

prohibited substance under the International Association of Athletics Federations ("IAAF") Anti-Doping Rules.

As provided for in the USADA Protocol for Olympic Movement Testing, USADA enforces the rules of the IAAF, which is the international federation for the sport of track and field.

II. APPLICABLE RULES

A. IAAF Definition of Doping.

The relevant IAAF definition of doping, as set forth in the IAAF handbook in Division III Control of Drug Abuse ("IAAF Rules"), Rule 55 is as follows:

Doping

1. Doping is strictly forbidden and is an offense under IAAF Rules.
2. The offense of doping takes place when either:
 - (i) a prohibited substance is present within an athlete's body tissues or fluids; or
 - (ii) an athlete uses or takes advantage of a prohibited technique; or
 - (iii) an athlete admits having used or taken advantage of a prohibited substance or a prohibited technique.

4. It is the athlete's duty to ensure that no substance enters his body or fluids which is prohibited under these Rules is present in his body tissues or fluids. Athletes are warned that they are responsible for all or any substance present in their body.

There is no requirement that USADA prove any element of intent to dope or intent to take a prohibited substance. *See IAAF v. Boulami* (CAS 2003/A/452). The IAAF's definition of doping is consistent with the rules of the vast majority of sports

organizations including the IOC and WADA¹, which have eliminated the element of intent as an aspect of proving liability in doping cases.

B. List of Prohibited Substances

The IAAF List of Prohibited Substances expressly classifies EPO as a prohibited substance in the class of Peptide Hormones. The IAAF Prohibited List states as follows:

"Prohibited Substances

S5. PEPTIDE HORMONES

The following substances, including other substances with similar chemical structure or similar pharmacological effect(s), and their releasing factors, are prohibited:

1. Erythropoietin (rh-EPO);
2. Growth hormone (hGH) and Insulin-like Growth Factor (IGF-I);
3. Chorionic Gonadotrophin (hCG) prohibited in males only;
4. Pituitary and synthetic gonadotrophins (LH) prohibited in males only;
5. Insulin
6. Corticotrophins.

III. BACKGROUND ON r-EPO

EPO is a hormone naturally produced by the human body, primarily in the kidneys. The naturally produced version of this hormone is sometimes referred to as endogenous or natural EPO. In both its synthetic and natural forms, EPO stimulates the production of red blood corpuscles, thereby increasing oxygen transport and aerobic power. Increased aerobic power leads to a higher level of performance for athletes such as Respondent.

¹ The Olympic Movement Anti-Doping Code ("OMADC"), at Article 2, contains a similar liability definition of doping. The World Anti-Doping Code ("Code"), at Article 2, also contains a similar liability definition of doping.

r-EPO is a synthetic version of the Erythropoietin hormone. All synthetic forms of EPO are substances prohibited by IAAF, the IOC, and WADA.

As recognized by the CAS Panel in *IAAF v. Boulami*, it should be noted that r-EPO is not produced by the human body, and its presence is indicative of administration of an external source.

IV. Stipulation of Uncontested Facts and Issues Between USADA and Respondent

The USADA and Respondent have stipulated and agreed to the following:

1. That the USADA Protocol for Olympic Movement Testing governs the hearing for an alleged doping offense
2. That International Association of Athletics Federations ("IAAF") definitions of doping, Classes of Prohibited Substances and Prohibited Methods, and sanctions are applicable to this hearing.
3. That Respondent gave the urine sample at issue here on January 31, 2004, as part of the USADA Out of Competition testing program;
4. That each aspect of the sample collection for Respondent's urine sample was conducted appropriately and without error;
5. That the chain of custody for Respondent's urine sample from the time of collection and processing at the time of collection site to the receipt of the sample by the International Olympic Committee accredited laboratory at the University of California in Los Angeles ("UCLA Laboratory") was conducted appropriately and without error;
6. That the UCLA Laboratory's chain of custody for Respondent's urine sample was conducted appropriately and without error.

V. ISSUES BEFORE THIS PANEL

The only contested issues are whether the UCLA Laboratory accurately found r-EPO in Respondent's urine sample and the consequences of its findings under the IAAF rules.

VI. THE LABORATORY METHOD USED BY THE UCLA LABORATORY HAS REPEATEDLY BEEN FOUND SCIENTIFICALLY VALID

A. The UCLA Laboratory's Direct Urine Test

The UCLA Laboratory's direct urine test, the name of the testing method given to the process used for detecting r-EPO and its analogues, has withstood review by four CAS Panels and has repeatedly been confirmed as scientifically reliable. Additionally, there have been three other CAS cases dealing with the analytical method for detecting r-EPO or its analogue darbepoetin, all of which have upheld the method for detecting these substances². All of the cases, including the four cases directly involving the UCLA Laboratory, have confirmed the scientific reliability of the analytical method used in the direct urine test. These cases also confirmed that the "80% basic area percentage" criteria for establishing a positive test for r-EPO is a scientifically reliable criteria for interpreting the electropherogram produced by the direct urine method.

Recently, the CAS Panel in *Boulami* applied the "beyond a reasonable doubt standard," as required under the IAAF rules, and held that the direct urine method including the 80% criteria for positivity was "a reasonable cut-off point that largely eliminates the risk of false positives." See *Boulami* at paragraph 5.26.

The UCLA Laboratory is one of the only laboratories to have its direct urine test reviewed by other experts and confirmed in a peer-reviewed published scientific article,

² See *IAAF v. Boulami* (CAS 2003/A/452), *Muehlegg v. IOC* (CAS 2002/A/374), *Lazutina v. IOC* (CAS 2002/A/370), *Meler v. Swiss Cycling* (CAS 2001/A/345), *UCI v. Hamburger* (CAS 2001/A/343), *Danilova v. IOC* (CAS 2002/A/371), and *USADA v. Sbeih* (AAA 30 190 01100 03).

and the UCLA direct urine test has been scrutinized and its validity upheld in four prior CAS cases. As held in *Muehlegg*, *Danilova* and *Lazutina*, the differences in the UCLA Laboratory's direct urine testing methods are improvements to the test as performed by other laboratories.

The Panel finds that the testing was in accordance with the scientific community's practices and procedures, indeed the SLC Lab [which for present purposes is the same as the UCLA Lab] was leading in the establishment of those very practices and procedures. (See *Muehlegg* paragraph 7,1,8.)

The direct urine test for r-EPO relies on the fact that endogenous EPO is glycosylated, meaning that it contains particular kinds of sugar molecules. R-EPO, on the other hand, contains different sugar molecules than endogenous EPO. As a result, endogenous EPO and r-EPO will have different electrical charges. Therefore, when separated out from the urine, EPO and r-EPO will respond differently when placed in an electrical field. Because r-EPO is more basic, it will move under the influence of an electric field to the more basic area of the gel, while endogenous EPO, being less basic will move predominantly (although not exclusively) to the acidic area of the gel. The end result, which captures this separation of r-EPO and endogenous EPO, is an electropherogram. The electropherograms of Respondent's urine sample clearly indicate the presence of r-EPO.

The UCLA Laboratory's direct urine test involves four steps: (1) sample preparation; (2) isoelectric focusing; (3) immuno-blotting; and (4) visualization. The methodology was set forth in detail in *Lazutina v. IOC* and relied on in *Muehlegg v. IOC* and will not be repeated here.

B. UCLA Laboratory r-EPO Positivity Criteria.

At the time Respondent's sample was analyzed, the UCLA Laboratory considered three alternative criteria in determining whether a sample was positive for r-EPO. These criteria were: (1) the "two-band ratio" analysis, (2) the "location" of the most intense band analysis, and (3) the "basic area percentage" analysis. The two-band ratio and location criteria are more sensitive than the basic area percentage criteria- meaning that they produce fewer false negative results. The UCLA Laboratory is confident that either the two-band ratio or location criteria standing alone accurately establish proof of the use of r-EPO. Following a full evidentiary hearing analyzing these three criteria, the *Sbeih* Panel concluded that "the methodology utilized by the UCLA Lab for testing r-EPO is scientifically sound and that the results produced by the tests are reliable. See *Sbeih* at paragraph 6.10.

In light of the CAS decisions in *Hamburger*, *Meier* and *Boulami* where CAS has specifically recognized the basic area percentage criterion as a scientifically reliable measure of positivity, UCLA also applies that criterion to take advantage of the certainty of CAS precedent.

1. **The "80% basic area percentage" analysis as a measure of positivity.**

The 80% criteria for positivity is determined by identifying the most acidic band of the r-EPO standard as the "0" band then comparing the density of those bands in the athlete's sample which are as basic or more basic than the "0" band with the density of all the EPO bands in the athlete's sample. In the case of Respondent's sample, that density, as measured with a densitometer, was 85% for the A sample and 87% for the B sample.

The scientific validity of the 80% basic area percentage criteria has been acknowledged in at least four prior CAS cases: *Meier*; *Hamburger*, *Boulami* and *Sbeih*. For example:

- In *Boulami*, the Panel stated, "In light of this, Respondent and Professor Stambouli have failed to cast doubt on the evidence brought forth by the IAAF that 80% is a reasonable cut-off point that largely eliminates the risk of false positives in urinary r-EPO test [.]" (*Boulami* paragraph 5.26)
- In *Hamburger*, the Panel stated, "Having heard the evidence, the Panel is 'comfortably satisfied' that a level of 80% can, in any event, prove the presence of r-EPO[.]" (*Hamburger* page 19, section V.1.2.3.2.)
- In *Meier*, the Panel stated, "Following the evidence heard, the Panel is convinced that the method used in the Lausanne laboratory (referencing the 80% basic area percentage criteria) is suitable for proving the presence of r-EPO[.]" (*Meier* page 16, section V.3.2.4.)

The *Hamburger*, *Meier*, and *Boulami* cases make reference to a number of studies that establish the scientific reliability of the 80% basic area percentage criteria and undermine any suggestion that Respondent's 85% basic area percentage is due to anything other than his use of r-EPO. Based on the studies referenced in the cases, all four CAS Panels found that there was more than ample evidence to establish the scientific validity of the 80% basic area percentage criteria.

The UCLA Laboratory has done its own more recent and much more extensive studies examining criteria which may be used to establish the positivity of a sample for

r-EPO. In 2003 Dr. Catlin et al of UCLA published an article in *Clinical Chemistry* entitled, "Detection of Recombinant Human Erythropoietin in Urine by Isoelectric Focusing". That article describes a study performed by UCLA in which baseline urines were obtained from 96 normal volunteers and a double-blind r-EPO administration study was conducted involving 25 volunteers. That study focused on the two-band ratio as the numerical criterion for positivity. One conclusion of this peer-reviewed study was that a two-band ratio of 1.19 was 99% reliable in detecting the administration of r-EPO. Expanding on this study, the UCLA Laboratory has now analyzed the urines of 704 normal volunteers to establish a statistical population base for all three positivity criteria (two-banded ratio, location, and 80% basic area percentage). These data provide overwhelming evidence that the EPO found in the basic range of Respondent's electropherogram was not naturally produced and was indeed r-EPO. The UCLA data establishes that the likelihood of an individual having a natural basic area percentage of 80% is one in 30 billion.

2. The Two-Band Ratio as a measure of positivity.

The Two-Band Ratio criterion is described in a *Clinical Chemistry* article by Dr. Carlin et al, entitled, "Detection of Recombinant Human Erythropoietin in Urine by Isoelectric Focusing". Simply described, the Two-Band Ratio approach compares the combined density (as measured by a machine called a densitometer) of the two bands on the basic side of the first basic band in the athlete's sample with the two bands on the acidic side on that band. The Two-Band Ratios of the isoforms in Respondent's A and B samples were 5 and 5 respectively. In his *Clinical Chemistry* study, Dr. Catlin was able to conclude that on the data available at the time, a much lower Two-Band Ratio of 1.19

had 99% margin of safety. The data from additional samples, which Dr. Catlin has analyzed, established that the margin of safety associated with a Two-Band Ratio of 1.8 would result in a false positive ratio of less than 1 in 100,000. A Two-Band Ratio of 5 would reduce that risk to an infinitesimal number. This Respondent's urine sample had a Two-Band ratio of 5. This evidence was not rebutted by Respondent.

3. Band Location as a measure of Positivity.

Band Location as a measure of positivity is also described in Dr. Catlin's *Clinical Chemistry* article under the heading "Visual Data Analysis". As set forth in that article, a sample will be called positive for r-EPO if all three of the following criteria are met:

The first criterion was that bands that focus in the basic area of the lane, as determined by the location of the rHuEPO marker, must be darker than other bands in the same lane. The second criterion was that these bands must have the same ph values as the bands in the nearest lane containing a rHuEPO marker. The third criterion was that band 0 and the adjacent two bands in the direction of the cathode must be present.

Respondent's sample is positive under this Band Location criterion as well. First, as can be seen from the densitometry results for the different bands set, the basic bands in Respondent's sample (0, -1, -2) are darker than any of the other bands in his sample. Second, as can be seen in the electropherograms of Respondent's sample, the basic bands in his sample do indeed have the same ph value (i.e., line up with) as the bands in the nearest lane containing a positive control sample. Third, band 0, band -1, and band -2 are present. Thus, Respondent's sample is positive under the Band Location analysis as well.

C. The new WADA positivity criteria for r-EPO.

One of WADA's most important roles under the World Anti-Doping Code is to develop best practice standards for the various parts of the anti-doping program.

Pursuant to that mandate, WADA developed the International Standard for Laboratories and it has subsequently developed various Technical Documents which then become part of the International Standard for Laboratories. The International Standard for Laboratories provides inter alia:

The International Standard for Laboratories, including all Annexes and Technical Documents, is mandatory for all Signatories to the Code.

Technical Documents are issued, modified, and deleted by WADA from time to time and provide direction to the Laboratories on specific technical issues. Once promulgated, Technical Documents become part of the International Standards for Laboratories.

Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the International Standard were performed properly.

(WADA International Standards for Laboratories pages 4 and 5).

The WADA scientific staff, working with a panel of international experts, has developed a new criterion for determining whether a sample is positive for r-EPO. That criterion has been incorporated into a Technical Document and was formally approved by the WADA Executive Board at its meeting on November 20, 2004. (See WADA Technical Document entitled "Harmonization of the Method for the Identification of Epoetin Alfa and Beta (EPO) and Darbepoetin Alfa (NESP) by the IEF-Double Blotting and Chemiluminescent Detection". The WADA standard for r-EPO positivity is similar to Dr. Catlin's Band Location criteria. The WADA standard as set forth in the Technical Document is as follows:

r-EPO

1. in the basic area there must be at least 3 acceptable, consecutive bands assigned as 1, 2, 3 or 4 in the corresponding reference preparation.
2. the 2 most intense bands in the basic area must be consecutive and the most intense band must be 1, 2 or 3.
3. the two most intense bands in the basic area must be more intense

than any other band in the endogenous area as measured by densitometry. Alternatively, if a visual or other qualitative method of comparison is used, then the two most intense bands in the basic area must be unequivocally more intense than any other band in the endogenous area.

Respondent's sample is clearly positive for r-EPO under the WADA standard.

First, there are three acceptable, consecutive bands assigned as numbers 1, 2, and 3 in the basic area of Respondent's A and B specimens. Second, the two most intense bands in Respondent's A and B specimens are consecutive, with the most intense band being number 2. Third, the two most intense bands of Respondent's A and B specimens are more intense than any other bands in the corresponding lanes.

The new WADA standard for determining r-EPO positivity is only "required for analysis performed after [the date of WADA Executive Board approval]." However, that does not mean that the new WADA standard should not be used to establish that Respondent has committed a doping violation in this case. As provided in the Code and International Standard for Laboratories, compliance with a Technical Document is sufficient to conclude that the procedures covered by that Technical Document were performed properly. Since Respondent's sample is also positive under the new WADA Standard the Panel has no reasonable doubt that Respondent's sample contains r-EPO.

VII. PRESUMPTION IN FAVOR OF THE LABORATORY

Under the USADA Protocol, there is a presumption that a laboratory conducted all procedures in accordance with acceptable current scientific standards. USADA Protocol provides:

The IOC laboratories used by USADA shall be presumed to have conducted testing and custodial procedures in accordance to prevailing and acceptable standards of scientific practice. This presumption can be rebutted by evidence to the contrary, but the accredited laboratory shall no onus in the first instance to show

that it conducted the procedures other than in accordance with its standard practices conforming to any IOC requirement (USADA Protocol, section 9(b)(v)(n)).

Respondent's expert witness, Dr. Allen Murray, stated that there were areas where the WADA approved EPO test could produce potential errors. Apparently, Dr. Murray has a test that can directly detect the presence of r-EPO. However, as Dr. Murray did not test the urine sample in question in this dispute using his test, nor did Respondent request the right to have Dr. Murray conduct such a test on his disputed samples, the concerns raised by Dr. Murray were mere speculation and could not be relied upon to question the validity of Mr. Hellebuyck's positive test.

VIII. SANCTIONS

A. Presumptive Sanction Pursuant to IAAF Rules.

The IAAF Rules provide that for a first doping offense involving a positive test for a prohibited substance or method, the athlete will be ineligible for "a minimum of two years from the date of the hearing at which it is decided that a Doping Offense has been committed." (IAAF Rules 40(1)(a)(i) and 40(9)). The presumptive sanction length of two years for a first offense involving use of a prohibited substance or method was adopted by all stakeholders who approved the World Anti-Doping Code. Further, the IAAF rules provide for the disqualification of results obtained by the athlete between the date of the positive test and the date on which the period of ineligibility begins pursuant to IAAF Rule 39.4.

No reasonable conclusion can be reached other than that Respondent used r-EPO. Certainly the finding of r-EPO in Respondent's urine cannot be explained by supplement contamination or the legitimate use of properly prescribed medicinal product and no such

explanation was offered at the hearing. As the Panel in *Boulami* stated, "[m]oreover we note that r-EPO is not a substance that can be accidentally introduced into the athlete's body." (*Boulami* paragraph 5.57.)

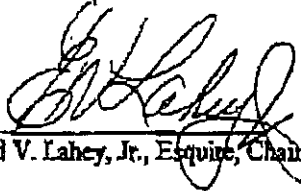
IX. DECISION AND AWARD

The Panel decides as follows:

1. A doping violation occurred on the part of Respondent, Eddy Hellebuyck.
2. The minimum suspension for a first offender of two (2) years is imposed on Respondent to take effect from January 31, 2004.
3. The Administration fees and expenses of the American Arbitration Association and the compensation and expenses of the Arbitrators shall be borne by USADA.
4. The parties shall bear their own costs and attorney's fees.

This Decision and Award is in full settlement of all claims submitted to this Arbitration.

This 9th day of December, 2004.


Edward V. Lahey, Jr., Esquire, Chair

Christopher L. Campbell, Esquire

Hon. James Murphy (ret)

explanation was offered at the hearing. As the Panel in *Boulami* stated, "[m]oreover we note that r-EPO is not a substance that can be accidentally introduced into the athlete's body." (*Boulami* paragraph 5.57.).

IX. DECISION AND AWARD

The Panel decides as follows:

1. A doping violation occurred on the part of Respondent, Eddy Hellebuyck.
2. The minimum suspension for a first offender of two (2) years is imposed on Respondent to take effect from January 31, 2004.
3. The Administration fees and expenses of the American Arbitration Association and the compensation and expenses of the Arbitrators shall be borne by USADA.
4. The parties shall bear their own costs and attorney's fees.

This Decision and Award is in full settlement of all claims submitted to this Arbitration.

This 9th day of December, 2004.

Edward V. Lahey, Jr., Esquire, Chair



Christopher L. Campbell, Esquire

Hon. James Murphy (ret)

explanation was offered at the hearing. As the Panel in *Boujami* stated, "[m]oreover we note that r-EPO is not a substance that can be accidentally introduced into the athlete's body." (*Boujami* paragraph 5.57.).

IX. DECISION AND AWARD

The Panel decides as follows:

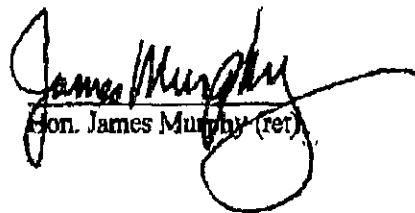
1. A doping violation occurred on the part of Respondent, Eddy Hellebuyck.
2. The minimum suspension for a first offender of two (2) years is imposed on Respondent to take effect from January 31, 2004.
3. The Administration fees and expenses of the American Arbitration Association and the compensation and expenses of the Arbitrators shall be borne by USADA.
4. The parties shall bear their own costs and attorney's fees.

This Decision and Award is in full settlement of all claims submitted to this Arbitration.

This 9th day of December, 2004.

Edward V. Lahey, Jr., Esquire, Chair

Christopher L. Campbell, Esquire


Hon. James Murphy (ret.)