AMERICAN ARBITRATION ASSOCIATION
Arbitration Tribunal

In the Matter of the Arbitration between
United States Anti-Doping Agency,)
Claimant,)
)
v.)
)
Tyler Hamilton,)
Respondent.)
)

Case No: 30 190 00130 05

AWARD OF ARBITRATORS

WE, THE UNDERSIGNED ARBITRATORS, having been designated by the above named parties, and having been duly sworn, and having duly heard the proofs and allegations of the Parties, do hereby, FIND AND AWARD as follows:

INTRODUCTION

USADA seeks for the first time ever to sanction an athlete for the presence of transfused blood. This proposed sanction is based upon a laboratory analysis and its interpretation of a blood sample given by Tyler Hamilton on September 11, 2004, during the cycling race Vuelta d'Espana {Tour of Spain described hereafter as ("Vuelta")}. This is the first case brought to arbitration in which a new World Anti-Doping Agency ("WADA") approved homologous blood transfusion test has been used to analyze a blood sample.

USADA seeks the mandatory minimum suspension for a first offender, which is a two-year period of ineligibility from the date of this decision as provided for in Union Cycliste Internationale ("UCI") Anti-Doping Rules and the USADA Protocol. They also seek Tyler Hamilton's disqualification from the Vuelta and all subsequent competitions to the date of this award. Mr. Hamilton has not competed since September 23, 2004.

BACKGROUND AND FACTS

Tyler Hamilton is an elite level cyclist. In 2003 he finished fourth at the Tour de France, a three week road race, considered to be cycling's premier event. Although Mr. Hamilton was a serious contender for the 2004 Tour de France, he had to withdraw from the race after he sustained injury from a fall during the early stages of the race. He recovered sufficiently to compete in the cycling "time trial" event at the 2004 Olympic Games in Athens, Greece and won the gold medal for the United States.

On the day after his Olympic victory, Mr. Hamilton provided a blood sample for testing by the International Olympic Committee at the on site WADA approved laboratory in Athens, Greece. Subsequently, Mr. Hamilton's 'A' sample was eventually reported by the testing agency established within the Athens laboratory as being positive for the presence of transfused blood on the basis that it contained a mixed red blood cell population. The ' B' sample was inadvertently frozen by the Athens lab thereby destroying the red blood cells in that specimen. Therefore, the 'B' analysis of Mr. Hamilton's Olympic sample was not able to confirm the positive 'A' sample finding and no doping offense was found to have occurred. As a consequence, Mr. Hamilton was confirmed as the gold medal winner of the Olympic time trial cycling event.

Elite riders such as Mr. Hamilton are subject to the UCI program designed to ensure the health of riders and the overall safety of the sport. As part of this program the UCI implemented its Sporting and Safety Regulations which involves the collecting of blood samples from licensed riders on the morning of a race for analysis of certain parameters including hematocrit, hemoglobin 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. The results of these health tests are not considered positive for doping control purposes, although these results are considered by UCI in the administration of its anti-doping program.

In May 2004, Mr. Hamilton's health test results displayed certain abnormalities that prompted UCI to conduct several meetings with Mr. Hamilton and representatives from his cycling team, ARcycling. During these meetings, UCI officials voiced their concern over these abnormal test results. See *ARcycling AG v/UCI* CAS *2004/A/777* for a general description of the UCI meetings with the team.

UCI sent a warning letter to Mr. Hamilton, dated June 10, 2004. In this letter he was advised that "the blood checks that took place during the Tour de Romandie 2004 ...showed an abnormal profile" and that the blood values showed "strong signs of possible manipulation" *(as translated)*. The letter also goes on to state that Mr. Hamilton would be closely monitored in 2004 in terms of his doping tests.

On September 11, 2004, at the Vuelta cycling competition, Mr. Hamilton was targeted for testing at the request of UCI. Mr. Hamilton's blood samples were then sent to the WADA accredited laboratory in Lausanne, Switzerland for testing. The Lausanne laboratory reported Mr. Hamilton's sample as positive for the presence of transfused blood. The laboratory's conclusion that the September 11, 2004, sample was positive for homologous blood transfusion was based on the detection of mixed populations for three different red blood cell markers (F_y^a, J_k^a, and J_k^b) in Mr. Hamilton's blood. The criteria established by WADA to declare a sample positive for homologous transfusion requires the presence of two mixed populations of red blood cell markers. The test used to determine the presence of mixed populations involves the use of flow cytometry. The use of flow cytometry in sport to identify the presence of mixed blood population caused by a homologous blood transfusion, was introduced at the Athens Olympics.

Under UCI rules, a blood transfusion that is not required for valid medical reasons, constitutes doping. Mr. Hamilton has denied receiving any type of transfusion during the relevant period.

On September 23, 2004, Tyler Hamilton was suspended by his team ARcycling as a result of the doping charges. He was therefore no longer able to compete in professional road cycling. On November 30, 2004, Mr. Hamilton was dismissed from his team as a result of the doping charges.

On February 27, 2005, a hearing was commenced in Denver, Colorado. Testimony and closing arguments were concluded on March 2, 2005. The claimant was represented by Mr. Richard R. Young, and Mr. Travis T. Tygart, Attorneys at Law. The respondent was represented by Mr. Howard L. Jacobs and Ms. Jill A. Benjamin, Attorneys at Law. Additional information was supplied to the Panel at their request, and the hearing was subsequently declared closed on April 8, 2005.

APPLICABLE RULES

At its meeting held July 22-23, 2004, the UCI Management Committee implemented the World Anti-Doping Code ("Code") into the UCI Anti-Doping Rules effective for all licensed cyclists on August 13, 2004. Both the USADA Protocol for Olympic Movement Testing and the UCI Anti-Doping Rules have adopted the mandatory provisions from the Code that include the definitions of doping, burden of proofs, prohibited substance and methods, and sanctions.

The relevant UCI definition of doping, as set forth in the UCI Anti-Doping Rules, Chapter II Doping, Article 15.2, states 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.

The word "Use" is defined in Appendix 1 of the UCI Anti-Doping Rules as "the application, ingestion, injection or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method."

The UCI Anti-Doping Rules, 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 are prohibited:

- Blood doping including the use of autologous, homologous or heterologous blood or red blood cell products of any origin, other than for medical treatment.

THE PARTIES ARGUMENTS

The arguments raised by the Respondent, Tyler Hamilton can be summarized as follows:

- The test method is insufficiently validated for use in an anti-doping context;
- A quantitative as opposed to a visual standard should be used to determine a "positive" result.
- A "positive" result means the presence of a mixed red cell population only and does not prove homologous blood transfusion;
- There are other possible explanations for the presence of a mixed red cell population such as disease, bone marrow transplantation, intrauterine twin-twin transfusion, and chimerism.

USADA takes the position that there were two essential questions for the panel to consider. First, did Tyler Hamilton have mixed populations for two or more blood cell markers in his Vuelta blood sample? USADA submits that all expert witnesses have answered that question in the affirmative, and that there is no argument that the blood sample was not Mr. Hamilton's. USADA argues that the second issue for the Panel to decide is whether Tyler Hamilton advanced a reasonable explanation for the presence of the mixed red blood cell populations, other than that of transfusion. USADA submits that the only reasonable conclusion that can be drawn is that the presence of the mixed red blood cell population was due to a homologous blood transfusion.

ANALYSIS

This is the first case of its kind in the world. The result is that there have been a number of arguments raised by the Respondent in respect of the science involved in the case.

Human red blood cells {RBC} express many distinct proteins. Some of those proteins are called surface antigens, also referred to as surface markers. They are expressed, meaning located, on the surface of the RBC. The most widely known RBC surface markers are the common blood types O, A and B. Another common RBC marker is Rh(D). Other more minor surface markers include, but are not limited to, F_y^a, J_k^a, and J_k^b.

There are many different markers on the surface of each RBC. They are all determined by human genetics. Therefore, any individual human being will have an identical set of markers for all of their RBCs.

Using F_y^a as an example, if the F_y^a marker is present on the surface of the RBC, then the individual is described as being an expressor for the surface marker F_y^a. Another term to mean the same thing is to describe the presence of F_y^a as + (positive). By the same logic, if F_y^a is not present on the surface of the RBC, then the individual is described as being a non-expressor for F_y^a; the lack of the presence of F_y^a is described as – (negative).

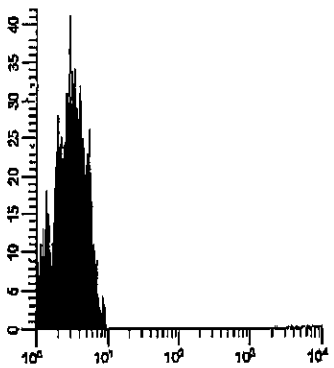
The Homologous Blood Transfusion Test

The Homologous Blood Transfusion Test[1] {HBTT} involves the use of the flow cytometer in identifying and counting all the RBCs present in a blood sample.

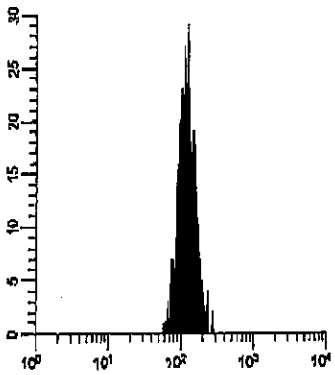
In order to use the flow cytometer the RBCs must first be isolated from the blood sample. After isolation, the RBCs are then exposed to a series of "primary" antibodies, each of which is engineered to bind to a single specific RBC surface marker. Next the RBCs are exposed to a "secondary" antibody that is marked with a fluorescent tag. The secondary antibody is engineered so as to bind only to the primary antibody.

It is the fluorescent tag that notionally lets the binding process be "seen" by the use of the flow cytometer. As the treated RBCs flow through the flow cytometer, each RBC is then identified and counted. The data generated from this process is presented in the form of a histogram.

It is the fluorescence treatment that enables the visualization of the flow cytometer data. The "seeing" agent enables the software of the flow cytometer to generate a histogram. The histogram depicts the data as a frequency plot of numbers of cells versus the amount of fluorescence. An illustration of the histograms for an expressor and non-expressor for F_y^a is set forth below.



Non-expressor for F_y^a

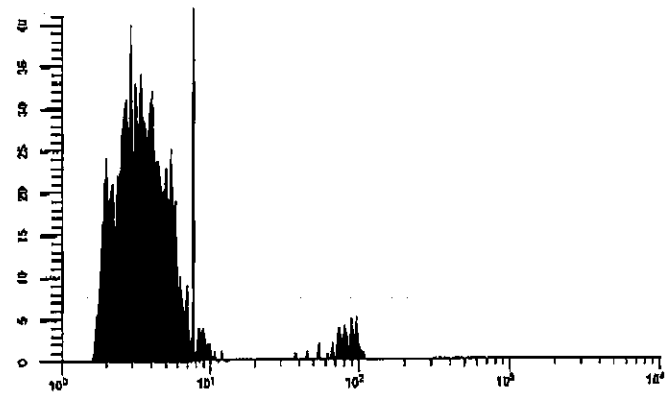


Expressor for F_y^a

If a histogram contains only one visibly identifiable peak then the indication is that all the RBCs in the blood sample have one identical set of surface markers i.e. the blood sample contains only one population of RBCs. However, if the histogram displays two visibly identifiable peaks, this is an indication of two different populations of RBCs being present in the blood sample. The flow cytometer has identified two non-identical sets of RBC surface markers. In this way, the

[1] The Nelson-Ashenden Group initially developed the use of the flow cytometer in the Homologous Blood Transfusion Test. For a thorough review of the test protocol and the use of the flow cytometer as part of the test protocol, see Nelson et al., *Proof of Homologous Blood Transfusion Through Quantification of Blood Group Antigens*, 88 Journal of Hematology 1284 (2003); Nelson et al., *Detection of Homologous Blood Transfusion by Flow Cytometry: A Deterrent Against Blood Doping*, 87 Haematologica 881 (2002); Nelson et al., *Validation of a Test Designed to Detect Blood-Doping of Elite Athletes by Homologous Transfusion*, 25 Australian Journal of Medical Science 27 (2004).

flow cytometer and the various primary and secondary antibodies[2] may be used to identify a blood sample with two different populations of RBCs. An illustration of a third party transfused blood histogram could look like the illustration below.



Patient's own blood F_y^{a-} Third-Party transfused blood F_y^{a+}

There is no division of opinion or conflicting scientific evidence that indicates any dispute between the various experts and the published scientific literature that the flow cytometry methodology can identify a mixed blood population. The reliability of the flow cytometer to identify two blood populations is not challenged in these proceedings.

The Blood Transfusion Identification Process

Before a blood transfusion is undertaken the medical practitioner exercises extreme caution to match blood for the major surface markers A, B, O and Rh(D).
Typically no effort is made to match the donor blood to be transfused for the many minor surface markers present on the recipient's RBCs. It is that fact that enables identification of the fact a transfusion of blood has occurred.

The recipient of a blood transfusion will most likely have received blood that is not identical with respect to one or more of the minor surface markers present on his own RBCs. An illustration would be that the recipient is a F_y^a expressor but the donor is a F_y^a non-expressor.

If after a transfusion the recipient's RBCs are passed through a flow cytometer for the purpose of analyzing the minor red cell surface markers there will appear to be two blood populations represented as two separate peaks on the histogram. These are described as mixed populations for that particular surface marker.

This process for identifying that a particular sample of RBC has a mixed blood population is not challenged in these proceedings. The challenge is whether that identification means the cause is homologous blood transfusion.

[2] Primary and Secondary antibodies are available from commercial sources.

Use of the Histogram in Sport

In medicine a single peak accompanied with a shoulder or tail on one side of the peak is all that may be required to indicate that there are mixed populations of RBCs in a blood sample. In sport the WADA protocol[3] has erred on the side of caution and required that there be a distinct peak for two different markers on the histograms before it is concluded that a blood sample contains a mixed population of RBCs. Therefore, the WADA criterion gives the benefit of the doubt to the athlete and is a conservative approach to the assessment of a doping infraction.

One of the issues raised by the Respondent is in relation to the percentage "threshold" down to which the histogram ought to be accepted as identifying a mixed blood population. The percentage represents the quantity of RBCs on whose surface a particular marker is found against the total quantity of RBCs found present in the analysis of the blood sample, which is then calculated as a percentage.

The test is one of **identification.** The results of an analysis of a blood sample will indicate there is a mixed RBC population; or, that the population is homogenous. The Respondent argues that the lower limit of detection for a positive analytical result ought to be 5%. It does so primarily by reliance on the comments made by a peer reviewer of a foundation article on the test.[4] Everyone agrees and the evidence establishes that the test performs the identification process in a valid and reliable manner. The argument of the Respondent focuses upon what percentage level ought to be applied.

The percentage quantifies the number of RBCs with a particular marker as a percentage of the total RBCs in the sample. The launching point for this analysis has to be that RBCs that are genetically not identical to other RBCs in the blood sample is what has been identified. The science literature indicates that the flow cytometer has such an identification effect right down to a value of 0.07%[5].

The Nelson-Ashenden group's work[6] unequivocally indicates that identification of a mixed population can occur below 5%. Depending on the specific surface marker being investigated, a mixed population of 1.5% - 2.9% is clearly distinguishable from a person's endogenous RBCs.[7] The issue is what is the lower limit of detection that is above what is called "noise" by scientists. As stated earlier, the HBTT is a test of identification. There is either a mixed blood population or a single one. In this context, quantification of the RBCs is completely unrelated to that yes or no outcome. Therefore, it can be asserted that at any percentage level above "*noise*" the test is identifying two populations or a homogenous population. Apart from that logical deduction there is scientific support for a lower limit.

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[3] "Positivity Criteria July 28" a document prepared by Ross Brown, an expert witness in these proceedings and his colleagues Ashenden and Nelson. It was approved by WADA for implementation at the 2004 Athens Olympic Games. USADA Exhibit #8.

[4] Nelson et al., *Proof of Homologous Blood Transfusion Through Quantification of Blood Group Antigens*, 88 Journal of Hematology 1284 (2003) at p. 1295.

[5] Nelson et al., *Proof of Homologous Blood Transfusion Through Quantification of Blood Group Antigens*, 88 Journal of Hematology 1284 (2003) at p. 1284.

[6] *Supra*, note 1.

[7] Nelson et al., *Fact Sheet on the Blood Test for Homologous Transfusion*, (2003) at p. 1.

Using the HBTT, the Nelson-Ashenden group has observed a blood sample with a mixed population of 0.4%.[8] This observation was made 111 days after the blood sample was initially taken from the individual.[9] Additionally, the *noise* level of the flow cytometer used in conducting the HBTT has been calculated at 0.1%, a value that is well below the 5% threshold argued by the Respondent.[10] These results, in combination with the conservative approach taken by WADA in visually identifying two distinct peaks on the histograms, justifies the WADA protocol as a reliable and specific method by which to test for mixed RBCs in a blood sample to a threshold percentage of at least 1.3% the lowest limit in Mr. Hamilton's histogram. Therefore, the Panel is comfortably satisfied that the WADA protocol criterion for positivity is acceptable for use in this proceeding.

In addition to being satisfied with the WADA protocol, the Panel must also be comfortable that a false positive result is unlikely. It is a fact that there are no scientific studies that detect false positives in the use of the HBTT. However, there is no need to do so because there is no suggestion in the use of the HBTT that it produces false positives. The HBTT is a yes/no identification process. The vast number of tests are going to have a single blood population. Within that apparent homogenous blood group there may be a risk of a false negative. However, that concern merely raises the possibility of the guilty going free and is not a reason to reject the WADA protocol. The grave concern is the false positive in a mixed blood population analysis. Could it occur?

The markers on the RBCs of a person are the result of predetermined human genetics. The test identifies two different human blood populations based on this genetic certainty. Nothing more than that occurs from the test. Therefore, if the HBTT identifies two different RBC populations in a blood sample, it stands to reason that one of the RBC populations must have come from another person who has his or her own unique, genetically pre-determined set of RBC surface markers. There can be no risk of a false positive. In fact in the 48 subjects reported in the literature there was 100% accuracy.[11] There is no risk of a false positive and no need to do so called validation studies. The test is reliable in doing what it does without risk of a false positive for a mixed blood population. The Panel is comfortably satisfied that there is an extremely low probability of a false positive result in a histogram revealing a mixed blood population.

Does a mixed blood population result mean homologous blood transfusion has occurred?

The HBTT identifies mixed RBC populations in a blood sample. The question that arises for sport is one of determining the cause of what the histogram shows.

The presence of mixed RBCs in a blood sample has four possible causes other than homologous blood transfusion. It could be the result of: (i) disease, (ii) bone marrow transplant, (iii) intrauterine twin-twin transfusion; or, (iv) chimerism.

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[8] Nelson et al., *Proof of Homologous Blood Transfusion Through Quantification of Blood Group Antigens*, 88 Journal of Hematology 1284 (2003) at p. 1288.
[9] *Ibid.*
[10] *Ibid.*
[11] *Supra*, note 1.

In a sporting context the first two possible causes are unlikely in a healthy elite performance athlete. If they were the cause then the evidence would be brought forward to indicate such a cause. In this case the medical history of the athlete was provided and the first two causes can be ruled out as having a zero probability.

If there is to be a conclusion that a homologous blood transfusion has taken place then the probability of the causes being either intrauterine twin-twin transfusion or chimerism must be ruled out or the probability of those being the causes is so small that the panel is comfortably satisfied the histogram result is caused by a homologous blood transfusion.

It is admitted by Mr. Hamilton that he is not a twin. However, that does not rule out the possibility of the "vanishing twin phenomena" in conception and the first trimester of gestation there could have been a twin whose existence disappeared. The frequency of this phenomenon in natural pregnancy rather than through *in vitro* fertilization is obscure.[12] The testimony of Dr. Brown is that it is highly unlikely that 34 years later Tyler Hamilton would have mixed RBC populations indicated on some histograms including the one in question and have other histograms with no mixed population indicated. Therefore, the vanishing twin phenomena can be ruled out as being extremely remote and not to have been the likely cause of the mixed RBC population[13].

The foregoing conclusion leaves the fourth cause chimerism as the only alternate cause to blood transfusion as an explanation for the histogram. Does this possible cause mean that there is sufficient doubt to find blood transfusion as the cause not proven? This is the thrust of the Respondent's arguments before the Panel.

The submissions of the parties on chimerism are at opposite extremes. USADA and its experts suggest that the likelihood of such an occurrence is too remote to be taken account of as the cause. The Respondent and its experts suggest that chimerism can occur in up to 30% of the population. The Panel must evaluate the differing perspectives and come to its own conclusion.

Chimerism occurs where a human or other animal has two different, genetically distinct, populations of cells. In the context of this case, the Respondent would be a human chimera if he was genetically predetermined to have two different populations of RBCs. The Respondent offers human chimerism as an alternate cause of the mixed RBC populations found in his blood sample. In relying on this cause the Respondent is relying on the van Dijk paper to assert that human chimerism is not as rare as scientifically thought.[14]

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[12] Landy et al., *The Vanishing Twin: A Review*, 4 Human Reproduction Update177 (1998), at p. 178 ["Caution should be used in interpretation, given that (i) there are relatively low numbers of spontaneous conceptions from which these data derived compared to study patients with pregnancies achieved after assisted reproductive development"]

[13] In doing so, the Panel remains cognizant of Dr. Housman's testimony, in which he refers to a study conducted by Maloney, et. al. *Microchimerism of maternal origin persists into adult life* J. Clin. Invest. 41-47 (1999). This study demonstrates evidence of maternal cells in males in their 20s in 8 out of 15 control subjects. Dr. Housman relies on this study in his testimony to assert that Tyler Hamilton may be chimeric as a result of maternal transfer of cells to his body during pregnancy. However, the Panel is satisfied that the micro-chimerism referred to by Dr. Housman can only be detected genetically and occurs at too low a level to be responsible for the Vuelta results.

[14] van Dijk et al., *Blood Group Chimerism in Human Multiple Births*, 61 American Journal of Medical Genetics 264 (1996).

The van Dijk paper seems to be an isolated paper in the medical literature[15]. A review article on the subject of blood group chimeras has stated that slightly more than 70 cases of human chimera are known.[16] A more recent survey of the medical literature of the world undertaken by the Nelson-Ashenden group as testified to by Dr. Brown reveals only up to 100 known cases of human chimerism. Dr. Brown has also testified that he has never observed a chimera in testing over 20,000 human blood samples. As further evidence of the rarity of human chimeras, Dr. Brown testified that only one case of chimerism has been observed by the American Red Cross in testing millions of blood samples over a 20-year period. In light of this evidence is Tyler Hamilton the one hundred and first known case a reasonably probable explanation of his histogram?

The question posed cannot be answered in the absolute simple terms of yes or no. However, an assessment of all the evidence that is provided in this case can lead the Panel to an estimate of probability or degree of likelihood as to the explanation of the cause. In that event, the Panel can and should come to an assessment of whether it is comfortably satisfied that blood transfusion was the cause of the Vuelta histogram.

It is known that RBCs have a life of approximately 90 days[17]. The experts' testimony before the Panel indicated that the life of RBCs could be as long as 120 days. For two populations to exist in a blood sample, there has to be a method of generating two genetically different sets of markers that are reflected on the histogram. Transfusion of course will result in two such peaks. This will occur as long as the transfused RBCs are still present in the recipient's blood sample.

In Tyler Hamilton's case we have two occasions where the histogram reveals only one peak. The first is in February 5, 2005. The second histogram was revealed by the Respondent's own expert Dr. Housman in his testimony (although the histogram was not produced in evidence). Dr. Housman indicated he did a flow cytometry test on a blood sample from Tyler Hamilton and the histogram had only one peak.

This raises the question of whether a human chimera can express a mixed population of RBCs on one day and a single population of RBCs on another day. Once again, the Respondent relies on scientific research conducted by van Dijk[18] to suggest that such fluctuations are probable. However, the van Dijk study remains an isolated paper in the medical literature. While other scientific studies have shown such fluctuations in other animal chimeras, the van Dijk research is the only scientific study of its kind relied on by the Respondent to suggest that such fluctuations are possible in human chimeras.[19] This assertion loses considerable strength when it is accepted that human chimerism is an extremely rare occurrence.

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[15] Dr. Brown in his cross-examination indicates the figures in the study are "just basically all so wrong, and there 's so many mistakes in the paper that we basically discounted it". Dr. Brown also testifies that his colleague Nelson at a recent meeting of 5,000 hematology professionals asked for information or samples from chimeras and no one responded. They would like to study such a case or sample but have never found one to be studied.

[16] Tippet, P. *Blood Group Chimeras* Vox Sang. 44: 333-359 (1983).

[17] Nelson et al., *Fact Sheet on the Blood Test for Homologous Transfusion*, (2003) at p. 1.

[18] *Supra*, note 13.

[19] The Panel remains cognizant of Dr. Housman's testimony, in which he refers to a study conducted by Maloney, et. al. *Microchimerism of maternal origin persists into adult life* J. Clin. Invest. 41-47 (1999). This study demonstrates evidence of maternal cells persisting in males into their 20s. Dr. Housman relies on this study in his testimony to assert that Tyler Hamilton may be chimeric as a result of maternal transfer of cells to his body during pregnancy. However, the Panel is satisfied that the micro-chimerism referred to by Dr. Housman can only be

Based upon all of the foregoing the Panel comes to the conclusion that it is comfortably satisfied that the mixed RBC population arising from the Vuelta sample analysis has a very high probability of having caused by a blood transfusion, and an extremely low to the point of negligible probability of having been caused by Tyler Hamilton being a human chimera.

The finding of a mixed RBC population in Mr. Hamilton's blood sample is based upon the state of the science known and brought to the attention of the Panel as of the date of this decision. The conclusion is also based upon the evidence and state of the record of these proceedings before the Panel at the time of this decision.

DECISION AND AWARD

The finding that the presence of the mixed blood population in Tyler Hamilton's Vuelta sample was due to a homologous blood transfusion, brings the UCI Anti-Doping Rules into application. Rule 15.2 states that an anti-doping rule violation occurs when there is use or attempted use of a Prohibited Method such as blood transfusion UCI Anti-Doping Rule 261 provides for a suspension of two years upon the finding of a doping offense.

UCI Anti-Doping Rule 275 provides for the commencement of any suspension period to be the date of the hearing decision, except "where required by fairness, such as delays in the hearing process or other aspects of Doping Control not attributable to the [athlete], 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." The facts and chronology of this case do not justify the application of the exception provided for in Rule 275.

UCI Anti-Doping Rule 256 provides that a violation of the rules in connection with an in-competition test automatically lead to disqualification of the individual results obtained in the competition. The application of Rule 274 disqualifies any results in competitions subsequent to the anti-doping violation. However, the Panel understands that Mr. Hamilton has not competed since his suspension by his team on September 23, 2004.

The Panel therefore finds that a doping violation has been committed by Tyler Hamilton. The minimum suspension for a first offender in accordance with UCI Anti-Doping Rule 261 is two years. Tyler Hamilton is therefore suspended from competition for a period of two years commencing, April 18, 2005. All of his competitive results from September 11, 2004, including the Vuelta competition are cancelled.

The administrative fees and expenses of the American Arbitration Association ("the Association") and the compensation and expenses of the arbitrators shall be borne by the United States Anti-Doping Agency.

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detected genetically and occurs at too low a level to be responsible for the Vuelta results. A histrogram could not reveal this level of micro-chimerism which can only be tested genetically.

This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. All claims not expressly granted herein are hereby, denied.

This Award may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute together one and the same instrument.

Date	Prof. Richard H. McLaren, Arbitrator
4-18-05 Date	Hugh L. Fraser Hon. Hugh L. Fraser, Chairman
Date	Christopher L. Campbell, Arbitrator

This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. All claims not expressly granted herein are hereby, denied.

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4-18-05
Date

Prof. Richard H. McLaren, Arbitrator

Date

Hon. Hugh L. Fraser, Chairman

Date

Christopher L. Campbell, Arbitrator

UNITED STATES ANTI-DOPING AGENCY v. TYLER HAMILTON
American Arbitration Association No. 30 190 00713 03
North American Court of Arbitration for Sport Panel

Christopher L. Campbell, dissenting.

I. THE LAUSANNE LABORATORY'S FAILURE TO PROVIDE THE MEASURE OF UNCERTAINTY MEANS ITS TESTING METHOD FAILED TO MEET THE PREVAILING STANDARDS OF THE SCIENTIFIC COMMUNITY.

The World Anti-Doping Agency ("WADA") has the right to establish methods for the testing of a prohibited substance. Yet, that right is not without limits. The testing methods established by WADA must be reliable, established upon sound scientific practice and procedure, and meet the prevailing standards of the scientific community. *UCI v. Hamburger*, CAS 2001/A/343, 15; *Muehlegg v. IOC*, CAS 2002/A/374, ¶7.1.7.

The WADA's Addendum to the International Standard for Laboratories, ¶5.4.4.3 requires that laboratories provide an estimation of the measurement of uncertainty (i.e., rate of false positives) for testing methods involving blood.[1] This policy, as a matter of law, establishes the prevailing standards of the scientific community regarding the need to identify the rate of false positives when adopting new testing methods. The UCLA laboratory, under the direction of Dr. Catlin, provides an example of how to properly meet this standard in the validation of its EPO testing. *See USADA v. Hellebuyck*, AAA 30 19000 686 04, p. 9 (validation studies established that the likelihood of false positive for EPO at 80% basic area percentage is 1 and 30 billion). The UCLA laboratory used 704 volunteers in its study and identified them by age, sex and race.

USADA presented a peer-reviewed study conducted by Margaret Nelson and associates ("Nelson Study") as the validation for the new WADA Transfusion Positivity Criteria in question in these proceedings ("WADA Criteria"). The WADA Criteria implemented the testing method ("Testing Method") in dispute in this case. [2] The Testing Method is not a direct test for homologous blood transfusion. It merely detects the presence of a second red blood cell ("RBC") population in an individual's blood. As a consequence, the Testing Method should have accurately calculated the rate of false positives when the presence of a second RBC population was not caused by a homologous blood transfusion.[3]

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[1] World Anti-Doping Agency, *Addendum To The International Standard For Laboratories, Requirement For Anti-Doping Analysis Of Whole Blood, Plasma, Serum Or Other Blood Fractions*, July 1, 2004 ("WADA Addendum").

[2] Nelson et al., *Proof of Homologous Blood Transfusion through Quantification of Blood Group Antigens*, 88 Journal of Hematology 1284 (2003) ("Nelson Study").

[3] USADA vs. Tyler Hamilton, Transcript of Proceedings, AAA No. 30 190 00130 05, February 28 through March 2, 2005, pp. 388-390 ("Hearing Transcript")(Dr. Housman, professor at MIT, stated, "Nowhere in the paper is a discussion of the true occurrence of false positives or any way to even address the problem.")

For the purposes of these proceedings, the fatal flaw of the Nelson Study is that it failed to calculate the rate of false positives. The Lausanne laboratory implementing the Testing Method also failed to estimate the rate of false positives.

The Nelson Study failed to provide the rate of false positives because it assumed that, "false positive results do not appear to be a problem."[4] It comes as no surprise that Dr. David E. Housman, M.D., a professor at MIT who teaches validation of testing methods and proper analysis of scientific data, opined that this assumption without any quantitative analysis fails to meet the prevailing standards of the scientific community.[5]

Moreover, on its face, the Nelson Study demonstrated its assumption regarding the rate of false positives was incorrect. The Nelson Study admitted that a second RBC population could be present in an individual who has not had a homologous blood transfusion in the case of disease, "instance of hemorrhage between mother and fetus, intrauterine twin-twin transfusion, or in the rare tetragametic chimeras." [6] It failed to mention chimerism of the hematopoietic system. An individual with a naturally occurring second RBC population is a chimera.

The Nelson Study left out the possibility of false positives as a result of faulty laboratory practices. This omission is odd because it was a Nelson validation study that demonstrated that in its quantitative testing method, laboratories falsely identified second RBC populations where none were present up to a level of 1.1%. The Nelson Study called these false positives background events and stated they were caused by incorrect gating and other problems. [7] Mr. Hamilton's sample in this case was within the range of a background event.[8] Concerning background events, it is significant that the WADA Criteria and the Testing Methods fail to require a consistent method of gating. [9]

In addition, with respect to improper gating, there was testimony that in the case of a subjective, visual identification of a second peak (used in this case), if a test was gated in the wrong region it would also impact a peak. [10] This also refutes any argument that if a second peak is visible the only explanation is a second RBC population.

An even greater concern is that the Testing Method will be used with women. Women who have had children may have fetal cells circulating in their blood system for

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[4] Nelson Study, p. 1292.

[5] Hearing Transcript, pp. 376 and 408 (Dr. Housman stated, "hearsay criteria, nobody told me they saw it, is not scientifically acceptable. You need to find a more objective way to measure those numbers, the frequency.")

[6] Nelson Study, p. 1293.

[7] Nelson et al., *Validation of a Test Designed to Detect Blood-Doping of Elite Athl*etes by Homologous Transfusion, 25 Australian Journal of Medical Science 27, p. 32 (2004)

[8] Hearing Transcript, p. 316 (Dr. Saugy testified that the Vuelta sample did not accurately calculate the percentage volume of the very low level of the second population of RBCs in Mr. Hamilton's sample)

[9] *Id.* at 311 (Dr. Saugy, of the Lausanne Laboratory stated, "It's not right to gate in the same way.")

[10] Hearing Transcript, p.102 (Dr. Davis, USADA's expert witness, stated, "so if you select the relatively smaller cells versus the relatively larger cells, just because there's more surface area on that – based on that distinction, you could induce small shifts in where those peaks are.")

decades after giving birth.[11] Pregnancy in and of itself may establish a long-term, low-grade chimeric state in the human female. [12]

Evidence was introduced that 1 in 3 of human conceptions fail.[13] A woman could not be aware she was pregnant, test positive under the WADA Criteria, spontaneously abort the child thereafter and be unable to prove that the false positive was due to a pregnancy. It is outrageous, reckless and unacceptable that the individuals involved with the Nelson Study were aware of the potential problems associated with woman yet failed to investigate or accurately calculate the rate of false positives in these situations.[14]

WADA had a scientific and legal duty to accurately account for all of the problems identified above.[15] *B. v. ITU*, 1999/98/222, ¶56. A test with a high rate of false positives would falsely accuse a number of athletes of doping, a clearly unacceptable outcome. If the rate of false positives is not accurately calculated, whether an individual such as Mr. Hamilton is likely to have a false positive is mere speculation, a lot of which has taken place in this case.

The requirement that the laboratories accurately calculate the rate of false positives is mandatory and a critically important policy aimed at avoiding tragic errors. [16] Failure to adhere to this policy cannot be overlooked as inadvertent error or an error that does not affect the test result. The failure to accurately calculate the rate of false positives goes to the very heart of the validity of the testing method. Its proper calculation is vital for the protection of all athletes.

Because the WADA Transfusion Positivity Criteria and the Testing Methods fail to provide an accurately calculated rate of false positives, it fails to satisfy the prevailing standards of the scientific community. In this situation, USADA should not be able to sustain its initial burden of proof and the case against Mr. Hamilton should be dismissed. *See N., J., Y., W. v. FINA*, CAS 98/208, p. 247, ¶13.

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[11] Bianchi et al., *Male fetal progenitor cells persist in maternal blood for as long as 27 years postpartum*, Prac. Natl. Acad. Sci. USA, Vol. 93, pp. 705-708, January 1996 (In the 32 pregnancies, male DNA was detected in 13 of 19 women carrying a male fetus. In 6 of the 8 nonpregnant women, male DNA was detected. Male DNA was detected even in women who had her last son 27 years prior to blood sampling).

[12] *Id.*

[13] Hearing Transcript, p. 369 (Dr. Housman stated, "Human conceptions actually don't do well. That 1 in 3 conceptions fails.")

[14] *Id.* at 186 (USADA's witness, Dr. Brown stated, "That's what we were talking about before, where a baby's cells might be in a mother. It's probably the most common in the community, common thing - - if you find them, a mixed population, it could be a mother's fetus thing, yes.")

[15] Hearing Transcript, p. 382, 390 (Summarizing Dr. Housman' testimony in this regard, to comply with the prevailing standards in the scientific community you have to consider the peer-reviewed studies that show these potentials for false positive and state why they are not relevant to your testing method and you would have to go out and test the specific groups who may be false positives to calculate your estimate of false positives.)

[16] WADA Addendum, ¶1.0.

II. THE TESTING METHOD APPLIED SUBJECTIVE EVALUATION AND THIS METHOD HAS NOT BEEN PROPERLY VALIDATED

Testing methods used in the Olympic movement should be objective, quantitative and verifiable. *See UCI v. Hamburger*, CAS 2001/A/343, 18-19 (it is imperative that the laboratory applies reliable and verifiable criteria, making it possible for third parties to objectively understand the conclusions reached). The Nelson Study used an objective and quantitative approach to identify second RBC populations in individuals. The Testing Method implemented by the WADA Criteria does not use objective criteria. It is a subjective, qualitative approach relying on the laboratory technician to identify two separate peaks in a histogram, i.e., "I know it when I see it."

A. The Testing Method Should Be Objective And Quantitative.

USADA's expert witness, Dr. Bruce H. Davis, M.D., testified that the WADA Criteria and testing method could be very quantitative. [17] Dr. Davis stated:

> if you have a rule-based approach such that everybody would set the same region, positions, and gate, the red cell cluster the same, you would get exactly the same result no matter who did it or where you were. . . it could [be spelled out in an SOP]. . .[So it wouldn't be difficult to have consistency in protocol so that every lab would have similar data that would be objective, verifiable, and not just visually interpreted] . . . and that was the point of the . . .Nelson articles that . . . when laboratories are set up with rules, they get exactly the same result and interpretation with this test. . . . [That's just not done here] . . . it would seem [that the Lausanne and Athens labs are gating differently].[18]

Dr. Davis' testimony makes it clear that an objective and quantitative approach can be used in this case. Given this admission, such an objective approach should be required. *UCI v. Hamburger*, CAS 2001/A/343, 18-19.

An objective and quantitative approach is also consistent with the very foundation of sound scientific practice – objective, reproducible results. This is not obtainable with the WADA Criteria's subjective approach. Nothing demonstrates the problem with the subjective Testing Method like what happened with Mr. Hamilton's Athens Olympic Games blood test.

The truth is Mr. Hamilton did not test positive at the Athens Olympic Games. The laboratory analysis report dated August 22, 2004 and signed by the Laboratory

[17] Hearing Transcript, p. 24.

[18] *Id.* at 60-62.

Director ruled Mr. Hamilton's sample to be negative.[19] The Athens laboratory was not incompetent. It passed all proficiency testing before the Athens Olympic Games.[20]

Nevertheless, on September 16, 2004, almost a month later, the IOC formed an external expert group that ruled Mr. Hamilton's Athens sample was positive.[21] This group of experts apparently consisted of individuals paid for developing the Testing Method and individuals who knew the sample belonged to Mr. Hamilton. Two of the cardinal rules of drug testing are that the individual doing the analysis (1) should not have a vested interest in the outcome, and (2) should not know the identity of the individual providing the sample. So, if this subjective Testing Method is so reliable and is an "I know it when I see it" type of test, why did it take an expert committee to rule that Hamilton's sample was positive one month after the Athens Olympics? There have been a number of bizarre and inappropriate occurrences related to this Testing Method in Mr. Hamilton's case. This is an example of just one of them.

It should also be noted that Mr. Hamilton's Vuelta sample, the sample in question in this case, had a significantly lower reading of second RBC populations then the Athens' sample. Therefore, it could logically be concluded that the Athens Laboratory would also have ruled the Vuelta sample negative. If an IOC accredited laboratory trained in the Testing Method could rule Mr. Hamilton's sample negative, how can this panel be comfortably satisfied that Mr. Hamilton tested positive? These inconsistencies and problems illustrate the need for objective criteria.

B. The WADA Criteria Uses A Subjective, Visual Identification Method That Has Not Been Peer Reviewed Or Properly Validated.

Dr. Davis' testimony also highlights another very troubling issue concerning the WADA Criteria. The WADA Criteria rejected the very foundation of the Nelson Study.[22] It was fascinating listening to the testimony of USADA's witnesses alternately praising the Nelson Study as the basis for the panel's acceptance of Lausanne Laboratory's testing method and then refuting the very foundation (objective, quantitative approach) of the Nelson Study to support the subjective, qualitative testing method used by the Lausanne Laboratory.[23] This looks like a classic case of bait and switch.

Because the WADA Criteria rejected the peer-reviewed, objective, quantitative Nelson Study, it was incumbent upon USADA to present evidence that the WADA Criteria's subjective, qualitative approach has been peer-reviewed, validated, and provided an accurate calculation of the rate of false positives. The evidence demonstrated that the WADA Criteria's subjective, quantitative approach has not been peer reviewed.

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[19] World Anti-Doping Agency, Independent Observers Report, Olympic Summer Games 2004, Athens ("Independent Report"), ¶3.1.
[20] Hearing Transcript, p. 190.
[21] Independent Report, ¶3.1.
[22] *Id.* at 305 (we [WADA] disagree [with Nelson] on the fact that numbers should have been brought in that case for the interpretation)
[23] *Id.*

When questioned how many individuals were used to validate the subjective, quantitative approach of the WADA Criteria, the Lausanne Laboratory witness testified he could not provide an answer to that question.[24] This is a far cry from the validation methods of the UCLA laboratory. Finally, no measurement of uncertainty has been calculated. I submit, this is not a close case. The WADA Criteria has not been validated in a manner acceptable to the scientific community. It should not be used to test athletes at this time.

Dr. David E. Housman professor at MIT who teaches validation and testing methods succinctly evaluated the problem with the WADA Criteria and the Testing Method when he stated:

> Let me make this comment. . . I take the use of science in society very seriously, and I have a very passionate view about the accurate use of science in the world of society, and I have to say that I do not regard the [WADA] criteria, and its use in this context, in any way, shape, or form being appropriately applied. [25]

I agree with Dr. Housman. The panel's acceptance of the deficiencies in the WADA Criteria and Testing Method establishes a dreadful precedent.

III. APPEARANCE OF A FAIR HEARING

Mrs. Haven Hamilton was asked whether the statements made in the press by high ranking WADA and IOC officials gave her concerns regarding whether Mr. Hamilton would receive a fair hearing.[26] She stated the following:

> Absolutely. Absolutely. And I think that especially when Jacques Rogge, the president of the IOC, came out two days before Christmas and said Tyler Hamilton's entire career should be called into question because of this test result. That's an unbelievably horrible thing to say about someone. Especially somebody like my husband, who has accomplished so much. He has never had a doping issue before in his life. Our thinking and our fear was that how are we going to come into this room, and defend Tyler in front of USADA, who helped fund this test, who has a lot invested in defending this test, who may or may not be, but appears, even, maybe not directly, but maybe through the media, of being, you know, affected by WADA and the IOC. And what they clearly believe to be an open- and-shut case before the facts were heard. I mean that has been our primary concern since the beginning. And the people that we have met all

[24] *Id.* at 293. (Question: So you couldn't give us a number as to how many different individuals you tested samples from in your validation, would that be right? Answer: I can't).
[25] Id. at 408.
[26] Counsel for USADA appropriately observed that no one from USADA has made public statements about this case. USADA's conduct, and the conduct of its counsel in this case, are beyond reproach.

> through this process, who are experienced in the anti-doping process, have said to us, you know, I hope Tyler gets a fair trial. I mean, we kept hearing that over and over again. I mean – maybe we're naïve, but I just took for granted that he would. And then hearing all these things and hearing the hurtful things, and the media, and then having them repeated over and over again. . .I could give you a document of all the terrible things said. I just think it's inappropriate, and I don't think any athletes should be subjected to any of that, because it can't help but influence people. . .[27]

The Olympic movement is a small community. The arbitrators who sit on panels in doping disputes may in fact do legal work for the IOC, the International Federations, the National Olympic Committees, and the National Federations. Indeed, the IOC and WADA from time to time may select individuals as arbitrators in certain cases. There is nothing improper about these relationships. However, if it is at all desirable for athletes to believe they will obtain a fair hearing, it is imperative that high-ranking officials within the Olympic community refrain from making statements demonstrating bias against an athlete before that athlete has a hearing.

Mrs. Hamilton's statements are by no means an exaggeration or unreasonable. As she so eloquently stated, athletes should not have to worry that high ranking officials are sending clear messages to the arbitrators to find the athlete guilty regardless of the facts of the case. The IOC and WADA should consider making rules prohibiting such conduct to comply with a very important fundamental principle of the Olympic movement, fairness.

Dated: April 18, 2005

Chris Campbell

Christopher L. Campbell

[27] Hearing Transcript, pp. 480 and 481.