

### CAS 2005/A/884 Tyler Hamilton V/USADA & UCI

### ARBITRAL AWARD

# Delivered by the

### COURT OF ARBITRATION FOR SPORT

Sitting in the following composition:

President:Mr Malcolm Holmes QC, Barrister, Sydney, AustraliaArbitrators:Ms Maidie Oliveau, Attorney-at-Law, Los Angeles, USAMr David W. Rivkin, Attorney-at-Law, New York, USA

In the arbitration between

TYLER HAMILTON, USA Represented by: Mr Howard Jacobs and Ms Jill Benjamin, Attorneys-at-Law, Los Angeles, California, USA

Appellant

and

UNITED STATES ANTI-DOPING AGENCY ("USADA"), Colorado Springs, USA Represented by Mr Richard Young, Attorney-at-law, Colorado Springs, Colorado, USA and by Mr Travis Tygart, Director of USADA Legal Affairs,

First Respondent

UNION CYCLISTE INTERNATIONALE ("UCP"); Aigle, Switzerland Represented by Mr Philippe Verbiest, Attorney-at-Law, Leuven, Belgium

Second Respondent

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### PART I: INTRODUCTION

- Tyler Hamilton ("the Appellant") was a member of the Phonak Professional Cycling Team which participated in the 2004 Vuelta de España (Tour of Spain), which was a stage race held in September 2004 ("Vuelta") as part of the international race calendar organised by the Union Cycliste Internationale ("UCI").
- 2. On 11 September 2004, the Appellant won a stage of the Vuelta and underwent a blood test. The World Anti-Doping Agency ("WADA") accredited laboratory in Lausanne, Switzerland ("the Lausanne Laboratory") reported that the Appellant's sample was positive for the presence of transfused blood. Under UCI's Anti-Doping Regulations, a blood transfusion, whether it be an homologous blood transfusion – which is the transfusion of a third person's blood –, or an autologous transfusion – which is the transfusion of a person's own blood – which is not required by medical necessity, is an anti-doping rule violation.
- 3. By way of background, the increase in the number of an athlete's red blood cells by use of a blood transfusion increases an athlete's oxygen transport and aerobic power thereby increasing the athlete's level of performance. This is particularly true for a cyclist where endurance, stamina and aerobic recovery are necessary to perform well.
- 4. The Lausanne Laboratory used the homologous blood transfusion test ("HBT test") to detect the presence of the transfused blood in the Appellant's sample. Using this test, the Lausanne Laboratory detected the presence of mixed populations of three different red blood cell markers ( $F_y^{a}$ ,  $J_k^{a}$  and  $J_k^{b}$ ) in the sample.
- 5. The Appellant denied having any blood transfusion in the relevant period for medical purposes or otherwise and disputed the positive test result.
- 6. USADA was the responsible body for the results management of the positive blood test and was required to follow the results management procedures set out in Article 9 of the USADA Protocol for Olympic Movement Testing ("USADA Protocol"). This led to a hearing before an American Arbitration Association ("AAA") Panel which by its Award dated 18 April 2005, found that there had been a transfusion of a third person's blood and accordingly that an anti-doping rule violation had been committed by the Appellant. He was suspended from competition for a period of two years commencing 18 April 2005 (ie, the date of the decision

of the AAA panel) and all of his competition results from 11 September 2004 including those obtained in the Vuelta competition were cancelled.

- 7. The Appellant then appealed to the Court of Arbitration for Sport ("CAS") in accordance with the Code of Sports Related Arbitration (the "Code"). The appeal to CAS is by way of a complete rehearing of the dispute (Art. R57 of the Code) between the parties where it was necessary for the Respondent to establish an anti-doping rule violation by the Appellant (see *French v Australian Sports Commission and Cycling Australia*, CAS 2004 A/651).
- 8. The Appellant stated in his appeal brief that the HBT test was "a brand new test" apparently used for the first time at the 2004 Olympic Games in Athens. The basis of the appeal was that "the validation studies of this brand new test are limited, incomplete and unsatisfactory." The Appellant also contested "the reliability of the alleged positive findings in connection with the Vuelta sample".
- 9. The Appellant's appeal brief was submitted on 27 May 2005 and USADA's pre-hearing brief submitted on 11 July 2005. The Appellant filed a motion to preclude the Respondents from relying on certain scientific material relating to the HBT test and in the alternative that the Respondents and the laboratories concerned produce specified documents. By consent, production of documents was agreed to and the motion by the Appellant was declined. The experts from all Parties were directed by the Panel to confer and to identify points of agreement and disagreement on the scientific issues and evidence. This occurred and agreement was reached on certain matters, some of which are referred to below.
- 10. The case proceeded to a hearing in Denver, Colorado on Tuesday 6 September through to Thursday 8 September 2005 when the hearing was adjourned at the request of the Appellant to enable the Appellant's representatives to inspect various documents from the Lausanne Laboratory, from the laboratory in Athens, Greece, which used the HBT test during the Athens Olympics in August 2004 and from the laboratory in Sydney, Australia which had originally developed the HBT test to detect the presence of mixed blood populations in athletes.
- 11. The Appellant on gaining access to this material sought to have the infraction notice summarily dismissed and sanctions imposed on the Respondents for nondisclosure of the documents obtained during the adjournment. This was not acceded to by the Panel although this material was the focus of much attention by the Parties.

- 12. At the time of the Vuelta test the Lausanne Laboratory did not have specific accreditation for the HBT test. In October 2005, as part of the laboratory's regular ISO reassessment, specific accreditation under ISO 17025 was given to the laboratory to perform the HBT test.
- 13. The hearing resumed on Tuesday 10 January 2006 in Denver. After further evidence had been presented by the Parties and the parties had made their closing submissions, the Panel reserved its decision.

### PART II: JURISDICTION AND APPLICABLE RULES

- 14. The jurisdiction of CAS in casu is based on Articles 280 ff of the Anti-doping Rules of the UCI ("ADR"). It is confirmed by the signature to the order of procedure signed by all the Parties.
- 15. Article 290 ADR provides as follows:

"The CAS shall decide the dispute according to these Anti-Doping Rules and the rules of law chosen by the parties or, in the absence of such a choice, according to Swiss law."

16. Article 291 ADR provides as follows;

"The decision of the CAS shall be final and binding on the parties to the case and to all License-Holders and National Federations. It shall not be subject to appeal: "

17. At its meeting held on 22 to 23 July 2004, the UCI Management Committee implemented the World Anti-Doping Code ("the WADA Code") into the ADR effective for all licensed cyclists on 13 August 2004. Both the USADA Protocol and the ADR have adopted the mandatory provisions from the WADA Code that include the definitions of doping, burdens of proof, prohibited substances and methods, and sanctions.

18. In the definition of doping in the ADR, Chapter II Doping, Article 15.2 ADR, it is stated that:

"The success or failure of the Use of a Prohibited Substance or Prohibited Method is not material. It is sufficient that the Prohibited Substance or Prohibited Method was Used or Attempted to be Used for an anti-doping rule violation to be committed,"

19. The word "Use" is defined in Appendix I of the ADR as "the application, injection or consumption by any means whatsoever of a Prohibited Substance or Prohibited Method".

20. The ADR, Chapter III, Article 21, incorporate the Prohibited List (Categories of Prohibited Substances or Prohibited Methods) which is published and revised by WADA. Section M1 of the 2004 WADA List refers to Enhancement of Oxygen Transfer and states that the following is prohibited:

> "Blood doping including <u>the use of</u> autologous, <u>homologous</u> or heterologous <u>blood</u> or <u>red cell products of any origin</u>, <u>other than for medical treatment</u>, "(emphasis added).

21. The ADR do not define or specify how the use of homologous blood (ie, a blood transfusion) is to be established. Article 17 ADR states that "facts relating to anti-doping violations may be established by any reliable means, including admissions". This is to the same effect as Article 3.2 of the WADA Code. The most common method of establishing a blood transfusion is the report of a WADA accredited laboratory stating that a mixed red blood cell population has been found in an athlete's sample. Such a finding by a WADA accredited laboratory will have the benefit of the presumption of Article 18 ADR and which provides that:

"WADA-accredited laboratories or as otherwise approved by WADA are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for laboratory analysis. The Rider may rebut this presumption by establishing that a departure from the International Standard occurred.

If the Rider rebuts the preceding presumption by showing that a departure from the International Standard occurred, then the UCI or the National Federation shall have the burden to establish that such departure did not cause the Adverse Analytical Finding."

### PART III: THE HISTORY OF THE HBT TEST

- 22. In order to evaluate the reliability and use in the present case of the HBT test during the Vuelta in September 2004 to detect the presence of transfused blood in an athlete, it is necessary to understand the nature and methodology of the test.
- 23. The surface of each red blood cell contains numerous types of surface markers called antigens and the most widely known are the common blood types O, A and B. Medical science has for a considerable period of time been detecting the red blood cell surface markers by using an instrument called a flow cytometer. Using this instrument, the patient's red blood cells are separated from the white cells and are exposed to a primary antibody which is engineered to bind only to a specific surface marker. These are then exposed to a secondary antibody which is marked with a fluorescent tag which has been engineered to bind only to the primary antibody. The red blood cells are then run through a flow cytometer which counts both the

number of individual red blood cells passing through the instrument and measures the amount of cell associated fluorescence on each red cell. It is the fluorescent tag which enables the instrument to detect the particular type of blood cells. There are many different markers on the surface of each red blood cell. An individual who has a particular surface marker on his red blood cells is called an "expressor" or is "positive" for that marker. An individual who does not have that surface marker on his red blood cells is called a "non-expressor" or "negative" for that surface marker.

24. The flow cytometer then generates a "histogram" which depicts the data as a frequency plot of numbers of cells versus the amount of fluorescence. For example, histograms of an expressor (positive) and a non-expressor (negative) for the surface marker Fy<sup>B</sup> are shown as follows:



25. If a histogram for each surface marker contains only one visibly identifiable peak on the right or left hand side then the indication is that all the red blood cells in the blood sample have one identical set of surface markers, that is, the blood sample only contains one population of red blood cells. If however the histogram displays a major peak on one side and also a small peak on the other side it indicates the presence of both red blood cells which do have the marker and also those red blood cells which do not have the marker. Whether or not a marker is on the surface of a person's red blood cell will be determined by human genetics. Any individual human being will have an identical set of markers for *all* of their red blood cells. Accordingly, if the histogram shows the presence of red blood cells which do have the particular marker and also red blood cells which do not have the particular marker, then it is an indication that there are two different populations of red blood cells present in the blood sample.

- 26. For many years persons performing transfusions have been extremely careful to match blood for the major marker types A, B, O and Rh(D) because of the risk of an adverse reaction to incompatible blood. On the other hand, however, no effort is generally made to match the donor with the recipient for all of the very many minor blood marker types. Thus, individuals who have had transfusions with third party blood are likely to have received blood which whilst identical for the major common blood marker types, will not be identical with respect to one or more of the minor red blood cell markers. For example the recipient could be an  $F_y^a$ expressor and the donor could be an  $F_y^a$  non-expressor. By analysing an individual's blood for these minor red blood cell markers using flow cytometry, mixed populations for that marker can be detected.
- 27. If an individual is a non-expressor for Fy<sup>a</sup>, there will be a large peak on the left hand side of the histogram, showing no fluorescence, representing that particular individual's naturally produced blood. If the transfusion donor was an expressor for Fy<sup>a</sup>, then also there will be a small peak on the right hand side of the histogram, showing fluorescence, reflecting the relatively smaller number of transfused cells which did have the Fy<sup>a</sup> surface marker expressed and which fluoresced when they went through the flow cytometer as a result of the attached primary and secondary antibodies. This would appear as follows:



28. On the other hand a histogram for a person who has had a blood transfusion and who is an expressor for the surface marker Fy<sup>a</sup> but who has been transfused with some red blood cells from an individual who is a non-expressor for Fy<sup>a</sup> would appear as follows:



29. Flow cytometry has been routinely used for many years in medicine to detect mixed blood populations in circumstances where it is critical to ensure that the donor's blood is the same as the recipient's blood. For example, it is used to determine whether a bone marrow transplant has engrafted in a bone marrow transplant recipient. The major population after a successful engraftment should reflect the donor's surface markers and a small percentage of the recipient's markers may not be of medical concern. It is important that these percentages remain relatively stable because an increase in the percentage of the recipient's red blood cells suggests a return of the recipient's leukaemia with potentially dire consequences for the patient. Another critical example involves the surface marker Rh(D). An Rh(D) negative nonexpressor mother may have an Rh(D) positive baby in her womb. If a small amount of blood from the baby leaks through the placenta into the mother's system, it may cause an immune reaction in which the mother's immune system begins attacking the foreign Rh(D) positive cells in the mother's system and eventually the baby's cells in the mother's uterus. To carefully monitor this potential risk and as the diagnostic indicator for treatment, the mother's blood is analysed by flow cytometry to detect whether there is a small population of the baby's Rh(D) positive cells in the mother's blood.

#### The use of flow cytometry in sport

30. In 2002 and 2003, work was carried out in Australia by the Institute of Haematology at Royal Prince Alfred Hospital in Sydney, the Department of Mathematics and Statistics at the University of Melbourne and the Science and Industry Against Blood Doping Research

Consortium in Queensland to "develop tests capable of detecting a mixed red cell population by flow cytometry utilising the likelihood of differences in minor blood group antigens". This research work was supported by a financial grant from USADA and support from the WADA. The results of this research were published in the Journal of Haematology in November 2003 in an article entitled "Proof of homologous blood transfusion through quantification of blood group antigens" by Margaret Nelson, Hazel Popp, Ken Sharp and Michael Ashenden. This publication was peer reviewed by two external referees and by Professor Carlo Brugnara, the Deputy Editor of the journal. Subsequently a study was undertaken to validate the flow cytometric method for the detection of homologous blood transfusion by elite athletes using a panel of different red blood cell antibodies to detect mixed red blood cell populations which was described in that article. The subsequent study by Margaret Nelson and others was published in an article entitled "Validation of a test designed to detect blood doping of elite athletes by homologous transfusion" in the Australian Journal of Medical Science in February 2004.

- 31. This research work and series of publications led to consideration being given to using flow cytometry at the Athens Olympics to detect homologous blood transfusion. In February 2004 Michael Ashenden and Margaret Nelsen prepared a "Fact Sheet on the Blood Test for Homologous Transfusion". At a scientific meeting in Dallas, Texas, USA, on 3 April 2004, representatives from the IOC, USADA, WADA, the Athens Olympic Organising Committee and the Athens Laboratory which was to conduct the drug testing for the Athens Olympics, considered the possible use of the HBT test during the Athens Olympics. Those present decided that there were "enough grounds" which were the publication in peer review journals and the results which had been reproduced in at least three laboratories, to move forward to implement the test in Athens but that a final decision was to be taken at a time closer to the time of the Athens Olympics.
- 32. In the period June through August 2004 the laboratories in Sydney, Athens and Lausanne worked together to determine whether or not the Athens Laboratory and the Lausanne Laboratory would be sufficiently proficient to use the HBT test which had been developed in Sydney in time for the Athens Olympics. Many of the communications between the laboratories were by email and became part of the evidence in the proceedings. During the course of the hearing, the Appellant submitted that these communications demonstrated the unreliability of the HBT test when used by the Lausanne Laboratory. Numerous emails were

put in evidence and referred to by the Parties and particular reliance was placed on the contents of one email dated 13 August 2004 which is considered below.

33. During this period consideration was given to the positivity criteria which would be required before a test would be regarded as positive for homologous blood transfusion. On 28 July 2004, it was suggested by Michael Ashenden that before a test could be declared positive, there needed to be detected the presence of mixed populations for two minor blood antigens. The positivity criteria suggested to evidence a mixed population of an antigen were in the following terms ;

#### "a) Evidence of a mixed antigen population

A mixed antigen population will be concluded to exist if there is a clearly definable right sided peaked minor population or a clearly definable left sided peaked minor population in the histogram for any antigen (whether using visual interpretation as will be the case for the Athens Olympics, or in the near future an algorithm-based approach as proposed by Lausanne).

For histograms with suspected but not discrete minor peaked population (right or left sided), the test should be repeated, modifying the titration (with at least two more titers : for example, one double and one half the recommended SOP titer for this specific antibody) and reassessed. If the histogram using different titers yields a clearly definable minor peaked population a mixed antigen population will be concluded to exist (if the histogram remains uncertain it will be considered negative)."

34. This statement of the positivity criteria was adopted by WADA and was applied by the laboratories in Lausanne and Athens during the Athens Olympics and also at the time of testing of the sample from the Appellant taken during the Vuelta.

#### Relevant blood testing of the Appellant

35. Elite riders such as the Appellant are subject to a UCI programme designed to ensure the health of riders and the overall safety of the sport. As part of this programme the UCI has adopted Sporting and Safety Regulations which involve the collection of blood samples from licensed riders on the morning of a race for analysis of certain blood parameters including hematocrit, haemoglobin and reticulocyte percentage. If a rider's blood parameters are higher than the thresholds established by UCI, the rider is considered medically unfit and is not allowed to compete for a period of time. These health tests do not involve analysis of a B sample and the results of these health tests are therefore not considered positive for anti-doping

purposes. Nevertheless these results are considered by UCI in the administration of its antidoping program and the sport overall.

- 36. On 24 April 2004, the Appellant underwent a UCI health test during the Liège-Bastogne-Liège race and his reading was a little high although it was thought to be due to "dehydration".
- 37. On 29 April 2004, the Appellant had a UCI health test along with other members of the Phonak team and the readings were high although the Phonak team claimed the readings were higher than the team's own blood measurements. This sample and another taken on 8 June 2004 were subsequently tested for a homologous blood transfusion using flow cytometry.
- 38. As a result of these test results, UCI held several meetings with the Appellant and representatives from the Phonak team. During the presentations at these meetings, Dr Zorzoli of the UCI warned that a test on red blood cell antigens was in the process of being validated as an anti-doping test to detect an homologous blood transfusion. On 10 June 2004, UCI sent a warning letter to the Appellant in which he was advised that "the blood checks that took place during the Tour de Romandie 2004...showed an abnormal profile" (as translated) and that the blood values showed "strong signs of possible manipulation". The letter warned the Appellant that he would be "closely monitored" in 2004.
- 39. Some of the blood samples taken for the UCI health tests during this period were tested using flow cytometry and the results suggested the presence of mixed red blood cell populations. At a meeting on 14 June 2004, Dr Zorzoli presented to the Appellant and the team manager the results which were said to show mixed populations and again said that they would be watching the Appellant. At this stage a final decision on the adoption and implementation of the HBT test had not been made by UCI, WADA or the IOC.
- 40. The Appellant continued to be subjected to UCI health tests during the Tour de France in July 2004 although he was forced to leave the Tour de France as a result of a crash on 17 July 2004.
- 41. On 18 August 2004, the Appellant competed in the Athens Olympics and won the gold medal for the time trial. A blood sample was taken from the Appellant and the A sample was tested for homologous blood transfusion at the Athens Laboratory using flow cytometry. The B sample was frozen and this process destroyed the red blood cells in the sample and as a result no testing of the B sample was undertaken.

- 42. On 2 September 2004, the Appellant had a UCI health test and this sample was subsequently tested for a homologous blood transfusion using flow cytometry
- 43. On 11 September 2004, the Appellant during the Vuelta was subjected to a doping control blood test. The A and B samples were sent to the Lausanne Laboratory which used the HBT test. The Lausanne Laboratory found mixed populations for three different markers, namely F<sub>v</sub><sup>a</sup>, J<sub>k</sub><sup>a</sup> and J<sub>k</sub><sup>b</sup> in the A sample. This is the test which has given rise to the present proceedings,
- 44. On 16 September 2004, the Appellant was notified of the positive result of his sample taken on 11 September and he decided to withdraw from the Vuelta. On 21 and 22 September 2004, the B sample was tested at the Lausanne Laboratory in the presence of an Italian haematologist representing the Appellant, Dr Giuseppe Pericimi. The B sample also tested positive for the presence of a mixed blood cell population with the same markers.
- 45. On 23 September 2004, the Appellant was suspended by his team as a result of the doping charges and he has therefore no longer been able to compete in professional road cycling.
- 46. On 30 November 2004, he was dismissed by his team.

### PART IV: BURDEN OF PROOF

47. As is described in this section, each Party bears various burdens of proof in this case. We are principally guided by the burden of proof set out in the WADA Code. Article 3.1 of the WADA Code provides as follows:

> "The Anti-Doping Organization [in this case, USADA] shall have the burden of establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether the Anti-Doping Organization has established an anti-doping rule violation to the comfortable satisfaction of the hearing body bearing in mind the seriousness of the allegation which is made,"

The Code goes on to define this standard as "greater than a mere balance of probability, but less than proof beyond a reasonable doubt." Because the standard is relatively new, there have been few CAS cases defining the standard. Nevertheless, the Code itself notes that the standards should be interpreted in light of the seriousness of the allegations, and since the issue in such cases involves the continued livelihood of a dedicated athlete, the comfortable satisfaction standard may not be much different from the standard of "beyond a reasonable doubt." Indeed, according to CAS jurisprudence (*USADA v. T. Montgomery*, CAS 2004/O/645; confirmed in *USADA v. Ch. Gaines*, CAS 2004/O/649).

"From this perspective, and in view of the nature and gravity of the allegations at issue in these proceedings, there is no practical distinction between the standards of proof advocated by USADA and the Respondents. It makes little, if indeed any, difference whether a "beyond reasonable doubt" or "comfortable satisfaction" standard is applied to determine the claims against the Respondents. This will become all the more manifest in due course, when the Panel renders its awards on the merits of USADA's claims. Either way, USADA bears the burden of proving, by strong evidence commensurate with the serious claims it makes, that the Respondents committed the doping offences in question."

48. The WADA Code also provides that an anti-doping violation "may be established by any reliable means" (WADA Code, Article 3.2). There is no dispute that this is the relevant standard. It is important to note that this rule gives great leeway to USADA and other anti-doping agencies to prove violations, so long as they can comfortably satisfy a tribunal that the means of proof is reliable. As a result, it is not even necessary that a violation be proven by a scientific test itself. Instead, as some cases have found, a violation may be proved through admissions, testimony of witnesses, or other documentation evidencing a violation. For instance, in USADA v. T. Montgomery and in USADA v. Ch. Gaines, the CAS Panels held:

"The fact that the Panel does not consider it necessary in the circumstances to analyse and comment on the mass of other evidence against the Athlete, however, is not to be taken as an indication that it considers that such other evidence could not demonstrate that the Respondent is guilty of doping. Doping offences can be proved by a variety of means; and this is nowhere more true than in "nonanalytical positive" cases such as the present."

See also USADA v M. Collins, AAA No 30 190 00658 04

- 49. One consequence of this rule is that WADA need not designate a specific test to prove that a doping violation has occurred. Rather, WADA and its accredited laboratories are free to develop tests based on appropriate scientific principles to demonstrate the existence of a prohibited substance or the use of a prohibited method. This flexibility necessarily provides WADA and other anti-doping organizations with the means to combat new forms of doping.
- 50. USADA and other anti-doping organizations are generally aided by the presumption that WADA-accredited laboratories are presumed to conduct sample analysis in accordance with international laboratory standards. The WADA Code, in Article 3.2.1 which is reproduced in Article 18 ADR provides that;

"WADA-accredited laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for laboratory analysis. The Athlete may rebut this presumption by establishing that a departure from the International Standard occurred...."

- 51. WADA sets out general principles and requirements in the International Standards for Laboratories. WADA may in certain instances impose specific positivity criteria, as it did in this case, but there is no formal requirement as to how that must be done.
- 52. However, when WADA has not specifically accredited the laboratory for the particular test, the burden shifts to the anti-doping agency. As was held by the Panel in IAAF v. Boulami (CAS 2003/A/452) at § 5.49:

"LAD's [the Lausanne Laboratory's] lack of specific accreditation to conduct r-EPO testing is not fatal to the legal validity of its r-EPO tests. However, the lack of specific accreditation shifts the burden to the IAAF to show that LAD conducted its testing in accordance with the scientific community's practices and procedures, and that it satisfied itself as to the validity of the method before using it. See Muehlegg v. IOC, (CAS 2002/A/374, at ¶ 7.1.8). The Panel believes such a burden-shifting rule provides the necessary balance between the needs of IOC laboratories to implement new, reliable testing methods as quickly as possible, on the one hand, and the interests of athletes and the sporting community in ensuring trustworthy test results, on the other."

- 53. The necessity for the standard particularly exists where a test is new, as is the case here. In this appeal, USADA bears the burden of proving that the HBT test conducted by the Lausanne Laboratory is "in accordance with the scientific community's practice and procedures and that [the Lausanne Laboratory] satisfied itself as the validity of the method before using it." (Id.)
- 54. If the HBT test is valid, then the presumption mentioned above in Article 3.2.1 returns. An athlete must then prove by a preponderance of the evidence that the testing was not conducted in accordance with international standards.
- 55. For the reasons described below, the Panel believes that USADA has met its burden of proof by demonstrating that the HBT test conducted on the Vuelta sample by the Lausanne Laboratory was in accordance with the scientific community's practice and procedures, and the Appellant has not proven that the specific testing on his samples was not performed in accordance with international standards.

### PART V: THE PARTIES' SUBMISSIONS

56. USADA submitted that the Panel would be comfortably satisfied that the histograms of the Appellant's samples "accurately reflect the presence of mixed red blood cell populations for at least two of the following three markers:  $J_k^a$ ,  $J_k^b$  and  $F_{\nu}^{a}$ ". USADA's case was "based principally on the finding of a mixed red blood cell population" in the 11 September 2004

sample which was confirmed by the testing of the B sample. An alternative submission was made by USADA that the results of the testing of the Appellant's blood samples taken on 29 April 2004 (UCI health tests), 8 June 2004 (UCI health tests), 18 August 2004 (Athens Olympic A sample) and 2 September 2004 (UCI health test) which were tested using the flow cytometry method and which were said to show the presence of mixed red blood cell populations, provide further "*independent evidence of doping*." The results of these tests were said to "*corroborate*" the results of the Vuelta test. This reliance and use of UCI health test was disputed by the Appellant and said to be inappropriate and unauthorised. A subsidiary issue was advanced by USADA which was consequential upon a finding of the presence of mixed red blood cell populations, namely that this was the result of a homologous blood transfusion rather than chimerism or some other cause.

- 57. A further submission was made by the Appellant that the test method was insufficiently validated at the time of the Vuelta test for its use in an anti-doping context. It was acknowledged by the Appellant that flow cytometry had been utilised in the past in other areas of medicine such as in phenotypic analysis, sterile sorting of transfectants, DNA analysis and assessment of apoptosis. Further it was accepted that flow cytometry had been used to detect maternal/foetal bleeding as well as a test to match patients for organ transplant. Nevertheless, it was submitted that there had been inadequate control studies, that there had been no proper study of false positives, that there had been no measure of uncertainty and that there remained unresolved flaws in the test method itself when used to test elite athletes in an anti-doping context.
- 58. More specifically, the Appellant submitted that the comfortable satisfaction standard could not be met in this case because of the following matters:
  - A. The Respondents and some of the laboratories had been guilty of "concealment of documents."
  - B. There had been "inconsistent statements of witnesses" called by the Respondents.
  - C. That there had been "serious doubt" raised by the co-creator of the HBT test concerning the Lausanne Laboratory test methodology, in an email to the IOC dated 13 August 2004 which "was never retracted" and which concerned the methodology that had never been changed.
  - D. There were problems with controls used in the HBT test.

- E. There were problems with false positives being produced by the HBT test.
- F. There was documented concern regarding the "*false positives*" produced by the HBT test which contradicted the testimony of USADA's witnesses.
- G. There was "disagreement among USADA's own experts over the meaning of the basic terms of the WADA positivity criteria."
- H. The test methodology was flawed because there had been a disregard for the "previously recommended 5% threshold for inappropriate and non-scientific reasons."
- 59. In the Appellant's appeal brief, a number of alternate submissions were made suggesting other possible causes for a second red blood cell population in the sample taken from the Appellant such as chimerism. During the course of the hearing DNA testing was carried out on a sample of the Appellant's blood by Dr Busch, which indicated that the Appellant was not a chimera and that this would not explain the positive test result for the presence of a mixed blood population in the Appellant's blood sample taken during the Vuelta. While the Appellant submitted a reply from an expert concerning this testing, the Appellant did not participate in the testing, as he was invited to do. The Appellant and his expert presented no scientific evidence to refute Dr Busch's analysis. Particularly given the extreme rarity of chimerism, this DNA testing eliminated the possibility that the mixed blood population in the Appellant's Vuelta sample was caused by chimerism. Therefore, the Panel has focussed on whether or not the results of the Vuelta test were sufficiently reliable to establish the presence of a mixed blood population and an anti-doping rule violation to the comfortable satisfaction of the Panel.

### PART VI: ANALYSIS

60. The Panel notes that the HBT test was not a completely new test nor a test designed to measure a particular threshold of a substance in the blood. The test is one of identification and not measurement. There was as such no requirement for there to be a measure of uncertainty. The test criteria require a clearly definable peak to be produced on testing. This is an objective fact. It may not require a numerical percentage threshold but it is either there or it is not. The Panel notes that the HBT test had been published in peer reviewed journals. By agreement of the experts of the Parties these studies established proof of principle. These studies did not set a minimum threshold. Rather they indicated that the test was effective in finding mixed populations at very low levels of concentrations. In one case the HBT test found a blood sample with a mixed population down to 0.4%.

- 61. The test criteria used in anti-doping are conservative in that the positivity criteria adopted by WADA and applied in this case require positive results for two antigens whereas in the usual clinical use of flow cytometry one may be sufficient. In the case of the Vuelta sample mixed populations were found for three antigens.
- 62. The HBT test was based upon a long-standing methodology using flow cytometry for determining markers in the blood. Evidence was given by leading practitioners and scientific researchers in the area that at the time of the Vuelta test, the HBT test was a valid and reliable test for determining the usage of the prohibited method of blood doping through homologous blood transfusion. The rigorous protocol of the HBT test is evident in the measures taken on each test to ensure that the controls are working as intended and that there is no possible washover effect from the controls to the samples. At the time of the Vuelta test, there was no specific accreditation to perform the test and it was up to the director of the particular laboratory to decide if the test as used in his/her laboratory was scientifically valid. Michael Ashenden, a co creator of the test confirmed in his deposition that the validation of the test was "laboratory specific". The HBT test satisfied the director of each of the three laboratories at the time as being valid and fit for the purpose. This view has since been confirmed by the broader scientific community, and by the testimony of independent expert witnesses called by the Respondents such as Dr Bruce Davis from Trillium Diagnostics, located at the Maine Medical Center Research Institute in Scarborough, Maine, USA, and who is the committee chairman of the Clinical and Laboratory Standardization Institute responsible for writing diagnostic flow cytometry standards.
- 63. Further, on 5 October 2005, the methodology used by the Lausanne Laboratory when conducting the HBT test was certified after an ISO inspection by the Swiss Accreditation Service under the ISO 17025. By subsequent letter dated 5 November 2005, the Swiss Accreditation Service confirmed that their visit was "focussed on the evaluation" of the HBT test and stated that the outcome of the evaluation was positive and the assessment team considered that the method was *well-validated* and *fit for purpose*. The Swiss Accreditation Service therefore approved the method as at the date of the assessment visit, 4 October 2005. The evidence before the Panel indicates that the methodology at the time of the visit in October 2005 was substantially the same methodology as had been used in the Lausanne Laboratory at the time of the Vuelta test. While there have been minor changes in the protocols and standard operating procedure used for this method in the Lausanne Laboratory over this time, they have been immaterial. The evidence reveals that these minor changes have

> improved the sensitivity of the test in the Lausanne Laboratory but there has been no effect on the specificity of the HBT test.

64. In summary, the Panel notes in particular that :

- 1. the HBT test has been used for many years for important medical purposes and has been scientifically reliable.
- 2. the methodology to be applied for testing of athletes was published in peer reviewed articles;
- the experts appointed by both parties in this case agreed that these articles provided "proof of principle";
- 4. the experts also agreed that "ISO 17025 and WADA ISL are the controlling documents in doping, and a proper validation under these documents must be done.";
- 5. the test methodology was validated prior to the Vuelta test in three different WADA accredited labs according to ISO 17025 and WADA ISL; and
- the independent Swiss ISO accreditation team subsequently found in 2005 that the Lausanne Laboratory's HBT test methodology was in compliance with the ISO 17025 and fit for the purpose.
- 65. The Panel finds that the HBT test as applied to the Appellant's Vuelta sample was reliable, that on 11 September 2004, his blood did contain two different red blood cell populations, and that such presence was caused by blood doping by homologous blood transfusion, a Prohibited Method under the UCI Rules. In these circumstances it is not necessary to consider the Respondents' alternative submission based on the results of the other testing of the Appellant which was said to corroborate the accuracy of the Vuelta analysis.
- 66. This conclusion is reinforced when each of the particular matters, evidence and arguments relied upon by the Appellant summarised above are considered.

### A: Concealment of documents

67. As mentioned above, the hearing of this appeal in September 2005 was adjourned at the request of the Appellant so that he could have access to further documents from the Lausanne Laboratory, the Athens Laboratory and the Sydney Laboratory. Documents were specified by the Appellant and produced from the Sydney Laboratory. Documents were specified by the Appellant to the Lausanne Laboratory and the Athens Laboratory and as events transpired, the Appellant and his legal representative visited both of these laboratories to inspect their records.

In subsequent evidence the Appellant confirmed that he and his legal representative had virtually unrestricted access to all documents and records of the Athens Laboratory. In relation to the Lausanne Laboratory, the Appellant and his legal representative spent two days at the laboratory inspecting documents although it appears they did not access the computerised records and data relating to all of the validation testing in the laboratory.

- 68. Particular attention was drawn to the email dated 13 August 2004 which was obtained by the Appellant during the visit to the Athens Laboratory in which Michael Ashenden wrote to the IOC informing them that the Lausanne Laboratory had significant flaws in its methodology and that all results should be disregarded. This email had not been produced earlier in the proceedings and was only obtained as a result of the inspection of records at the Athens Laboratory which had received a copy of the email. Dr Saugy from the Lausanne Laboratory gave evidence that this was part of the ordinary scientific exchange concerning the implementation of the test within the laboratory and was not considered important and that as a result it was not subsequently archived and printed for production in the proceedings.
- 69. This is but one of the documents relied upon by the Appellant. The Appellant had requested documents by letter dated 19 January 2005 in relation to the initial AAA hearing. A further request had been made to USADA by letters dated 20 January 2005 and 8 February 2005. It is apparent that some documentation was produced at that time. When these appeal proceedings commenced the Appellant filed a motion to produce specific documents stipulated by him. That motion was granted in July 2005 and an agreement was reached to produce specific documents in terms specified by the Appellant. These arrangements were made well in advance of the September 2005 hearing. At the time of the Appellant's request in September for an adjournment of the proceedings, the Appellant confirmed that the documents then being sought had not been specified by him in the order that he earlier sought and obtained by agreement.
- 70. The Panel has given serious consideration to the history of the requests and production of documents both before the current appeal Panel and before the original AAA hearing and whilst there may be some concerns about the way in which documents have been produced the Panel finds that there was no concealment such as would cast doubt on the validity of the test. On the contrary, the complete and open production of documents and the totally unfettered access that was given by the Athens Laboratory to the Appellant confirms that those involved in the implementation and validation of the test had nothing to hide. It is unfortunate that this

case, because it involved the consideration of a new test, did place a necessarily increased burden on the laboratories concerned to produce documents and did involve the Appellant in travel to the Athens and Lausanne Laboratory and the further extensive production of documents by the Sydney Laboratory. Nevertheless, the Panel finds that this was necessary in view of the fact that the test had only been recently begun to be used by the scientific community prior to the Vuelta test to determine the presence of mixed blood cell populations in elite athletes in the anti-doping context.

#### B: Inconsistent statements of witnesses

- 71. In the Appellant's closing presentation, the Appellant sought to reject the whole of the testimony of certain witnesses on the basis of what was said to be false testimony in material respects. The particular statements were in the written and oral testimony of the USADA witnesses used at the September 2005 hearing prior to the Appellant gaining access to the inter-laboratory communications of June, July and August 2004 during the visit to the Athens Laboratory.
- 72. One example was an email dated 16 July 2004 which suggested that ideally other monoclonal antibodies should be used in the tests but unfortunately a particular laboratory did not have the reagents available. In contrast the author of the email in oral and written testimony during the hearing in September had said that the reagents used in the laboratories were of the highest standards suggesting that no better reagents could have been used.
- 73. Another example was when a witness gave testimony to the Panel that "if an incorrect antibody concentration is used, it cannot give rise to two distinct peaks on the histogram (i.e. there is no risk of a false positive)". Subsequently an email dated 20 July 2004 was produced in which that same witness had said that the Lausanne Laboratory "have generated a false positive result by changing the titers" thereby acknowledging that high antibody concentrations could possibly affect the results produced by the test.
- 74. Again, the Panel has considered each of the particular statements referred to by the Appellant and in some respects they do cast some doubt on the credibility of the particular witness concerned. However, this oral testimony generally reflected a very positive view of a test which by the time of the hearing in September 2005 had then been used by the anti-doping scientific community in the three laboratories and elsewhere for a period of some 12 months. This oral testimony reflected the scientific endorsement and support for the tests in late 2005

described above. The earlier email interchange in mid-2004 was an exchange of contrary views which were reconciled by those involved at the time. This took place at a time when there was a rigorously independent examination of the HBT test which was then being implemented in laboratories other than the laboratory where it had been devised. As such it could naturally be expected that those involved in its creation would look critically at how the test was being implemented elsewhere.

- 75. Further criticism was directed at those witnesses called by the Respondents who in oral testimony generally asserted that the test used in Athens and Lausanne was exactly the same as the test used in the Sydney Laboratory. It is clear to the Panel that each laboratory implemented the HBT test substantially along the lines of the same operating procedure although there were minor differences in methodology. Such differences as have been established do not provide grounds for criticism. Having read the standard operating procedure used in the Lausanne Laboratory from mid-2004 up to late 2005, the Panel recognises that there have been some minor changes but essentially it remains the test as devised by Margaret Nelson, Michael Ashenden and others in the Sydney laboratory from 2002 to 2004.
- 76. One area of concern to the Panel was the assertion by the Respondent's witness, Dr Brown in his written and oral testimony, suggesting that any use of a 5% positivity criteria was nonsense. The email interchange in mid 2004 obtained during the adjournment of the hearing revealed that in the course of the implementation of the tests in Lausanne the use of these same positivity criteria was discussed and seriously considered by the same witness and others. Nevertheless, after due consideration, it was rejected before the Vuelta test. It is a concern to the Panel that the witness did not say that this had been considered as a legitimate criteria but ultimately had been abandoned. However, the Panel is satisfied that this apparent contradiction does not affect the overall validity of the test.
- C: The email to the IOC which the Appellant said "was never retracted, concerning a methodology that was never changed"
- 77. In view of the importance placed on this email by the Appellant it is reproduced in full below:

÷	"Sent:

tt: Friday, 13 August 2004 3:09 PM

To: Patrick Schamasch

Cc:

Olivier Rabin; Costas Georgakopoulos; Ross Brown; Ann-Muriel Steff; Martial Saugy

Subject: Flaws in Lausanne methodology

Importance: High

Dear Patrick,

I am writing to draw your attention to some anomalies in results emanating from the Lausanne lab, who are in the preliminary stages of implementing the blood test for homologous transfusion. I have sent you this email as a matter of urgency since I am aware that the IOC may begin using the homologous test at any moment, and you must therefore be aware of all pertinent information.

In particular, I wish to make you aware that recent results from Lausanne, including a false positive for one antigen in a recent blood sample, are unreliable and do NOT represent the methodology being considered for implementation by the IOC in Athens. Nor are any speculations or concerns raised by Lausanne as an outcome of their recent testing valid – since these conclusions are derived from an inappropriate application of methodology. The test used in Lausanne is NOT the same test used in Sydney and Athens.

As you are no doubt aware, the Royal Prince Alfred Hospital (RPA) in Sydney have been contracted to assist with the implementation of the test in Athens. Last week RPA sent some proficiency test samples to Athens, and Lausanne also requested that a duplication set be sent to their laboratory to enable them to self-assess their level of competency with the test.

Results from their analysis of the proficiency samples indicate that Lausanne are NOT yet capable of performing the test to an acceptable standard. As an outcome from repeated enquiries from RPA during the past 24-72 hours to ascertain the cause for Lausanne's difficulties, it became apparent that they have modified at least one, and probably multiple, critical aspect of the methodology published by Sydney (to the best of my understanding, the Sydney method is being used in Athens). Specifically, it appears that the variations in methodology used by Lausanne include some or all of the following:

1) Using CellStab in antibody incubations, which is known to promote agglutination of RBC (this is precisely the opposite goal we have when using flow cytometry, since cytometry is confounded by agglutinated RBCs).

2) Using a mix of two fluorescein-labelled secondary antibodies, which we think is unwise and certainly unnecessary, and could lead to false-positive results.

3) Failing to take account of the 'prozone' effect, caused by inappropriate concentration of antisera, which is also known to confound results.

Based on RPA's evaluation of the Lausanne proficiency results, and our current understanding of the modification Lausanne have chosen to experiment with, results emanating from Lausanne should be disregarded until such time as the flaws are eradicated and they have demonstrated a competency in the correct methodology. As we have published previously (Nelson et al. 2004 Aust J Med Sci 25(1)27-33), failure to comply with the correct methodology will lead to erroneous results.

It is unfortunate that Lausanne have failed to consult closely with Sydney when introducing variations to the method, and it is highly regrettable if the outcomes from their recent work have cast doubt upon the original method. As we highlighted in the 'Positivity criteria' document circulated on July 28<sup>th</sup> 2004 to Lausanne and Athens, it is imperative to use correct reagents, and to ensure correct titration. It seems this advice has not yet been heeded by Lausanne.

There is no chance of a false-positive when following the methodology implemented in Athens.

Should you desire further clarification or explanation, please do not hesitate to contact me.

Yours sincerely,

Michael Ashenden, PhD"

- 78. The Appellant's submission was that this was an email to the IOC "that was never retracted". The Panel has considered this submission and finds that there is no basis for it. The Lausanne Laboratory responded in detail to the criticism with a lengthy email sent on 15 August 2004. In this email the Lausanne Laboratory did not agree that "all results obtained with our method should be disregarded" and they referred to the fact that they had a new flow cytometer and the Lausanne Laboratory said "we will redo all that work next week". Further, they expressed the view that their work and their analysis of their work "demonstrated that the test is very robust as the results are not dependent on the reagents but only on the titration and gating process, leading to one of the more robust biochemical doping test accessible" (emphasis added). They did not agree that there had been any false positives and they said "we are ready to defend a positive result in front of a court".
- 79. Michael Ashenden from the Sydney Laboratory then responded to this detailed reply from the Lausanne Laboratory by email dated 16 August 2004. Significantly this email from the Sydney Laboratory was sent not only to the Lausanne Laboratory but also to the IOC and all other recipients of the original 13 August 2004 email. It began by an apology from the Sydney Laboratory by stating that "the sample that you found to have two peaks WAS in fact a mixed cell population, and was NOT a false positive as we originally stated". The email went on to state that Dr Ashenden was very sorry for the confusion that this had caused and he commended the Lausanne Laboratory on the steadfast faith that they showed and their willingness to objectively address the concerns relating to uncertain results obtained were due to the fact that the Lausanne Laboratory was still finalising software adjustments and establishing optimal titers for their new flow cytometer and that when this is completed they will rerun the proficiency samples.
- 80. The Lausanne Laboratory received a further apology from the Sydney Laboratory by email dated 17 August 2004 confirming a telephone conversation in which it was explained that the Sydney Laboratory had made a "human error" in relation to one of the proficiency tests. Finally, as Dr Brown acknowledged in his witness statement and oral testimony, the Sydney Laboratory concluded that the concerns they had about potential flaws in the Lausanne

Laboratory's methodology were unfounded. This was also corroborated by an email which he sent on 25 August 2004 to the Lausanne Laboratory in which he congratulated the Lausanne Laboratory on their proficiency with the HBT test.

81. The Panel finds that the 13 August 2004 email does not cast doubt on the validity of the methodology then or later. The email mistakenly sought to cast doubt on the competence of the Lausanne Laboratory at the time to correctly implement the test. The email does in fact recognise the work done by the Lausanne Laboratory in June to ensure that the correct concentration was being used when the test was being applied. There was a subsequent acknowledgment by the Sydney Laboratory to the IOC in which it apologised for the error in its complaints. The evidence reveals that the results obtained both on the old machine and the new machine when the tests were subsequently redone, were consistent. The complete chain of the email correspondence makes it apparent that each of the concerns raised in the email of 13 August 2004 was either unfounded for which there was an apology or resolved at least by 25 August 2004. It also confirms that the test was "very robust" and one which those involved in its use believed in at the time. Accordingly, for these reasons, the Panel does not find that the email referred to creates the doubt as alleged by the Appellant.

### D: Problems with controls

- 82. The Appellant argues that control test results on particular markers from the UCI health samples showed apparent mixed populations. Since each control consisted of a known single population, the Appellant urged that the testing must not be reliable if the tests on these controls had secondary peaks or at least tails on shoulders that generally indicate mixed populations. Indeed, at least a half dozen control histograms from the UCI health tests on five different markers showed such results, although none of them had the two distinct peaks required to find a marker positive under the WADA positivity criteria.
- 83. Nevertheless, the Panel does not find that these histograms undermine the validity and reliability of the HBT test in this case. First, the Appellant's own expert witness, Dr Carlo Brugnara, testified that problems with controls concerning one marker did not indicate that the controls did not work on other markers or that the test was unreliable with respect to other markers.
- 84. Second and more importantly, the possibly inaccurate control samples at the Lausanne Laboratory all occurred several months before the Vuelta test, while the laboratory was

validating the test and equipment. It is undisputed that following these tests, the laboratory bought new equipment, and there is no evidence that control samples showed similar results after the new equipment was installed. In particular, the controls for the testing on the Vuelta samples all performed correctly.

#### E & F: Problems with false positives and documented concern concerning false positives

- 85. The problem of false positives was highlighted by the email of 13 August 2004 where the Lausanne Laboratory was accused by the Sydney Laboratory of producing a false positive on a sample which had been previously tested by the Sydney Laboratory as negative. As mentioned above, the Lausanne Laboratory redid the test both on the machine that it was using then and on the replacement flow cytometer and maintained that the sample was positive. The Sydney Laboratory rechecked its test and acknowledged that the Sydney Laboratory had falsely reported it as negative when in fact on rechecking it was found that it should have been declared positive. This was one of a number of false positives which were said by the Appellant to cast doubt on the HBT test to reliably make a positive result.
- In the Appellant's closing submissions, more than twenty samples were said to be falsely 86. reported as positive for a mixed blood cell population. The Panel directed the Appellant to identify each and every sample said to be a false positive and the evidence relating to each such sample. These particulars were provided and USADA was then given the opportunity to specify the evidence it relied upon in relation to each such sample. The members of the Panel spent a considerable period of time examining and considering all of the particulars and evidence referred to by both Parties relating to each of these alleged false positives and are satisfied that each of the particular results referred to do not cast doubt on the validity of the Vuelta test. In each case there was a satisfactory answer for the apparently or alleged abnormal result. For example, in one case an abnormal histogram was intentionally created by the Lausanne Laboratory using the wrong antibody dilution as a demonstration. This does not cast any doubt on the reliability of the test. In another case referred to by the Appellant the antigen problem identified in the email correspondence caused agglutination which affected the results but the Panel notes that the particular problems were identified at the time of the histogram and then resolved by gating. In another case the mixed results of the histograms had been caused by a malfunction resulting from a "system pressure error" identified at the time by the flow cytometer machine itself. In other cases when the records were examined they were in fact not reported by the laboratory as positive and so could not be regarded as an example of a false positive.

#### G: Disagreement over the meaning of basic terms of the WADA positivity criteria

- 87. The positivity criteria adopted by WADA which are reproduced above, specify that "a mixed antigen population will be concluded to exist if there is a clearly definable right-sided peaked minor population or a clearly definable left-sided peaked minor population in the histogram for any antigen". Further it is specified that histograms "with suspected but not discrete minor peaked population (right or left-sided) the test should be repeated".
- 88. The Appellant sought to rely on some different language used by Dr Saugy from the Lausanne Laboratory when contrasted with the language used by Dr Paterakis from the Athens Laboratory when each gave evidence concerning their understanding as to how the WADA positivity criteria were to be applied. Dr Saugy stated that there could be a discrete minor peak even though it was "not separate" from the major peak. On the other hand, Dr Paterakis said that he needed "a separation" between the two peaks which could be recognised by independent observers very clearly. The difference in language used by these witnesses is consistent with the fact that some operators of a flow cytometer may read the results differently. However, in the present case, the point is irrelevant since by agreement of all the experts of the Parties there was a "clearly definable peak evidencing the presence of a mixed blood cell population" in the results of the Vuelta sample. It was not necessary to go to the areas of "suspected but not discrete minor peak". The peak in each case was clearly defined and this concern does not arise in relation to the Vuelta sample.
- H: During the course of the email exchange referred to above consideration was given to the use of a 5% objectivity criteria before there could be declared a positive result
- 89. As mentioned above this threshold was not adopted and the Panel does not find that there is any basis for doubting the validity of the test because no such threshold had been adopted.

### **General Submission**

90. More general criticisms were made by the Appellant along the lines that there had been an inadequate time to validate the test and that there had been valid scientific concerns raised by eminent scientists such as Dr Carlo Brugnara. Dr Brugnara referred to the extensive world wide testing in a wide range of conditions and in a wide range of subjects before the EPO test was introduced. That was a quite different circumstance to that which the scientific world was faced with in August 2004. In August 2004, a long-standing, well-recognised test which had been used in clinical situations for decades to detect the major antigens had been reformulated for use to detect minor antigens and as a result the presence of mixed blood cell populations.

This general criticism was not backed up by any facts, nor is Dr Brugnara a flow cytometrist. The circumstances under which the HBT test was developed, as detailed above, cannot be compared to the development of a test not based on a longstanding methodology. Further, this generalised concern is adequately answered by all the matter set out above particularly the finding in October 2005 by the independent Swiss ISO accreditation team that the HBT detection method employed by the Lausanne Laboratory had been properly valuated and was fit for purpose.

#### PART VII: DISPOSITION OF THE APPEAL

- .91. For the reasons described above, the Panel finds that the presence of a mixed blood population in Appellant's Vuelta sample as detected by the HBT test proves that the Appellant engaged in blood doping, a Prohibited Method, that violated the UCI Anti-Doping Rules; Chapter II, article 15.2 and Chapter III, article 21.
- 92. The ADR, Chapter X, Article 256, provides that "a violation of these Anti-Doping Rules in connection with an *In-Competition* test automatically leads to *Disqualification* of the individual result obtained in that *Competition*." Thus, the Appellant's result at the Vuelta is disqualified.
- 93. The ADR, Chapter X, Article 261 provides that the period of ineligibility imposed for Use of a Prohibited Method shall be two years' ineligibility for a first violation.
- 94. The ADR, Chapter X, Article 275, which corresponds to Article 10.8 of the WADA Code, provides that the period of Ineligibility shall start on the date of the hearing decision providing for Ineligibility. Further it provides that:

"Any period during which provisional measures pursuant to articles 217 through 223 were imposed <u>or voluntarily accepted</u> and any period for which Competition results have been Disqualified under article 274 shall be credited against the total period of Ineligibility to be served. <u>Where required by fairness</u>, such as delays in the hearing process or other aspects of Doping Control not attributable to the License-Holder, the hearing body imposing the sanction may start the period of Ineligibility at an earlier date commencing as early as the date of the anti-doping violation." (emphasis added)

95. Since Articles 217 through 223 refer only to decisions of the Anti-Doping Commission or the official doctor at a particular competition, and make no reference to voluntary acceptance of any provisional measure including a suspension, this provision is read to allow for the

voluntary acceptance of a suspension outside of the context of decisions of the Anti-Doping Commission or the official doctor, i.e. by the UCI Rider himself.

- 96. The Appellant voluntarily withdrew from the Vuelta on 16 September 2004 and was suspended from his team as of 23 September 2004 and the Panel finds that he therefore "voluntarily accepted", without the intercession of the Anti-Doping Commission or the official doctor, his suspension.
- 97. Of further guidance in determining the ineligibility start date, the ADR, Chapter IX provides that the proceeding before the hearing body of the *License-Holder's* National Federation must be completed within 1 (one) month from the time limit set for the dispatch of the summons, which is according to Article 225 ADR within 2 (two) working days of the receipt of the Anti-Doping Commission's notice to the *License-Holder's* National Federation. The Panel was not provided with the date of the Anti-Doping Commission's notice to the documentation package on the A & B samples was 7 October 2004 so it can be assumed that this notice was dated shortly thereafter. The AAA Panel was the hearing body of the Appellant's National Federation. The Sanel was the hearing body of the Appellant's National Federation. The AAA panel made its decision on 18 April 2005. Regardless of any reason for the timing of the decision, this date is far in excess of the one month requirement for completion of the proceeding provided for in the UCI rules.
- 98. On the basis of fairness based on the above facts, the two years' ineligibility will run from 23 September 2004 and will expire on 22 September 2006.

#### PART VIII: COSTS

99. The Parties agreed that all questions of costs, including their legal costs and the costs of the arbitration, would be reserved for subsequent consideration by the Panel and would be dealt with on the papers in accordance with the CAS Code and any applicable rules. Accordingly, the Parties are directed to file any submissions including any information which is relied upon as to the consequent costs orders sought within 28 days of the award. Each Party is directed then to file any submissions in Reply to the other Parties' submissions within 14 days thereafter. This Panel shall then issue an award on costs accordingly.

# ON THESE GROUNDS:

The Court of Arbitration for Sport hereby rules:

- 1. The appeal filed by Mr Tyler Hamilton against the award dated 18 April 2005 rendered by the AAA Panel is dismissed.
- 2. Mr Tyler Hamilton is ineligible to compete in cycling races for two years from 23 September 2004 until 22 September 2006.
- 3. All questions of costs are reserved for consideration and will be the subject of a separate award.

Done in Lausanne, 10 February 2006

# THE COURT OF ARBITRATION FOR SPORT

President of the Panel colm Holmes