirable and acceptable, particularly in the field of anti-doping. However, the Panel must bear in mind the seriousness of the allegations made against the Appellant when assessing whether it is satisfied that the decision limits with regard to hGH have been correctly determined. Consequently, the Panel has placed particular importance on the Appellant's concerns about the sizes of the datasets used to calculate the decision limits. Despite the high specificity requirements and the high tolerance margins, both of which were designed to safeguard the decision limit determination within a dynamic approach, the Panel is not comfortably satisfied that the sizes of the samples used were sufficiently large to permit an estimation of the 99.99% point that is sufficiently reliable.[249]

With regard to the Initial Study, the Panel is concerned that the sample sizes for both Kits were too low. From the information provided by the Respondent, it appears that only 154 male samples (109 Caucasians, 45 Africans) fulfilled the original concentration requirements (recGH and pitGH $\geq$ 0.05 ng/mL) for Kit 1

[249] The Panel notes that the requirement of the 99.99 % specificity of the Test is set by WADA in hGH Guidelines p. 9. Since none of the Parties has contested this specificity requirement in the course of these proceedings, it is not the task of this Panel to evaluate it.

and 165 male samples (117 Caucasians, 48 Africans) for Kit 2. It was found that the two ethnic groups could not be combined into a single distribution, which forced WADA to choose either one of the two groups. The African group was chosen. The numerical calculations on the published decision limits were thus based on the ratios of only 45 Africans for Kit 1 and 48 Africans for Kit 2. The Panel has not been convinced that estimates of the 99.99% from such small datasets would be sufficiently accurate.

Similarly, the Panel is not convinced that a sufficiently large dataset has been used to corroborate the decision limits for Kit 2. In the First Verification Study, only 38 new samples fulfilling the raised concentration requirements (recGH $\geq$ 0.1 ng/mL, pitGH $\geq$ 0.05 ng/mL) were analyzed with Kit 2. Although WADA decided to combine the two ethnic groups in this stage, and the samples from the First Verification Study were combined with the samples from the Initial Study, the total number of male samples fulfilling the increased concentration requirements analyzed with Kit 2 was still as low as 142. The Panel notes that this was the total amount of relevant samples analyzed with Kit 2 at the time when the decision limits were published in June 2010. No further studies on the decision limits were completed by January 29, 2011 when the Appellant's sample now under dispute was collected.

In the second Verification Study, the decision limits for Kit 1 were corroborated using data from 1297 samples, whereas 352 relevant samples could be used to corroborate Kit 2. This is not to say that this amount of 352 samples would, under any circumstances, always be insufficient for establishing a decision limit with high enough specificity. Under the circumstances of the case at hand, the Panel is not comfortably satisfied that the 352 samples analyzed in the Second Verification Study with Kit 2 would confirm the reliability of the decision limits originally established based on insufficient amount of samples. The Panel's reluctance to accept the results obtained in the Second Verification Study as a confirmation for the reliability of the original decision limits is based on the confusion caused by the switch of the distribution models between the studies. The decision limits were originally calculated in the Initial Study based on a lognormal distribution model. In the two Verification Studies, WADA decided to abandon the lognormal model and switched to a gamma distribution. It appears to the Panel that if WADA had continued with the lognormal distribution model in the two Verification Studies also, the Verification Studies' data had yielded significantly higher decision limits than the published ones. Even though the Panel accepts the Respondent's arguments on the inapplicability of the lognormal model in the Verification Studies for its bad fit to the data, the Panel is not comfortably satisfied that gamma distribution could have been used without any reservations. The Panel therefore cannot accept the Respondent's argument that the decision limits which were initially calculated based on an insufficient amount of samples, had been sufficiently confirmed by the subsequent Verification Studies. Such a straightforward conclusion must, in the Panel's opinion, be rejected because the distribution model which forms the very basis for any decision limit calculations has not remained the same between the three studies.

In conclusion, the Panel has not been convinced by the Respondent that the decision limit especially for Kit 2 has been based on a sufficiently large sample size to provide a reliable estimation for the 99.99% point. Therefore, the Panel accepts the Appellant's arguments that the decision limits at least for Kit 2, possibly also for Kit 1, are unreliable.

206. **The uncertainty relating to the distribution models used.** It is important to the Panel that the Respondent has provided varying and initially incorrect accounts of which distribution models (and why) were used to calculate the decision limits. As outlined above, the Respondent initially provided an incorrect explanation on the distribution models used to calculate the decision limits. Here the Panel notes again Dr. Barroso's statement that "… *log-normal … was the distribution used in calculations leading to the published Decision Limits*" and confirmed by Dr. Bassett at the Hearing that the "*large number of samples available from WADA labs*" were also fitted to such a lognormal distribution model. Discussion of the gamma distribution was notably absent from Dr. Basset's testimony and Dr. Barroso's witness statement. The Respondent has subsequently altered its position, submitting instead that a gamma distribution model was used in the Verification Studies. The Respondent did so only at a late stage in the proceedings and only in response to the Second Set of Panel Questions that tested Respondent's statements on log-normal distribution. Although the Panel does not consider that either the Respondent or WADA sought to mislead, the Panel is of the view that the Respondent has provided insufficient explanations and details about the way in which the decision limits were calculated, to such an extent that the Panel cannot comfortably conclude that they are reliable.[250]

The need for proper and sufficient explanations and clear documentation of the decision limit determination protocols and calculations is even more important in light of the fact that the Respondent has not provided evidence that they have been peer reviewed (as opposed to the Test's underlying assumptions, which has been peer-reviewed). In other words, only the Respondent and WADA know how exactly the decision limits have been calculated. Since Respondent has not explained during the present proceedings to the comfortable satisfaction of this Panel that the decision limits have been set in a scientifically correct way, particularly on the protocols for the datasets, exclusion of samples from the dataset and reasons thereof, the p-values for each of the datasets and distribution

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250 For the avoidance of doubt, the Panel underlines that it does not consider that the use of different models should, in itself, call the reliability of the decision limits into question. The Panel notes that the sample sizes and composition were different for the studies and accepts the Respondent's submission that "*different datasets (sample size, composition, number of labs, etc.) produced with the same analytical tool are fitted by different parametric distributions*" (Respondent Answers to the Second Set of Panel Questions, ¶37). At the same time, the Panel notes that even though different datasets may fit to different distributions, these datasets are just measurement results obtained by analytical tools from the underlying population of real human beings. It is the Panel's understanding that the distribution model of the real parameters of the underlying population should remain the same over time.

models, the actual calculations that were performed, which distribution models were trialed for 'fit', and whether alternative distribution models would have led to lower or higher decision limits, the Panel can, for this reason, only find in favor of the Appellant.

This is not to say that the Panel believes that the Test is necessarily unreliable or that the current decision limits are necessarily wrong. It only means that Respondent has not met the applicable standard of proof with respect to the procedure followed to set the aspects of the decision limits explained above. It may well be that new procedurally correct studies will confirm the current decision limits, or even set them at a lower or higher level; however, the procedural flaws that the Panel found in the statistical side of the WADA studies do not allow the Panel to conclude to its comfortable satisfaction that the Test as a whole is reliable with regard to its decision limits.

The Panel's inability to conclude that the decision limits are reliable inevitably leads the Panel to conclude that the possibility of the Appellant's sample, especially his B sample as analyzed with Kit 2, being negative cannot reasonably be excluded. While the hGH Guidelines require that all four Test results (A-sample Kit 1, A- sample Kit 2, B- sample Kit 1, B- sample Kit 2) must be positive to constitute an anti-doping rule violation, this Panel is not comfortably satisfied that such a violation has occurred, bearing in mind the seriousness of the allegation which is made.

D. Arguments Regarding the Appellant's Alleged Admission of Doping

207. As outlined at the outset of this award, the Respondent submits that even if a violation of the anti-doping rules could not be established by means of the Test's results, the Appellant's alleged admitting to the administration of hGH would be sufficient for this Panel to find in favor of Respondent and reaffirm the FIS Panel's decision.

208. The Panel agrees with this assertion. It is therefore necessary for the Panel to also revisit the issue of alleged admission here below.

a) The Appellant's Arguments

209. The Appellant's rejection of the Respondent's claim that he had admitted to doping rests on the following two submissions: first, that at no point did the Appellant explicitly admit or otherwise make an allusion to doping; and second, that his retirement was not an implied admission of guilt.

210. **Alleged explicit admission of doping.** The Appellant has sought to refute any allegation that he has admitted to doping, whether verbally or in any other

form.[251] The Appellant underlines that he has never communicated personally with the Secretary General of FIS or anyone else in the FIS headquarters.[252] The Appellant further submits that the Secretary General of NSA EST, Mr. Jüri Järv, who communicated with FIS on behalf of the Appellant, was never authorized by the Appellant to communicate any admission of doping and, in any event, had never done so.[253]

211. **Alleged implied admission of doping.** In response to the suggestion that the Appellant's admission was implicit from his withdrawal from the Nordic Ski World Championships, the Appellant argues that his withdrawal from the World Championships was motivated solely by his age at the time (40 years) and desire to maintain his reputation and that of the NSA Estonia.[254] The Appellant also argues that the delayed request for the opening of the B-sample must not be interpreted as an admission of guilt, as this was mainly caused by a misunderstanding by the NSA EST of the communication with the FIS Secretary General on the timing of the B sample analysis, and the lack of experience on behalf of the NSA EST in dealing with positive doping findings (the NSA EST has "*almost never*" had an athlete with an Adverse Analytical Finding before) and due to the NSA EST's negative experience with the adverse publicity arising from an athlete that had a positive A-sample but was subsequently cleared due to a clean B-sample (the Kristina Šmigun-Vähi affair).[255]

b) The Respondent's Arguments

212. **Alleged explicit and implied admission of doping.** The Respondent alleges that the NSA EST admitted to hGH doping on behalf of the Appellant by both explicitly stating so *vis-à-vis* Ms. Sarah Lewis and, implicitly, by delaying the B-sample request, in addition to the questionable timing of the Appellant's retirement the day before the Nordic Ski World Championships.[256] It cites Article 3.2 of FIS ADR which states that "*facts related to anti-doping rule violations may be established by any reliable means, including admissions.*"[257]

213. During the Hearing, the Respondent circulated several text messages received by Ms. Sarah Lewis, the Secretary General of NSA EST, that the Respondent claims contain the Appellant's admission to doping with hGH.[258] The transcript of the most relevant message is as follows:

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251 Appeal Brief at section 4; Appellant Post-Hearing Brief, ¶¶22-27.

252 Appeal Brief at section 4.

253 Appeal Brief at section 4; Appellant Post-Hearing Brief, ¶23.

254 Appeal Brief, at section 9; Appellant Post-Hearing Brief, ¶27.

255 Appellant Post-Hearing Brief, ¶24.

256 Appeal Response, ¶¶119-120; Respondent Post-Hearing Brief, ¶¶107-110.

257 Appeal Response, ¶¶48-49.

258 Respondent Post-Hearing Brief, ¶108.

"*Dear Sarah, I am bit confused about the B sample opening. In one of Your emails You wrote that possible B sample opening will be not earlier than 7th of March. Therefore I didn't rush sending official answer at the moment it seems we have two options: if wada will agree to make an exception for retired athletes and the information will not go public, we don't need B sample, but if it must be public, we must have B sample opening. Jüri*"

214. The Respondent seeks to rely on the contents of this text message to supports its allegation of the Appellant's admission to doping.

215. The Respondent also seeks to rely on the behavior of the Appellant in not immediately requesting the confirmation of the AAF with the B-sample and in delaying this request until he was informed that there would still be a proceeding before the FIS Doping Panel as evidence that he admitted to the use of hGH.[259]

c) Analysis and Findings of the Panel

216. **Alleged explicit admission of doping.** In this case, the Panel is satisfied that neither the Appellant nor anyone else on his behalf, in particular the Secretary General of NSA EST, Mr. Jüri Järv, admitted to the Appellant's hGH use. The evidence brought forward by the Respondent, in particular the text messages between Mr. Järv and Ms. Lewis, did not indicate any admission of doping. Therefore, the Panel dismisses the Respondent's claim in this regard.

217. **Implied admission of guilt.** The Respondent argued that the Appellant had impliedly admitted to the use of a prohibited substance, in particular through his delayed request to open the B-sample. The Panel will not make a finding as to whether or not the actions of a party, particularly in delaying a request for a confirmatory test, can constitute an implied admission as to doping use. However, the Panel notes that it could only infer an admission from an athlete's or authority's actions if those actions constituted an unequivocal admission of doping. In this case, the Panel considers that the actions of the Appellant were far below that high threshold, particularly as all communication took place through a third party, the Secretary General of NSA EST.

218. Therefore, the Panel concludes that the Appellant's arguments concerning the alleged admission of guilt should be upheld; the Panel rejects all of the Respondent's claims in this regard.

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259 Appeal Response, ¶¶119-120.

V. SPECIFIC PROCEDURAL ISSUES

219. The Appellant has raised specific procedural requests in the course of his comments on the Respondent's Answers to the First and Second Set of Panel Questions. The Appellant argues that the information provided by the Respondent in its answers to the Panel questions are inadmissible and should be disregarded, that the testimony of the Respondent's expert witnesses is unreliable, and that the procedures followed in the arbitration proceedings have prevented it from responding to the arguments of the Respondent contrary to Article 6 ECHR.

a) The Appellant's Arguments

220. **The admissibility of the information contained in the Respondent's Answers to Panel Questions.** The Appellant argues that the current arbitration proceedings are contrary to Article R56 of the CAS Code because they are not being conducted in a speedy manner: the Appellant submits that the Respondent failed to provide adequate evidence in its initial submission and has had an excessive length of time to answer the questions posed by the Panel.[260] Consequently, the Appellant requests that the new information provided by the Respondent be disregarded.[261]

221. The Appellant also argues that because the Respondent formulated a reply to the Appellant's Comments on the First Set of Panel Questions, it acted contrary to the orders of the Panel and that this part of the Respondent's submission should be excluded from the file.[262]

222. Further, the Appellant submits that the answers provided by the Respondent to the First and Second Set of Panel Questions represent supplemental or amended arguments, and that under Article R56 of the CAS Code they should not be admitted to the proceedings.[263]

223. **The role of the Respondent's expert witnesses.** The Appellant argues that the Respondent has relied on the opinions of its expert witnesses to such a great extent that the experts' independence is questionable and that their responses represent an intervention contrary to Article R41.3 of the CAS Code.[264] Further, the Appellant argues that the distinction between expert witness and counsel for the Respondent is blurred and that their statements should be inadmissible.[265] Consequently, the Appellant argues that unless the Respondent provides a power

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260 January 31, 2013 Comments on Respondent Answers, ¶¶3-4.

261 January 31, 2013 Comments on Respondent Answers, ¶5.

262 January 31, 2013, Comments on Respondent Answers, ¶97.

263 January 31, 2013, Comments on Respondent Answers, ¶17.

264 January 31, 2013 Comments on Respondent Answers, ¶¶7-8.

265 January 31, 2013 Comments on Respondent Answers, ¶9.

of attorney for the expert witnesses under Article R30 of the CAS Code, the Panel must disregard exhibits R-55 to R-61 and the entire Chapter B.[266]

224. **The effect of the procedures used on the Appellant's right to a fair hearing.** The Appellant argues that the Respondent has conducted itself during proceedings in such a way that the Appellant is unable to respond to its arguments. The Respondent failed to provide all the information that was necessary at the beginning of the proceedings and Respondent has changed its arguments during the course of proceedings. In particular, the Appellant points to the disparity in resources between the Parties and argues that this has prevented the Appellant from responding to arguments raised by the Respondent following the Hearing.[267] Consequently, the Appellant argues that a situation of inequality of arms exists that is contrary to Article 6 ECHR and Chapter 29(1) and (3) of the Swiss Constitution.

b) The Respondent's Arguments

225. **The admissibility of the information contained in the Respondent's Answers to Panel Questions.** In response to the Appellant's request that the information provided by the Respondent in its Answers to Panel Questions be disregarded, the Respondent submits that the additional information contained in its answers to the Panel's question should not be disregarded because it was included as part of a comprehensive reply to the Panel Questions.[268]

226. Further, the Respondent argues that its rebuttal of the Appellant's arguments in its Answers to the Second Set of Panel Questions should be admitted because it was necessary in order to respond to that round of questions properly.[269]

227. **The role of the Respondent's expert witnesses.** The Respondent submits that the Appellant's submission that the participation of the expert witnesses has resulted in a WADA intervention in the present arbitration is unfounded: the Respondent argues that the Appellant's arguments do not make sense, that WADA is not a party to the arbitration, and that WADA has not filed for an intervention.[270]

228. As for the Appellant's claim that the testimony of the witnesses cannot be distinguished from the submissions of the Respondent, the Respondent argues that "*the role and contribution of the experts have been made absolutely transparent throughout the entire proceedings. It was legitimate to integrate the scientific*

266 January 31, 2013 Comments on Respondent Answers, ¶10.

267 January 31, 2013, Comments on Respondent Answers, ¶¶12-14.

268 February 6, 2013 Comments.

269 February 6, 2013 Comments.

270 February 6, 2013 Comments.

answers of the experts into the Respondent's submission and it was explicitly identified for which part the Respondent's experts had been consulted."[271]

229. Further, the Respondent rejects the Appellant's submission that its expert witnesses have become its counsel.[272]

c) Analysis and Findings of the Panel

230. **The admissibility of the information contained in the Respondent's Answers to Panel Questions.** The Appellant has not convinced the Panel that the Respondent has amended or supplemented its arguments contrary to Article R56 CAS Code. Rather, the Panel considers that the additional information was provided only in response to the questions posed by the Panel in its orders. Therefore, the Panel rejects the Appellant's request to disregard those parts of the Respondent's submissions.

231. **The role of the Respondent's expert witnesses.** The Panel is also not convinced by the Appellant's arguments that the submissions of the expert witnesses cannot be distinguished from the pleadings of its counsel. It is the Panel's view that the Respondent has made it clear in its submissions which parts are expert witness testimony and which are the Respondent's submissions. Therefore, WADA cannot be considered as an intervener, the testimony of the expert witnesses is admissible, the expert witnesses need not be considered as counsel to the Respondent, and there is no requirement that those witnesses provide a power of attorney.

232. **The Appellant's right to a fair hearing.** The Panel is not convinced that the manner in which the proceedings have been conducted has created a situation of inequality of arms or violated any other principle contrary to Article 6 ECHR (which is only partially relevant in arbitration proceedings) or the Swiss Constitution. It is the Panel's view that the Appellant has had sufficient time to respond to the additional information provided by the Respondent following the Hearing, and – in light of the nature of the information provided by the Respondent and the fact that the Appellant has been able to consult an expert witness – the Panel finds that the alleged differences in resources between the parties has not impinged upon the fairness of the proceedings. Moreover, it is the Panel's view that the possibility of additional questions or other steps could reasonably have been foreseen by the parties prior to the proceedings, so that the Appellant cannot claim that any additional legal costs have infringed his Article 6 rights.

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271 February 6, 2013 Comments.

272 February 6, 2013 Comments.

VI. SUMMARY OF THE PANEL'S CONCLUSIONS ON THE MERITS

233. In conclusion, the Panel finds that the **Appellant** has failed to meet the required burden of proof regarding its pleas on the reliability of the Test (except for that of the decision limits), the Laboratory's accreditation, the pre-analytical handling of the blood sample pursuant to the ISL, as well as Appellant's arguments relating to his individual circumstances. The Panel finds that the **Respondent** has failed to meet its burden of proof in relation to the reliability of the decision limits and in establishing the violation of FIS ADR by means other than the Test, namely through admission.

234. Therefore, on the grounds that the Respondent has not established, to the Panel's comfortable satisfaction, that the decision limits are reliable, the Panel finds that the Appellant's AAF is not upheld. The Panel reiterates its view that the Respondent has proven that the Test itself is reliable, but that, as a matter of procedure, it has not proven the same in respect of the decision limits. The Panel notes that there are many factors in this case which tend to indicate that the Athlete did in fact himself administer exogenous hGH, but that for the reason that the decision limits have not been proven as reliable in the course of this proceeding, the violation of the FIS ADR cannot be upheld on appeal. Therefore, the ban imposed by the decision of the FIS Doping Panel is overturned.

235. The Panel also notes that the Appellant's counsel's written submissions, as well as his explanations given during the Oral Hearing, largely lacked clarity and specificity and required this Panel and presumably the Respondent to spend significant, additional time on this case, which warrants being taken into account in the allocation of the costs.

VII. SANCTION AND COSTS

A. Arguments Relating to the Harshening of the Sanction

236. Given that the Panel has found that the Appellant should be acquitted of the FIS ADR breach, the Panel will not address the arguments of the Parties relating to the sanction.

B. Costs

237. The basis for this arbitration is the Appellant's appeal against a disciplinary decision issued against him by the Respondent, namely an international federation. The Panel concludes that the costs of this proceeding shall be ruled based on Article R65 of the CAS Code.

238. Pursuant to Article R65.2, the proceedings shall be free with the exception of the Court Office fee of CHF 1,000 which the Appellant has duly paid, and which is to be retained by the CAS.

239. Pursuant to Article R65.3, the costs of the parties, witnesses, experts and interpreters shall be advanced by the Parties. In the award, the Panel shall decide which Party shall bear them or in what proportion the Parties shall share them, taking into account the outcome of the proceedings, as well as the conduct and financial resources of the Parties.

240. The Appellant has been successful in his appeal to have the ban imposed by the decision of the FIS Doping Panel overturned. The decision of this Panel is also of value to the Respondent as it provides further legitimacy to the Test as a means to detect and punish hGH anti-doping violations (except regarding the decision limits). This award also provides guidance as to how the reliability of the decision limits could be established in potential future or other pending proceedings. In this case, the Appellant has raised concerns regarding the validity of the Test and its application in his case that were neither spurious nor fabricated. In light of these considerations, and bearing in mind the financial resources of the Parties, the Panel holds that the Respondent shall partially compensate the costs incurred by the Appellant.

241. Furthermore, in the Panel's opinion, the Respondent has caused all parties involved to spend substantial additional time on the evaluation of the decision limit issue by disclosing the application of gamma distribution to decision limit calculations only in its very last submission on December 12, 2012, six months after the Hearing. This late disclosure of the switch from one distribution model to another has had a substantial effect on the Panel's deliberations and conclusions in this case. Finally, as mentioned above, the Panel has also taken into account the fact that the Appellant's counsel's written and oral submissions lacked clarity and caused additional work, which could have been avoided.

242. For these reasons, the Panel considers it appropriate for the Respondent to pay to the Appellant the amount of ten thousand Swiss francs (CHF 10'000) by way of partial compensation towards the costs incurred by the Appellant in the course of these proceedings.

ON THESE GROUNDS

The Court of Arbitration for Sport rules:

1. The Appeal filed by Andrus Veerpalu on 12 September 2011 is upheld.
2. The decision of the FIS Doping Panel of 22 August 2011 is set aside.
3. The award is pronounced without costs, except for the Court Office fee of CHF 1,000 (one thousand Swiss Francs) paid by Andrus Veerpalu, which is retained by the CAS.
4. The FIS shall pay to Andrus Veerpalu CHF 10'000 (ten thousand Swiss francs) as contribution towards his costs incurred in the course of these proceedings.
5. All further and other claims for relief are dismissed.

Lausanne, 25 March 2013

Mr. Romano Subiotto QC
President of the Panel

Prof. Massimo Coccia
Arbitrator

Mr. Olli Rauste
Arbitrator