

CAS 2011/A/2353 Erik Tysse v. Norwegian Athletics Federation & International Association of Athletics Federations

AWARD

delivered by

THE COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President: Dr. Martin Schimke, Attorney-at-law in Dusseldorf, Germany

Arbitrators: Mr Lars Halgreen, Attorney-at-law in Copenhagen, Denmark

Prof. Richard H. McLaren, Barrister in London, Ontario, Canada

Ad hoc Clerk: Ms. Erin C. McDermid, Barrister and Solicitor, London, Ontario, Canada

in the arbitration between

ERIK TYSSE, Oslo, Norway

Represented by Mr. Erik Flaagan, Attorney-at-law, Oslo, Norway

- Appellant-

and

NORWEGIAN ATHLETICS FEDERATION, Oslo, Norway

Represented by Mr. Tomas Kristensen, Attorney-at-law, Oslo, Norway

and

INTERNATIONAL ASSOCIATION OF ATHLETICS FEDERATIONS, Monaco

represented by Mr. Huw Roberts, IAAF Legal Counsel, Monaco

- Respondents-

1. THE PARTIES

- 1.1 The Appellant, Mr. Erik Tysse (hereafter referred to as “Tysse” or the “Appellant”) is a Norwegian athlete who participates in the sport of race walking.
- 1.2 The Respondent, Norwegian Athletics Federation (hereinafter “NAF”) is the organization responsible for the sport of athletics in Norway.
- 1.3 The Respondent, the International Association of Athletics Federations (hereinafter “IAAF”) is the world governing body for the sport of athletics. The IAAF is established as an association under the laws of Monaco.

2. FACTUAL BACKGROUND

- 2.1 Below is a summary of the main relevant facts and allegations based on the parties’ written submissions, pleadings and evidence adduced at the hearing. Additional facts and allegations may be set out, where relevant, in connection with the legal discussion that follows. Although the Panel has considered all the factual allegations, legal arguments and evidence submitted by the parties in the present proceedings, it refers in its Award only to the submissions and evidence it considers necessary to explain its reasoning.
- 2.2 On 1 May 2010, Tysse was called to perform a routine anti-doping control during an international competition in Italy.
- 2.3 Tysse’s sample was analysed at the Laboratorio Anti-doping FMSI in Rome (the “Rome Lab”). On 26 May 2010, the Rome Lab reported that the “A” sample contained Continuous Erythropoetin Receptor Activator (“CERA”). On 6 June 2010, following the “B” sample analysis, the Rome Lab reported the presence of CERA in Tysse’s urine sample again.
- 2.4 Pursuant to the World Anti-Doping Agency’s (“WADA”) technical guidelines for reporting of an Adverse Analytical finding for Erythropoetin, the Rome Lab sought a second opinion. Dr. Françoise Lasne of the doping laboratory in Paris (the “Paris Lab”) confirmed the analysis of the urine sample which took place in the Rome Lab.
- 2.5 On 8 July 2010, Tysse was temporarily suspended by the IAAF.

- 2.6 On 28 September 2010, the Prosecution Committee of Anti-Doping Norway charged Tysse with an Anti-Doping Rule Violation pursuant to Section 12(1) of the Statutes of the Norwegian Athletics Federation.
- 2.7 A hearing in relation to this matter was heard by the NAF Tribunal from 10-13 January 2011. On 31 January 2011, Tysse was found guilty of committing an Anti-Doping Rules Violation and sanctioned with two (2) years ineligibility, effective from 8 July 2010. It is this decision that is the subject of this Appeal.

3. PROCEEDINGS BEFORE THE COURT OF ARBITRATION FOR SPORT

- 3.1 On 16 February 2011, the Appellant filed his Statement of Appeal. In his Statement of Appeal, the Appellant nominated Mr. Lars Halgreen, attorney-at-law in Copenhagen, Denmark as arbitrator.
- 3.2 On 22 February 2011, the Court of Arbitration for Sport (“CAS”) wrote to the IAAF to advise of the nature of the proceedings, and requesting that if the IAAF intended to participate in the proceedings that it advised the CAS by no later than 4 March 2011.
- 3.3 At the outset, there was some uncertainty as to which rules ought to apply to these proceedings, whether it was the rules of the Norwegian Confederation of Sports, or whether the IAAF Rules ought to apply. On 2 March 2011, by way of a Joint Pleading, the Appellant and the NAF agreed to abide by the rules and timelines provided for in the IAAF Rules of Competition.
- 3.4 On 7 March 2011, the NAF appointed Professor Richard H. McLaren as its arbitrator.
- 3.5 On 7 March 2011, the IAAF wrote to the CAS confirming its intention to participate in the proceedings in accordance with its Rules. Neither the Appellant, nor the NAF objected to IAAF’s intervention in these proceedings. Accordingly, on 1 April 2011, the parties were advised that the Panel had accepted the IAAF’s request.
- 3.6 On 30 March 2011, the Appellant filed his Appeal Brief with the CAS. In his Appeal Brief, the Appellant made the following request for relief:

“Principally:

- 1. Erik Tysse to be acquitted.*

Alternatively:

2. *Erik Tysse to be subject to being deprived of the right to participate in competitions and organised training and of the right to hold elected and appointed offices, for a short period of less than two years, effective from 8 July 2010, as found appropriate by the CAS Panel according to the circumstances in favor for such relief.*

In both cases:

3. *The Norwegian Athletics Federation and the International Association of Athletics Federations is ordered to pay the costs of the case to Mr. Erik Tysse.*

3.7 The Appellant also requested several procedural measures including:

- (a) that the CAS Panel itself appoint expert witnesses, within the fields of biochemistry and with knowledge of the analysis methods isoelectric focusing (IEF) and SDS electrophoresis (SDS Page);*
- (b) that the CAS Panel assist in obtaining relevant information, including the original material used by the laboratory in Rome in reaching its conclusions;*
- (c) an oral hearing*
- (d) a reservation that further evidence may be produced and further submissions made.”*

3.8 On 19 April 2011, the Panel ordered the Appellant to file witness statements and translations of certain documents by no later than 10 May 2011. The Panel also confirmed that despite the concurrent appeal in Norway, as the Appellant was an international level athlete, the matter was properly brought before the CAS.

3.9 On 5 May 2011, the Appellant confirmed who he would be calling as witnesses at the hearing, and provided short summaries of the testimony of Dr. Franke and Dr. Heid.

3.10 The Appellant also requested CAS assistance in accordance with Article R57, and further advised that the Norwegian Confederation of Sports had given notice that they would abide by the CAS decision, and as such, the concurrent appeal in Norway would await such decision.

- 3.11 On 12 May 2011, the IAAF wrote to the CAS asking the Panel to confirm that the Appeal Brief was complete and that the Appellant would not be permitted to file any further evidence or documentation. The IAAF further requested that the Panel advised as to when the time limit would begin to run for the filing of the Answer Brief.
- 3.12 On 13 May 2011, the Panel wrote to the parties requesting, among other things, that the Appellant specify his requests for assistance. The Panel further directed the Appellant to decide within one week from receipt of the correspondence, whether or not he wished to call certain witnesses listed in his letter of 5 May 2011, and if so, to provide witness statements for those witnesses.
- 3.13 On 20 May 2011, the Appellant wrote to the CAS advising that it would not be calling certain witnesses listed in his letter of 5 May 2011. The Appellant also outlined his specific requests for assistance, which are reproduced below:

“According to Article R57, cf. R44.3 and the IAAF Competition Rules Article 42.9 any party filing an appeal shall be entitled to assistance from CAS to obtain relevant information. The Appellant requests the CAS Panel’s assistance obtaining such relevant information for his defence according to the specific list for this request provided in the Appellate Brief.

We further believe that no tests have ever been performed involving the medical and other factual circumstances that are present in this case. On this background we hereby request that the CAS panel make the following request to IAAF and/or directly to the WADA laboratory in Cologne, Germany:

Re-examination of the IEF and SDS-PAGE on urine sample 3511158 from Erik Tysse.

We are asking for re-analysis of the sample 3511158 at the WADA laboratory in Cologne, Germany.

Procedure.

- A. Use the same concentration of standard CERA as well as the test sample 3511158 applied in the WADA laboratory in Rome for both IEF and SDS-PAGE analyses. Control EPO and uEPO in the same concentrations used in Rome for IEF and SDS-PAGE.*
- B. Perform the same analyses but with a 1/5 dilution of both standard CERA and the test sample 3511158.*

C. *Standards CERA in a 1/10 and 1/20 dilution in both IEF and SDS-PAGE analyses.*

It is requested that the performance of the re-analysis is observed by Professor Bjarne Osterud. The sample 3511158 has to be made available by the WADA laboratory in Rome.”

3.14 On 31 May 2011, the IAAF made an application to the Panel in accordance with CAS Rule 44.3 to order the Appellant to produce documents that were in his custody or under his control. The IAAF requested the Appellant produce:

- (i) *All documents (records, tests, results, data etc.) related to and supporting the diagnosis of Mr Tysse with lack of iron anemia by Dr Tonneson in April 2010, including identifying the specific form of anemia that was diagnosed;*
- (ii) *All documents (records, test, results, data etc.) related to and supporting the diagnosis of Mr Tysse with a kidney or proteinuria condition by Dr Tonneson (or by any other doctor) including but not limited to all documents related to:*
 - *the athlete’s tested blood urea and creatinine levels; creatinine clearance rate estimated GFR and protein excretion in urine;*
 - *kidney imaging (e.g., kidney ultrasound)*
 - *antibody tests*
 - *complement levels*
 - *hepatitis serology*
 - *screening tests for diabetes, myeloma and other conditions affecting the kidney*
- (iii) *All documents (records, tests, results, data etc.) related to and supporting any other medical diagnosis of Mr Tysse by Dr Tonneson (or by any other doctor);*
- (iv) *All documents related to any iron supplementation nor iron injections prescribed in treatment of any of the above conditions by Dr Tonneson (or by any other doctor), including:*
 - *the date of each iron injection/supplement prescribed;*

- *the name of each iron injection/supplement prescribed;*
 - *the amount or quantity of each iron injection/supplemented prescribed;*
- (v) *All documents related to any other medical treatment of any of the above conditions, including any anti-hypertensive therapy (blood pressure medications) in the case of proteinuria; and*
- (vi) *All documents evidencing the disclosure of any of the above medical conditions or treatments to the Norwegian Athletics Federation and/or the Norwegian Olympic Committee.”*

3.15 On 3 June 2011, the Panel wrote to the parties and made the following orders:

- The Respondents were ordered to file their Answers with the CAS court office, no later than Thursday 23 June 2011;
- The Respondents were also ordered to:
 - Document the percentage value for the tests’ specificity for CERA;
 - Provide the Appellant and the Panel with a definition of “Band” according to the regulations and laboratory practice;
 - Provide the definition of “corresponding” according to regulations and laboratory practice;
 - Provide any information about any other analyses that were performed on the Appellant’s urine sample.
- The Respondents were also invited to request an explanation from the laboratory in Rome regarding the “manipulation” of the GASepo Analysis Report.
- The Respondents were further invited to request that the laboratories in Rome and Paris provide documented evaluation of the “Acceptance Criteria.”
- The Appellant was ordered to disclose the following:
 - All documents related to and supporting the diagnosis of his lack of iron anemia by Dr. Tonneson in April 2010, including identifying the specific form of anemia that was diagnosed;
 - All documents (records, tests, results, data, etc;) related to an[d] supporting the Appellant’s diagnosed kidney or proteinuria condition by Dr. Tonneson (or by any other doctor), including but not limited to all documents related to:
 - Tested blood urea and creatinine; creatinine clearance rate; estimated GFR and protein excretion in urine;
 - Kidney imaging;
 - Antibody tests;

- Complement levels;
- Hepatitis serology;
- Screening tests for diabetes, myeloma and other conditions which affect the kidney;
- All documents related to any iron supplementation or iron injections prescribed in treatment of any of the above conditions by Dr. Tonneson (or by any other doctor), including:
 - The date[d] of each iron injection supplement prescribed;
 - The name of each iron injection/supplement prescribed;
 - The amount or quantity of each iron injection/supplement prescribed;
- All documents related to any other medical treatment of any of the above conditions, including any anti-hypertensive therapy (blood pressure medications) in the case of proteinuria; and
- All documents evidencing the disclosure of any of the above medical conditions or treatments to the Norwegian Athletics Federation and/or the Norwegian Olympic Committee.

3.16 On 13 June 2011, the Appellant filed further documentation and witness statements as ordered by the Panel.

3.17 On 24 June 2011, the IAAF filed its Answer Brief including exhibits and witness statements. In its Answer Brief, the IAAF made the following requests for relief:

- (i) *The Appellant's appeal be rejected;*
- (ii) *The Panel upholds an anti-doping rule violation under IAAF Rules 32.2(a); and*
- (iii) *The Appellant be required to serve a 2-year period of ineligibility in accordance with IAAF Rules 40.2, expiring on 7 July 2012; and*
- (iv) *The Appellant be required to make a contribution to the IAAF's costs in the hearing to be assessed.*

4. THE CONSTITUTION OF THE PANEL AND THE HEARING

4.1 On 29 March 2011, the CAS Court Office informed the parties that the Panel to hear the appeal had been constituted as follows: Dr. Martin Schimke, Attorney-at-law in Dusseldorf, Germany, President of the Panel; Mr. Lars Halgreen, Attorney-at-law in Copenhagen, Denmark, arbitrator designated by the Appellant; and Prof. Richard H.

McLaren, Professor of Law in London, Ontario, Canada, arbitrator designated by the NAF.

4.2 A hearing took place at the CAS Headquarters in Lausanne, Switzerland on 28 and 29 June 2011. In addition to Erik Tysse, present on behalf of the Appellant was his counsel, Mr. Erik Flagan. For the Respondent IAAF were Mr. Thomas Capdevielle, IAAF Results Manager, and its counsel, Mr. Huw Roberts. For the Respondent NAF, its President, Svein Arne Hansen and counsel, Mr. Tomas Kristensen.

4.3 At the outset of the hearing, NAF advised that IAAF would be presenting the case on behalf of both parties.

4.4 The following witnesses were called by the Appellant:

- Erik Tysse; Appellant;
- Dr. Hege Tonneson, Family Physician;
- Mr. Stephan Platzer; Appellant's Coach;
- Dr. Helge Oftebro, Expert Witness;
- Dr. Bjarne Osterud, Professor, Expert Witness;
- Dr. Tore Skotland; Expert Witness;
- Prof. Jon Nissen-Meyer, Expert Witness;

4.5 The following witnesses were called by the Respondents:

- Prof. Giuseppe d'Onofrio, haematologist;
- Dr. Iain Macdougall;
- Dr. Gunter Gmeiner, Director of Seibersdorf Lab;
- Dr. Françoise Lasne, Director Paris Lab ;
- Prof. Francesco Botrè, Director of Rome Lab;
- Giorgia Corpetti, Senior Analyst at Rome Lab;
 - Ms. Corpetti provided her witness statement, but was not cross-examined at the hearing.

4.6 The testimony of Erik Tysse is summarized as follows:

- When he found out about the Adverse Analytical Finding his world crumbled;
- He did everything he could do to find out how he could have tested positive for CERA;
- Testified about his experience at the B sample opening and analysis;

- Dr. Oftebro, his expert was not able to attend the entire B sample analysis;
- He was left alone in the Rome Lab during the B sample opening and analysis and was uncomfortable that he was left alone and could walk anywhere in the Rome Lab;
- He gave the media access to all his medical information so that the truth could be discovered;
- The only injections he has ever had were iron injections as he has naturally low ferritin level;
- His two older sisters also have iron deficiencies;
- It has been suggested that he may suffer from a kidney problem;
- Urine is not the best matrix for CERA. Neither WADA nor the IAAF requested a blood sample from him to confirm the results from the urine sample;
- He does not have a Therapeutic Use Exemption (“TUE”) for his iron injections and has never been advised that he should be careful in that respect.

4.7 In cross-examination, Mr. Tysse stated:

- The refrigerator was unlocked when he was left alone in the Rome Lab, but it was not left open;
- When they were left alone, nobody touched his sample;
- He has never been diagnosed with a kidney condition. It was merely a theory because he excretes iron in his urine;
- One of his sisters was also a racewalker and she also took iron injections. She never tested positive for CERA;

4.8 Dr. Tonneson’s evidence is summarized as follows:

- In 1996, Mr. Tysse’s mother took him to the doctor because he felt tired and slack;
- The results of the tests showed that he had low iron stores;
- In June 1999, his iron stores were still very low despite his use of iron tablets. It was at that time that he began taking iron injections;
- Mr. Tysse’s two sisters also have low ferritin values.

4.9 In cross-examination Dr. Tonneson stated:

- She provided all medical records relating to Mr. Tysse to the Panel;
- She did not begin to care for the Appellant and his family exclusively until 2007;

- In terms of deciding whether or not the Appellant required an injection, she would consider whether he was going to a high altitude;
- Mr. Tysse's case is different than most patients' because he is an athlete;
- She has not diagnosed Mr. Tysse with anemia.

4.10 The evidence of Mr. Platzer is summarized as follows:

- He is Tysse's coach and has been coaching him since after the Olympic Games in 2004. He is also married to Tysse's sister;
- He described the procedure on the day they attended the B sample opening and analysis;
- He took notes during the visit;
- All the papers at the Rome Lab were in Italian so they were unable to follow every step that was being taken;
- During the second day, there was a problem with the CERA standard, and Prof. Botrè explained that as a result they had to run the scan again.

4.11 In cross-examination Mr. Platzer advised that when they were alone the Rome Lab, the Appellant's sample was in their sight at all times and that neither they, nor anyone else interfered with the sample.

4.12 The evidence of Prof. Franke is summarized as follows:

- He is a molecular biologist;
- He thinks there should be more transparency with the science that is used to sentence athletes in sports;
- The SDS Page analysis is completely unreliable and cannot be used to convict or sentence an athlete for doping;
- There is no positive identification of CERA in the SDS Page analysis and materials prepared by Dr. Gmeiner.

4.13 In cross-examination Dr. Franke stated:

- His declaration made in this case is based on the material and documents he had been given which were Dr. Gmeiner's report on the SDS Page analysis;
- He did not comment on the IEF analysis because it was not clear to him;
- He has not published any peer reviewed studies on the IEF method.

4.14 The testimony of Dr. Heid is summarized as follows:

- He is a protein scientist and has a lot of experience with antibodies;
- The antibody used does not recognize rEPO and that is his major concern;
- His concern with the SDS Page analysis is that the method must be improved and they ought to use better antibodies;
- The results of the SDS Page analysis are ridiculous and you cannot convict someone based on them.

4.15 In cross-examination Dr. Heid stated:

- He has testified in one other case before the CAS a few years ago;
- He does not recall what his testimony was in that case;
- He has a lot of experience with 3D gels;
- He did not look at the IEF results of the Rome Lab. His criticism of the Rome Lab's results is based entirely on the SDS page analysis.

4.16 The testimony of Dr. Skotland is summarized below:

- The IEF analysis clearly demonstrates that the urine sample is destroyed during storage;
- When performing the first analysis of the B sample, there is no sign of endogenous EPO in the sample. It is therefore likely that all bands observed in the CERA region originate from the endogenous EPO;
- There are smears on the gel for the confirmation of the A analysis which should have resulted in the analysis being invalidated;
- The IEF gel for the confirmation of the B analysis is the only one out of the five IEF analyses performed where the CERA standard protein shows a pattern that is somewhat similar to that described in TD2009EPO;
- The anti-human EPO antibody on which the IEF method is based has been reported to cross react with several proteins, therefore the bands appearing on the SDS Page do not necessarily prove that the protein contains EPO;
- The IEF method is performed in the absence of reducing agents such as DTT, which means that certain protein bonds are not cleaved whereby protein aggregates such as dimers and trimers might be present in the test samples;
- The original gel from the SDS electrophoresis shows that there is no CERA band in Tysse's sample. It is only after manipulation with the GasEPO software that

the Rome Lab was able to make it seem as though there was CERA in the Athlete's sample;

- It is likely that the bands which showed up on the SDS Page and which corresponded to CERA were an EPO dimer caused by the Athlete's injection of iron;
- There are no traces of CERA in the urine sample from Tysse;
- The Rome Lab performed five (5) runs of the IEF analysis and the positive finding is based on two of those results only;
- There is major instability in the sample and the results changed over time;
- The darker blots that are shown in the athlete's lane are electronically enhanced to appear darker;
- The Rome Lab results show there is a significant lack of reproducibility. When he showed the results to other scientists, they laughed at the results;
- The confirmation sample shows smears, the disqualification criteria that are provided for in the TD2009EPO are all present in the sample;
- If something is defined as being a "band", then it ought to be a "band" and not a smear;
- The smears are in fact protein, but it cannot be concluded that it is CERA – as the results do not meet the acceptance criteria;
- The second opinion that is provided for in TD2009EPO should not be performed the way it currently is. It should require the second laboratory to perform another analysis.

4.17 In cross-examination, Dr. Skotland stated:

- He finished teaching the IEF method thirty (30) years ago;
- He has no experience with the IEF method and doping;
- If you have a second analysis, such as the SDS Page in this case, that shows that a substance is clearly different, it doesn't matter what the original method is. The second method does not disclose the presence of CERA;
- His review of the data in the analysis is not made in accordance with TD2009EPO.

4.18 In response to questions from the Panel, Dr. Skotland stated that he was not aware of any scientific data that shows that iron is capable of producing a band like CERA;

4.19 The evidence of Dr. Osterud is summarized below:

- He agrees with the statements made by Dr. Skotland;
- Having reviewed the results of the Rome Lab he noticed there was very little endogenous EPO present in the Athlete's sample. Accordingly, he developed a theory that the iron injection received 3 days before the competition might have caused the unusual sample;
- He decided to perform a reconstruction by giving a new iron injection to Tysse and collecting samples both before and after the iron injection;
- A day after the injection there was a remarkable precipitation of reddish protein. Similar precipitation was present in the urine sample two days after the injection, whereas the same amount of precipitation appeared in the sample taken three days after iron injection;
- When comparing proteins from the samples collected 3 and 8 days after the iron injection, and subjecting them to SDS Page, he found that almost all EPO moved as a dimer in the sample taken 3 days after the iron injection but as a monomer in the sample collected 8 days after the iron injection;
- He believes there has been a favourable change in Tysse's kidney function;
- In conclusion, the reconstruction performed in October gave him a very good indication that what was observed by the Rome Lab on the SDS Page was a dimer form of EPO, which probably also explains the proteins in the CERA region on the IEF.

4.20 Prof. Nissen-Meyers has signed a statement indicating that he agrees with the conclusions drawn in Prof. Osterud's papers and statements regarding the Athlete's sample;

4.21 The testimony of Dr. Macdougall is summarized as follows:

- The medical records disclosed by Tysse do not support the assertion that Tysse suffers from iron deficiency anemia;
- The medical records do not support the assertion that Tysse suffers from proteinuria;
- The medical records do not support the assertion that Tysse has a kidney condition;
- The medical records do disclose that Tysse has a longstanding problem with iron deficiency which his physician has treated with iron injections;
- He finds the practice of treating the iron deficiency somewhat unusual;

- For an athlete treating the iron deficiency may be seen as a way of maximizing his performance and it would be hard to argue that iron management alone is inappropriate as a means of enhancing performance;
- The protein level recorded in Rome after Tysse's competition on 1 May 2010 is consistent with Prof. Svarstad's assessment that Tysse demonstrates a slight to moderate level of exercise-related proteinuria after heavy physical exercise. From a clinical perspective, the levels are not relevant;
- The evidence from nephrology literature strongly suggests that iron will complement the haematological effect of taking CERA.

4.22 In cross-examination Dr. Macdougall advised that he had seen the reconstruction of the Appellant's sample, but made no comment on it.

4.23 Prof. d'Onofrio's witness testimony is summarized as follows:

- The athlete's blood profile in the period of 2006-2008 is not a normal profile;
- The athlete's profile is characterized by an excess of variability for haemoglobin;
- The athlete's pattern could be considered suspicious for blood doping consisting of the administration of an erythropoetic stimulating agent ("ESA");
- The athlete's blood profile in the period of 2009-2010 is also not inconsistent with the administration of CERA;
- Iron has no effect on the production of red cells in healthy subjects;
- The administration of ESAs causes functional iron deficiency in patients with renal failure, even if iron is present in body stores.

4.24 In cross-examination, Prof. d'Onofrio stated:

- Immediately after long exercise there can be an increase in blood value of about 5-10%. After some time (less than one hour) this effect ceases;
- If a person is taking antibiotics, there is no specific change in blood value. You can have a change in white blood cells in response to an infection. The effect on the red cells is absent;
- It is possible to have a different red blood cell concentration if you are suffering from a very high fever, with sweating, or a very acute condition.

4.25 The evidence of Dr. Rabin is summarized as follows:

- In the sense of the TD2009EPO, a band is an aggregate of EPO isoforms with similar isoelectric or weight properties based on the homogeneity of physicochemical properties;
- The word “corresponding” in the TD2009EPO should be interpreted as “in the area of” the CERA reference substance for the analysis in question;
- Experts in the EPO working group agreed that the pattern of CERA was so distinctive that it was not necessary to define matching criteria in the form of assigned numbered bands or identification letters in the reference preparation to identify CERA, as with the more traditional EPOs;
- The specific approach for CERA reflects the fact that some factors can slightly affect the migration of the bands in the sample compared to the pure reference substance. Human metabolism can affect the isoelectric pattern and create a slight shift between the pattern of the native substance and its profile in urine;
- The second opinion requirement in the TD2009EPO is a document review process to be conducted based solely on the information generated by the laboratory conducting the analysis. No further analytical procedure is expected from the expert providing the second opinion;
- GasEPO software has been developed to analyze the images obtained by densitometry. GasEPO is merely image processing software that does not interfere with the initial analysis as obtained by the IEF method or by SDS Page. It is used to facilitate the reading and interpretation of such images.

4.26 The Appellant did not cross-examine Dr. Rabin.

4.27 The evidence of Prof. Botrè is summarized as follows:

- He is the head of the Rome Lab;
- The Rome Lab has been accredited for analysing EPO since 2003. CERA was added to the Rome Lab’s scope of accreditation in the second half of 2008;
- In the period of 2007-2010, the Rome Lab reported 35 Adverse Analytical Finding for EPOs, of which 27 were for human recombinant EPO, 5 for NESP and 3 for CERA;
- The Chain of Custody for both the “A” and “B” samples is intact and well documented;
- Prof. Botrè detailed the entire analysis of the “A” sample from the initial testing procedure through to the confirmation procedure and the second opinion;

- Prof. Botrè also detailed the entire procedure for the analysis of the “B” sample, including the steroid profile analysis, the SDS Page analysis and how he addressed questions from the athlete, and his expert, during the analysis.

4.28 In cross-examination Prof. Botrè stated:

- When using SDS Page you have to undertake extensive immunopurification which weakens the signal of the band in the CERA region;
- IEF is more sensitive for CERA than SDS Page;
- He would not have reported a positive finding for CERA based on the SDS Page results;
- Blood is a much more ideal substance to test for the presence of CERA. The urine matrix for detection of CERA is a nightmare;
- They performed 5 IEF analyses on Tysse’s urine. This is not usual but the Rome Lab wanted to ensure that it provided the most reliable and highest quality results possible.

4.29 The witness testimony of Dr. Lasne is summarized below:

- Dr. Lasne explained the process of developing the IEF method for identification of CERA in urine;
- The purpose of the analysis for CERA is to differentiate between endogenous and exogenous EPO;
- She has never seen a false positive for CERA;
- She has never come across a situation where a positive finding for CERA was a result of iron injections.

4.30 In cross-examination Dr. Lasne stated:

- She is the head of the WADA accredited laboratory in Paris, France;
- She was extensively involved in the development of the IEF analytical method currently used by WADA accredited laboratories for the detection of recombinant erythropoietin and analogues in doping control samples;
- She explained the method by which the IEF method was developed;
- The IEF method uses electrical charge to identify the CERA molecules, while SDS Page is about the weight of the molecules;
- The most important point of the development of the test for CERA was the demonstration of the specificity of the criterion for identification of CERA;

- In the report submitted to COFRAC – the accrediting body in France for ISO accreditation - 135 IEF profiles obtained from IEF analysis for EPO in urine before any authorization for commercialization of CERA (and thus negative for this drug) were provided as an example to demonstrate the specificity of the criterion;
- The specificity for the test for detection of CERA is further confirmed by the considerable experience in conducting doping control analyses. The Paris Lab analysed 3,292 urine samples for the detection of EPO using the IEF method between 2000 and 2007 (before CERA was available) and in no sample were the characteristic bands of CERA ever observed;
- The criterion for the identification of CERA is not quantitative, it is qualitative. All that can be said is that none of the 3,292 urine samples analysed in the Paris Lab before the invention of CERA in 2007 gave rise to a pattern characteristic of CERA;
- She has never observed or been notified of any protein that interferes in the CERA range using the IEF method;
- The effects of strenuous exercise on the isoelectric patterns of EPO have been carefully monitored and studied by the scientific community. The study shows that, in some rare cases, strenuous exercise could result in a slight shift of the endogenous bands into a more basic isoelectric point. However, there could not be any confusion with the CERA pattern for two reasons: (1) the CERA bands are located in the upper part of the basic area; and (2) the CERA bands, which can be characterized as being usually thick and very close to one another, are significantly different from the bands corresponding to endogenous EPO;
- The second opinion that she provided regarding the Rome Lab's analysis of Tysse's sample is that the analysis disclosed the presence of CERA in accordance with the International Standard for Laboratories and TD2009EPO;
- The acceptance, identification, and stability criteria set out under TD2009EPO for CERA were fulfilled;
- The Rome Lab did not commit any breaches of the International Standard for Laboratories or any other relevant rule or policy in analyzing Tysse's sample;
- Iron injections in athletes are not rare. If such injections were to create artefacts linked to protein precipitation, it would have been observed amongst the 3,292 samples analysed by the Paris Lab before the existence of CERA and the thousands of samples analysed for EPO each year;
- In her opinion, there is no other explanation than doping to explain the results of the analysis performed on Tysse's sample;
- The SDS Page confirms the IEF results.

4.31 The witness testimony of Dr. Gunter Gmeiner is summarized as follows:

- Dr. Gmeiner described the analytical method currently used by WADA accredited laboratories for the detection of recombinant erythropoietin and analogues in a doping control sample;
- He elaborated in particular on the use of the IEF method which uses at least three independent principles to gain specificity;
 - IEF separation of EPO isoforms according to their isoelectric properties;
 - A monoclonal antibody to specifically locate EPO isoforms on the membrane;
 - A second blotting step as a key improvement to significantly reduce possible interference of urinary proteins with the non-specific second antibody;
- If the IEF results show a profile that is not consistent with a typical endogenous profile, but do not allow a final conclusion, the TD2009EPO allows for additional evidence, generated by using methods such as SAR Page and SDS Page, to help confirm the nature of the finding;
- SDS Page is less sensitive for CERA than for other epoetins, because of interference between the SDS – containing PEG group of the CERA molecule and the primary antibody used for the Western blot. As a result, the method is not recommended for helping to confirm CERA in doping control samples;
- Criticism of the IEF method for the detection of EPO focuses on the specificity of the antibody used. The monoclonal antibody is not the sole source of specificity of the method. The publications by Khan et al. which criticize the method contain errors.
- Khan drew a fatal conclusion in his publication, namely that whatever happened on their 2D-Page method, was also true for the CA-IEF method.
- GasEPO is image evaluation software specifically designed to evaluate gel images for EPO testing methods. The software was validated via means of a phantom image demonstrating that no alteration of the raw image data occurs. The software is a tool used to visualize raw data to support the decisions of experienced specialists;
- The analysis conducted by the Rome Lab discloses the presence of CERA in accordance with the International Standards for Laboratories and TD2009EPO:
 - In the three accepted analyses that were conducted on the sample there are no spots, smears or areas of excessive background significantly interfering with the bands visible on each lane. While the A-sample confirmation

shows a small area of absent signal at the more basic band, this does not invalidate the lane due to the fact that the bands are clearly visible;

- On the repeated screening gel, as well as the confirmation gels, the sample lane shows, in each case, at least four bands;
- In the TD2009EPO, bands for CERA are not identified by numbers or letters, as in the case of rEPO or NESP, they are identified by regions;
- The figures produced (and unmanipulated) by the GasEPO software show that each analysis shows at least four distinct bands;
- The SDS Page analysis also supports the finding of CERA in the Athlete's sample;
- Having reviewed the Rome Lab's documentation, there is no indication that the Rome Lab breached any of the requirements of the International Standard for Laboratories in its current version which could have caused the adverse analytical finding reported by the Rome Lab;
- There is no evidence in the documentation package that the Rome Lab did not follow the recommended procedures for the proper storage of the sample concerned.

4.32 The Panel also held an expert witness conference prior to the parties' final submissions. In that conference the expert witnesses made the following comments:

- The experts debated the fact that the Rome Lab rejected the first initial screening run that was performed. Prof. Botrè stated that he rejected the results because the analysis didn't meet his standards, there was some migration on the gels, but it had nothing to do with there not being a positive finding for CERA;
- There was discussion regarding the use of the GasEPO software and whether it was used to manipulate the results, or whether it is simply a tool to read the results. The experts discussed the requirements in the TD2009EPO. Dr. Skotland said the guidelines are not appropriate, while the experts for WADA stated that it is their job to follow the guidelines and the guidelines have been validated;
- Prof. Osterud felt there was too much manipulation of the sample and the data in this case.

4.33 At the end of the hearing, both the Athlete and the IAAF agreed that their rights had been respected during the hearing and they had no outstanding procedural complaints regarding same.

5. JURISDICTION OF THE CAS

5.1 Article R47 of the CAS Code provides as follows:

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

5.2 IAAF Rule 42 states,

“Decisions subject to Appeal

1. Unless specifically stated otherwise, all decisions made under these Anti-Doping Rules may be appealed in accordance with the provisions set out below. All such decisions shall remain in effect while under appeal unless the appellate body orders otherwise or unless otherwise determined in accordance with these Rules (see Rule 42.15). Before an appeal is commenced, any post-decision review provided in these Anti-Doping Rules must be exhausted (except where WADA has a right of appeal and no other party has appealed a final decision under the applicable rules, in which case WADA may appeal such decision directly to CAS without having to exhaust any other remedies).

3. Appeals Involving International-Level Athletes: in cases involving International-Level Athletes or their Athlete Support Personnel, the decision of the relevant body of the Member may be appealed exclusively to CAS in accordance with the provisions set out below.”

5.3 The Appellant in an international level athlete. Accordingly, his appeal is properly brought before this court.

5.4 The parties agreed that the CAS has jurisdiction to hear this dispute.

* * *

6. APPLICABLE LAW

6.1 Article R58 of the CAS Code provides as follows:

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

6.2 IAAF Rule 42(22) provides that

“In all CAS appeals involving the IAAF, CAS and the CAS Panel shall be bound by the IAAF Constitution, Rules and Regulations (including the Anti-Doping Regulations). In the case of any conflict between the CAS rules currently in force and the IAAF Constitution, Rules and Regulations, the IAAF Constitution, Rules and Regulations shall take precedence.”

6.3 IAAF Rule 42(23) provides that *“In all CAS appeals involving the IAAF, the governing law shall be Monegasque law and the arbitrations shall be conducted in English, unless the parties agree otherwise.”*

6.4 The parties agree that the relevant rules for the purposes of this appeal are the IAAF Anti-Doping Rules and in particular:

**“RULE 32
Anti-Doping Rule Violations**

1. Doping is defined as the occurrence of one or more of the anti-doping rule violations set out in Rule 32.2 of these Anti-Doping Rules.
2. Athletes or other Persons shall be responsible for knowing what constitutes an anti-doping rule violation and the substances and methods which have been included on the Prohibited List. The following constitute anti-doping rule violations:
 - (a) Presence of a Prohibited Substance or its Metabolites or Markers in an Athlete’s Sample.
 - (i) it is each Athlete’s personal duty to ensure that no Prohibited Substance enters his body. Athletes are responsible for any Prohibited Substance or its Metabolites or Markers found to be present in their Samples. Accordingly, it is not necessary that intent, fault, negligence or knowing Use on the

Athlete's part be demonstrated in order to establish an anti-doping rule violation under Rule 32.2(a).

- (ii) sufficient proof of an anti-doping rule violation under Rule 32.2(a) is established by either of the following: presence of a Prohibited Substance or its Metabolites or Markers in the Athlete's A Sample where the Athlete waives analysis of the B Sample and the B Sample is not analysed; or, where the Athlete's B Sample is analysed and the analysis of the Athlete's B Sample confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the Athlete's A Sample.
 - (iii) except those Prohibited Substances for which a quantitative threshold is specifically identified in the Prohibited List, the presence of any quantity of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample shall constitute an anti-doping rule violation.
 - (iv) as an exception to the general application of Rule 32.2(a), the Prohibited List or International Standards may establish special criteria for the evaluation of Prohibited Substances that can also be produced endogenously.
- (b) Use or Attempted Use by an Athlete of a Prohibited Substance or a Prohibited Method.
- (i) it is each Athlete's personal duty to ensure that no Prohibited Substance enters his body. Accordingly, it is not necessary that intent, fault, negligence or knowing Use on the Athlete's part be demonstrated in order to establish an anti-doping rule violation for Use of a Prohibited Substance or a Prohibited Method.
 - (ii) the success or failure of the Use or Attempted 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.
- (c) Refusing or failing without compelling justification to submit to Sample collection after notification as authorized in applicable anti-doping rules or otherwise evading Sample collection.
- (d) Violation of applicable requirements regarding Athlete availability for Out-of-Competition Testing, including failure to file required whereabouts information and Missed Tests which are declared based on rules which comply with the International Standard for Testing. Any combination of three Missed Tests and/or Filing Failures within an eighteen-month period as determined by the IAAF and/or other Anti-Doping Organizations with jurisdiction over the Athlete shall constitute an anti-doping rule violation.
- Note: If an Athlete has a recorded missed test / filing failure on file with the IAAF prior to 1 January 2009, it may be combined with post-1 January 2009 missed tests and/or filing failures for the purposes of a violation of Rule 32.2(d) provided that all three missed tests and/or filing failures that are the subject of the anti-doping rule violation have taken place within an eighteen-month period.*
- (e) Tampering or Attempted Tampering with any part of Doping Control.

- (f) Possession of a Prohibited Substance or Prohibited Method.
 - (i) Possession by an Athlete In-Competition of any Prohibited Method or Prohibited Substance or Possession by an Athlete Out-of-Competition of any Prohibited Method or Prohibited Substance which is prohibited Out-of-Competition unless the Athlete establishes that the Possession is pursuant to a TUE granted in accordance with Rule 34.9 (Therapeutic Use) or other acceptable justification.
 - (ii) Possession by an Athlete Support Personnel In-Competition of any Prohibited Method or Prohibited Substance or Possession by an Athlete Support Personnel Out-of-Competition of any Prohibited Method or Prohibited Substance which is prohibited Out-of-Competition in connection with an Athlete, Competition or training, unless the Athlete Support Personnel establishes that the Possession is pursuant to a TUE granted to an Athlete in accordance with Rule 34.9 (Therapeutic Use) or other acceptable justification.
- (g) Trafficking or Attempted Trafficking in any Prohibited Substance or Prohibited Method.
- (h) Administration or Attempted administration to any Athlete In-Competition of any Prohibited Method or Prohibited Substance, or administration or Attempted administration to any Athlete Out-of-Competition of any Prohibited Method or Prohibited Substance that is prohibited Out-of-Competition or assisting, encouraging, aiding, abetting, covering up or any other type of complicity involving an anti-doping rule violation or any Attempted anti-doping rule violation.

IAAF Rule 33:

RULE 33
Proof of Doping

Burdens and Standards of Proof

1. The IAAF, the Member or other prosecuting authority shall have the burden of establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether the IAAF, the Member or other prosecuting authority has established an anti-doping rule violation to the comfortable satisfaction of the relevant hearing panel, bearing in mind the seriousness of the allegation which is made. This standard of proof in all cases is greater than a mere balance of probability but less than proof beyond a reasonable doubt.
2. Where these Anti-Doping Rules place the burden of proof upon the Athlete or other Person alleged to have committed an anti-doping violation to rebut a presumption or establish specified facts or circumstances, the standard of proof shall be by a balance of probability, except as provided in Rules 40.4 (Specified Substances) and 40.6 (aggravating circumstances) where the Athlete must satisfy a higher burden of proof.

Methods of Establishing Facts and Presumptions

3. Facts related to anti-doping rule violations may be established by any reliable means, including but not limited to admissions, evidence of third Persons, witness statements, experts reports, documentary evidence, conclusions drawn from longitudinal profiling and other analytical information. The following rules of proof shall be applicable in doping cases:
- (a) WADA-accredited laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The Athlete or other Person may rebut this presumption by establishing that a departure from the International Standard for Laboratories has occurred which could reasonably have caused the Adverse Analytical Finding. If the Athlete or other Person rebuts the preceding presumption by showing that a departure from the International Standard for Laboratories occurred which could reasonably have caused the Adverse Analytical Finding, then the IAAF, the Member or other prosecuting authority shall have the burden of establishing that such departure did not cause the Adverse Analytical Finding.
 - (b) Departures from any other International Standard or other anti-doping rule or policy which did not cause an Adverse Analytical Finding or other anti-doping rule violation shall not invalidate such results. If the Athlete or other Person establishes that a departure from another International Standard or other anti-doping rule or policy has occurred which could reasonably have caused the Adverse Analytical Finding or other anti-doping rule violation, then the IAAF, the Member or other prosecuting authority shall have the burden of establishing that such departure did not cause the Adverse Analytical Finding or the factual basis for the anti-doping rule violation.
 - (c) The facts established by a decision of a court or professional disciplinary tribunal of competent jurisdiction which is not the subject of a pending appeal shall be irrefutable evidence against the Athlete or other Person to whom the decision pertained of those facts unless the Athlete or other Person establishes that the decision violated principles of natural justice.
 - (d) The hearing panel in a hearing on an anti-doping rule violation may draw an inference adverse to the Athlete or other Person who is asserted to have committed an anti-doping rule violation based on the Athlete's or other Person's refusal, after a request made in a reasonable time in advance of the hearing, to appear at the hearing (either in person or by telephone as directed by the hearing panel) and to answer questions from the hearing panel or the IAAF, Member or other prosecuting authority asserting the anti-doping rule violation.

IAAF Rule 34

RULE 34 **The Prohibited List**

1. These Anti-Doping Rules incorporate the Prohibited List which shall be published by WADA from time to time.

IAAF Rule 36

RULE 36
Analysis of Samples

1. All Samples collected under these Anti-Doping Rules shall be analysed in accordance with the following general principles:

Use of Approved Laboratories

(a) For the purposes of Rule 32.2(a) (Presence of a Prohibited Substance or Prohibited Method), Samples shall be analysed only in WADA-accredited laboratories or as otherwise approved by WADA. In the case of Samples collected by the IAAF pursuant to Rule 35.7, Samples shall be sent only to WADA accredited laboratories (or, where applicable, to hematological laboratories or mobile testing units) which are approved by the IAAF.

Purpose of Collection and Analysis of Samples

(b) Samples shall be analysed to detect Prohibited Substances and Prohibited Methods on the Prohibited List (and such other substances as may be directed by WADA pursuant to its monitoring programme) and/or to assist in profiling relevant parameters in an Athlete's urine, blood or other matrix, including DNA or genomic profiling, for anti-doping purposes. Relevant profile information may be used to direct Target Testing or to support an anti-doping rule violation under Rule 32.2, or both.

Research on Samples

(c) No Sample may be used for any purpose other than as described in Rule 36.1(b) without the Athlete's written consent. Samples used (with the Athlete's consent) for purposes other than Rule 36.1(b) shall have any means of identification removed such that they cannot be traced back to a particular Athlete.

Standards for Sample Analysis and Reporting

(d) Laboratories shall analyse Samples and report results in conformity with the International Standard for Laboratories. Compliance with the International Standard for Laboratories (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the International Standard for Laboratories have been properly performed. The International Standard for Laboratories shall include any Technical Documents issued pursuant to the International Standard for Laboratories.

2. All Samples provided by Athletes in Doping Controls conducted at International Competitions shall immediately become the property of the IAAF.

3. If, at any stage, any question or issue arises concerning the analysis or interpretation of the results of a Sample, the person responsible for the analysis at the laboratory (or haematological laboratory or mobile testing unit) may consult the IAAF Anti-Doping Administrator for guidance.

4. If, at any stage, any question or issue arises in relation to a Sample, the laboratory (or mobile testing unit) may conduct any further or other tests necessary to clarify the question or issue so raised and such tests may be relied upon by the IAAF when

deciding whether a Sample has given rise to an Adverse Analytical Finding or other anti-doping rule violation.

5. A Sample collected under Rule 36.2 may be re-analysed for the purpose of Rule 36.1(b) at any time exclusively at the direction of the IAAF or WADA (with the consent of the IAAF). All other Samples collected in Athletics may be re-analysed exclusively at the direction of the Testing Authority or the IAAF (with the consent of the Testing Authority) or WADA. The circumstances and conditions for re-testing Samples shall conform with the requirements of the International Standard for Laboratories.
6. Where an analysis indicates the Presence of a Prohibited Substance or the Use of a Prohibited Substance or Prohibited Method, the WADA-accredited laboratory shall immediately confirm the Adverse Analytical Finding or Atypical Finding in encoded form in a report signed by an authorised representative of the Laboratory, sent either to the IAAF, in the case of an IAAF Test, or to the relevant Member in the case of a national Test (with a copy to the IAAF). In the case of a national test, the Member shall inform the IAAF of the Adverse Analytical Finding or Atypical Finding or Use and the name of the Athlete promptly on receipt of the information from the WADA accredited laboratory and, in all circumstances, within two weeks of such receipt.

IAAF Rule 40.2

Ineligibility for Presence, Use or Attempted Use or Possession of Prohibited Substances and Prohibited Methods

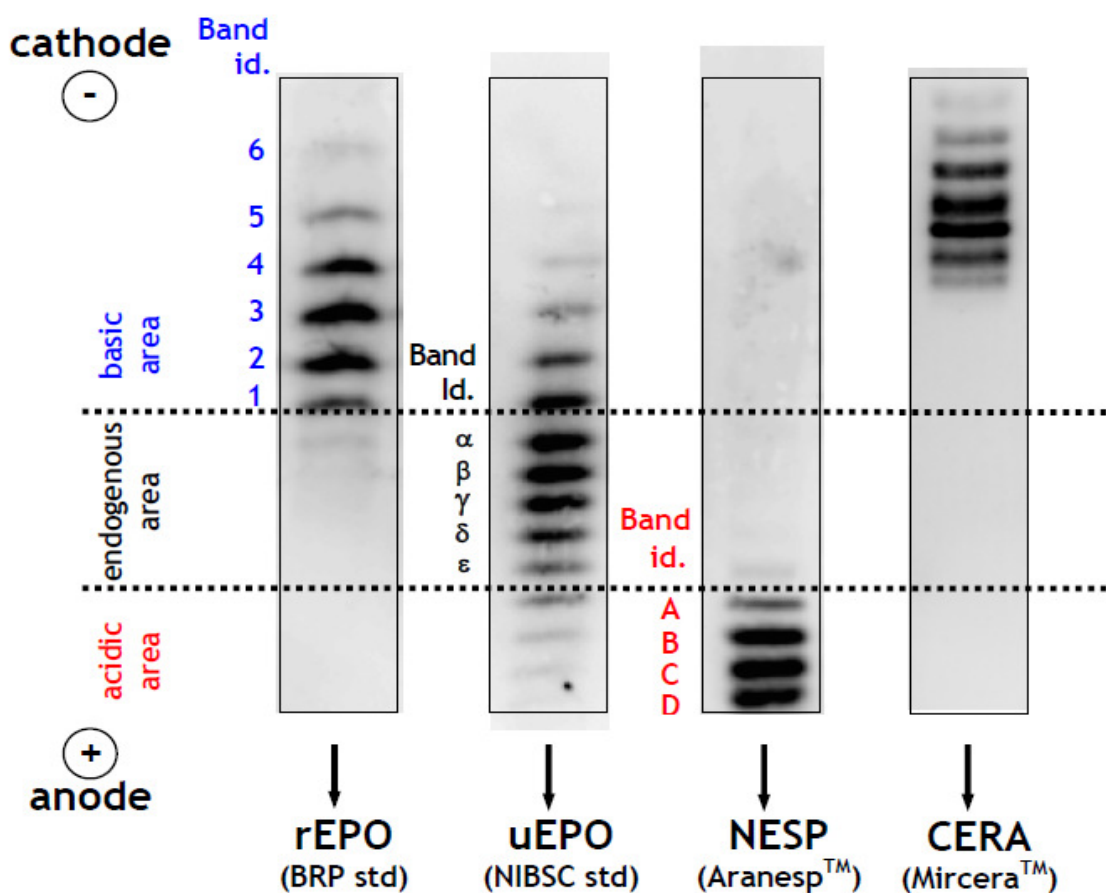
2. The period of Ineligibility imposed for a violation of Rules 32.2(a) (Presence of a Prohibited Substance or its Metabolites or Markers), 32.2(b) (Use or Attempted Use of a Prohibited Substances or Prohibited Method) or 32.2(f) (Possession of Prohibited Substances and Prohibited Methods), unless the conditions for eliminating or reducing the period of Ineligibility as provided in Rules 40.4 and 40.5, or the conditions for increasing the period of Ineligibility as provided in Rule 40.6 are met, shall be as follows:

First Violation: Two (2) years' Ineligibility.

- 6.5 WADA TD2009EPO states in relevant part as follows:

3. Evaluation and Interpretation of Results

Results from the Confirmation Procedure need to fulfil the quality, identification and stability criteria described herein. Figure 1 shows an illustration of a test result. The identification windows for each electrophoretic lane as well as the basic, endogenous and acidic areas are defined. Bands of the reference substances are identified by numbers and letters.



3.1 Acceptance criteria

The acceptance criteria define the requisites that the image shall fulfil to allow the application of the identification criteria in order to ascertain the presence of rEPO, CERA or NESP.

1. Spots, smears, areas of excessive background or absent signal in a lane that significantly interfere with the application of the identification criteria shall invalidate the lane.
2. Comparison to reference samples shall allow assignment of corresponding migrating bands in the athlete's sample.

3.2 Identification criteria

The following identification criteria define the requisites that the image shall fulfill to consider an Adverse Analytical Finding corresponding to the presence of rEPO, NESP or CERA.

3.2.4 METHOXYPOLYETHYLENE GLYCOL EPOETIN BETA (CERA)

In the basic area, there must be at least 4 consecutive bands corresponding with CERA reference substance.

3.3 Stability Criteria (applicable to urine *Samples* only)

Figure 1. Image of the identification windows of lanes obtained by the chemiluminescence acquisition system corresponding to the analysis of rEPO, CERA, NESP and uEPO.

The basic and acidic areas are defined, as described, by the position of the bands corresponding to the rEPO Biological Reference Preparation (BRP) of the European Pharmacopeia (equimolar mixture of epoetin alpha and beta) and NESP; by exclusion, the endogenous area is defined in between. In the figure the endogenous area is exemplified by uEPO (International Reference Preparation, IRP, from the National Institute for Biological Standards and Control, NIBSC, of UK). The bands of rEPO, uEPO and NESP in the basic, endogenous and acidic areas respectively, are identified by numbers and letters as shown. CERA shows a different pattern with some bands approximately co-localized with those defined by rEPO and others interspersed amongst rEPO bands. This band pattern specifically identifies CERA.

The evaluation of the image obtained is based on the consecutive application of:

- acceptance criteria;
- identification criteria;
- stability criteria.

3.3 Stability Criteria (applicable to urine *Samples* only) When, after applying the above identification criteria, a *Sample* is suspected of an *Adverse Analytical Finding*, the confirmation phase shall also establish the stability of the profile found or that the instability did not cause the *Adverse Analytical Finding*. Since it cannot be discounted that some rare factors may interfere with the stability of a urine *Sample* and may affect the interpretation of an *Adverse Analytical Finding* for EPO, a stability test shall be performed before reporting an *Adverse Analytical Finding* in urine (9).

[...]

The criteria to demonstrate stability are: 1. The method described above does not result in a substantial shift in the position of the bands or in the appearance of new band(s) in the

stability test lane compared to the reference standard lane(s) and; 2. The distribution of the most intense bands in the results of “A” Initial Testing Procedure, “A” Confirmation Procedure (and “B” Confirmation Procedure when available) is similar.

7. THE SUBSTANTIVE ARGUMENTS

The Appellant:

7.1 The Appellant’s argument is summarized as follows:

- The NAF Tribunal erred in confusing the quality of the tests and the interpretation of the test results and, as such, incorrectly concluded that Mr. Tysse’s doping tests were positive;
- The method used by the Rome Lab to detect CERA is unreliable nevertheless when interpreted correctly does not show the presence of CERA;
- The results from the Rome Lab do not meet the standards as set out in WADA TD2009EPO;
- All the disqualifying criteria set out in the WADA TD2009EPO are present in Mr. Tysse’s analytical test results:
 - In the lane attributable to Tysse, the IEF shows smears in the CERA area;
 - It was not until the fifth analysis (B sample no. 2) that the Rome Lab produced a band pattern that looked similar to what the TD2009EPO shows;
 - Consecutive bands corresponding with the CERA reference standard are absent;
- The Isoelectrofocusing (IEF) method used to analyze Mr. Tysse’s sample suffers from poor reproducibility:
 - Both tests of the A and B samples were initially negative;
- The SDS Page analysis that was performed on Mr. Tysse’s urine sample does not show the presence of CERA. The lane where the faint line shows up (that the Rome Lab concludes is CERA) is likely the EPO dimer;

- The SDS Page analysis was manipulated by the Rome Lab using the GASepo software in order to produce what looked like a positive result;
- An ELISA test ought to have been performed on Mr. Tysse's sample and had it been performed it would have shown the sample to be negative for CERA;
- The result of Tysse's test can be explained by the Cosmofer (iron) injection he received just prior to the doping control that took place in Italy;
- Mr. Tysse has a medical problem with proteinuria which causes the leakage of iron-rich proteins, it is likely these proteins caused the Adverse Analytical Finding ("AAF");
- Subsequent tests conducted on Tysse by his own expert reveal that almost all EPO was in the form of a dimer on day 3 after iron injection whereas it moved as a monomer on the sample from day 8.
- The EPO dimer that forms in Tysse's urine as a result of his proteinuria shows up in an IEF in the same location as CERA;
- Expert witnesses conclude that Tysse's sample does not contain CERA;
- The NAF Tribunal places too much weight on the practice of the laboratories, as opposed to what the TD2009EPO actually requires;
- The sample was unstable during storage;
- The Rome Lab's Documentation does not show how the samples were stored from the time the aliquot was taken out for EPO analysis on 3 May 2010 until the analysis of A-sample no. 1 took place on 7 May 2010. This applies for other samples as well;
- The iron injection received by Mr. Tysse prior to the sample collection had the effect of making his urine sample more unstable;
- The second opinion requirements in the WADA TD2009EPO are incomplete and WADA ought to require an additional analysis be performed on the sample, not merely a review of the analytical results from the original testing laboratory;
- There were several procedural errors at the Rome Lab including:

- The Rome Lab breached the quality control standards stipulated by WADA in ISL 5.2.4.3.1.4 when the analysis of the A-sample no. 2 was carried out on the retentate from A-sample no. 1;
- WADA's International Standard for Laboratories ("ISL") requires that the result of the analysis be reported to the relevant sports authority (in this case to the IAAF) within ten (10) working days;
- All subsequent doping tests performed on Tysse were negative;
- Tysse has stable sporting results and a stable blood profile;
- The strict liability standard present in the sporting regulations is unlawful according to the European Convention for Human Rights and principles of law established by the European Court of Human Rights.

The Respondents:

7.2 The Respondents' arguments are summarized below:

- The IEF method is a validated and reliable method for detecting rEPO and analogues;
- The journal articles quoted by the Appellant to discredit the IEF method suffer from fatal flaws;
- The IEF method for detecting CERA in urine is not new – it involves the same four procedures as detecting EPO. The internal validation for the method of detecting a new recombinant drug consists of establishing identification criteria for the substance and then checking to ensure the established criteria could not lead to false-positive findings. The identification criteria for CERA has been accepted by the WADA working group. The Paris Lab analysed 3,292 urine samples for the detection of EPO between 2000 and 2007 (before CERA was on the market) and no sample displayed the characteristic bands of CERA;
- The analytical data from the Appellant's sample was correctly interpreted and clearly meets the requirement of WADA TD2009EPO:
 - The Rome Lab rejected the first A sample screening and the first B sample confirmation analysis due to technical issues arising from the Rome Lab's internal procedures. They were not due to errors on the Lab's part – nor were they rejected because they were not positive;

- There were no spots, smears or areas of excessive background which significantly interfered with the bands in the A repeat screening, the A confirmation, nor the B repeat confirmation;
- The A confirmation shows a small area of absent signal at the more basic band but this does not invalidate the lane given that the bands are clearly visible;
- Four consecutive bands can clearly be seen in each case in both the 2 and 3D images;
- The CERA bands “correspond” with or are “in the same area” as the CERA reference substance;
- The authenticity of the data can be confirmed by comparison to the images in the full documentation packages;
- The GasEPO software that was used is an appropriate and validated tool for use in connection with EPO analysis. GasEPO software is used by practically all WADA-accredited laboratories which have the EPO detection method in place;
- GasEPO software is not mentioned in the WADA TD2009EPO because it would be inappropriate for WADA to promote a specific piece of software in one of its Technical Documents;
- The Appellant’s sample was stable during storage:
 - The internal chain of custody of the sample is intact. Dr. Botrè’s witness statement provides that the aliquots were properly stored at all times;
 - The correspondence between the results of the A and B steroid profile analyses conducted 45 days apart is further confirmation of this;
 - Stability tests conducted on the A and B samples gave clear results that excluded any evidence of instability;
 - Dr. Lasne and Dr. Gmeiner confirm in their respective reports that there is no evidence that the Rome Lab breached recommended procedures for handling and storage of samples;
 - There is no evidence that sample degradation could lead to an adverse analytical finding for CERA. On the contrary, any degradation would have been likely to destroy all of the sample;

- The SDS-Page analysis is not required to make a positive finding regarding the presence of CERA in a sample. The SDS-Page results are irrelevant and cannot contradict the clear evidence of an adverse analytical finding under the IEF method;
- In any event, Prof. Botrè, Dr. Gmeiner and Dr. Lasne maintain that the SDS-Page results are positive for the finding of CERA;
- As to the Appellant's arguments regarding the alleged breaches of procedures:
 - Section 5.2.6.5 of the ISL does not require that the result of the analysis be reported to the relevant sports authority within 10 days. Rather, the ISL recommends that laboratories report within 10 working days;
 - Section 5.2.4.3.1.4 of the ISL relates to a repeat of the A sample confirmation procedure and has nothing to do with the initial testing. The relevant section of the ISL regarding initial testing procedure on urine is section 5.2.4.2 and that section contains no provision concerning a repeat of the initial screening from a new aliquot of the A sample;
 - The Rome Lab conducted the analysis in accordance with the ISL and no ISL documentation or reporting requirements were breached. The Respondent relies on the witness statement provided by Prof. Botrè in making this point;
 - The provider of the second opinion in accordance with the TD2009EPO is not required to perform a second analysis of the sample before delivering an opinion;
 - There is no evidence to suggest that the Rome Lab was motivated by self-interest to find a positive result. The reporting of the AAF was supported by at least 3 other WADA-accredited laboratory directors;
- No conclusions can be drawn from the fact that the Appellant's sample given in a competition several days later did not give a positive result for CERA. The sample was held up in customs for more than 10 days and was unsuitable for analysis;
- No conclusions can be drawn from the fact that the Appellant did not have enhanced performance;

- The Appellant's blood profile is not inconsistent with the administration of CERA. Furthermore, the use of iron injections is also consistent with taking CERA.

8. THE PANEL'S FINDINGS ON THE MERITS

8.1 The issues this Panel must deal with are as follows:

- (i) Did the appellant commit a doping violation? The Panel must address the following questions:
- a. How is a CERA doping violation established pursuant to TD2009EPO?
 - b. Did the Appellant's iron injection cause the adverse analytical finding?
 - c. Are there any other issues or reasons which ought to nullify the results in this case?
 - i. The second opinion requirement.
 - ii. The failure of the Rome lab to present the test results within the prescribed time limit of ten (10) working days.
 - iii. Did the Lab breach the International Standards by analyzing the second A sample using retentate from the first A sample?
 - iv. Was there an issue with sample storage?
 - v. Was there poor quality control?
 - vi. Is IAAF Rule 32 in contravention of the European Convention for Human Rights?

a. How is a CERA doping violation established pursuant to TD2009EPO?;

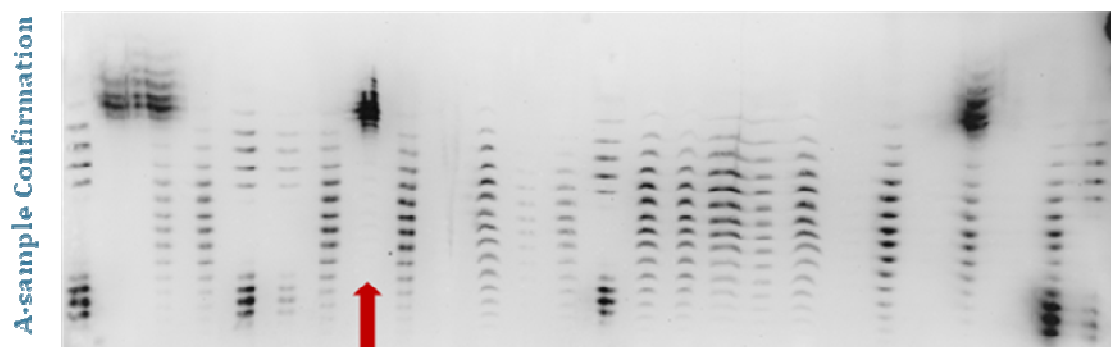
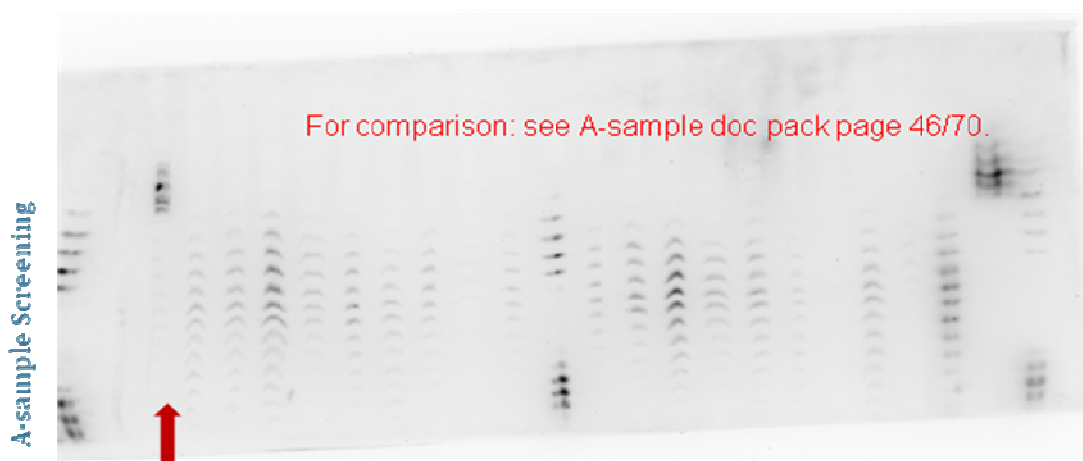
8.2 The Panel notes first and foremost that this case operated very much in parallel universes. While the Appellant and his experts concentrated on the results of the SDS Page analysis performed by the Rome Lab, the Respondents concentrated on the results of the IEF analysis.

8.3 The lab is required and, therefore, the Panel must look to, in determining this case, the applicable Technical Document and what it requires. TD2009EPO provides that the criteria presented therein has been established to ensure harmonization in the performance of the EPO test.

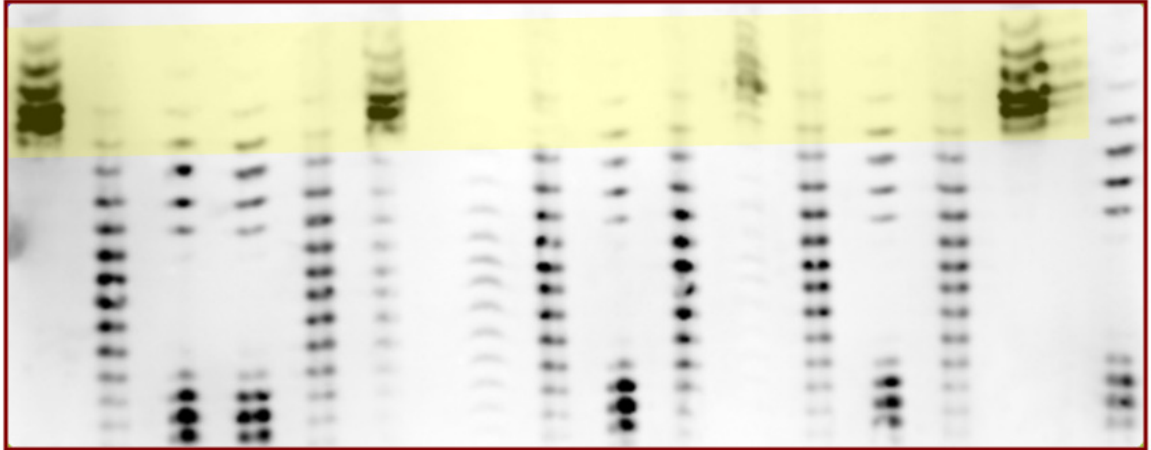
8.4 For the detection of EPO, and in this particular case, CERA, the IEF analysis must first meet the acceptance criteria - meaning there must be no spots, smears, areas of excessive background or absent signal in a lane that significantly interfere with the application of

the identification criteria. In comparing the reference samples, the lab must be able to assign corresponding migrating bands in the athlete's sample.

- 8.5 Once the analysis meets the acceptance criteria, which occurred here, the TD2009EPO requires that the lab apply the identification criteria. In the case of CERA the TD2009EPO states that in the basic area there must be at least 4 consecutive bands corresponding with the CERA reference substance.
- 8.6 Having then identified the 4 consecutive bands corresponding with the CERA reference substance, the lab, once it suspects an Adverse Analytical Finding in the confirmation phase, must perform a stability test on the sample.
- 8.7 In the case at hand, there are three final accepted analyses or determinations which were performed on the Athlete's sample; the A-sample screening, the A-sample confirmation and the B-sample confirmation. The gel images of the raw data are reproduced below.



B sample confirmation:



- 8.8 Applying the acceptance criteria, this Panel find that there are no spots, smears or areas of excessive background or absent signal, that “*significantly interfere* with the application of the identification criteria” in any of the above images. [Emphasis of Panel.] The Panel finds that the critical wording here is “significantly interfere”. While the IEF image and bands may not be perfect, the TD2009EPO does not require perfection. So long as any spots, smears, areas of excessive background or absent signal do not significantly interfere with the laboratory’s ability to apply the identification criteria, the lane is acceptable.
- 8.9 In reviewing these images for the identification criteria, the Panel finds that there are 4 consecutive bands in the reference area in each of the above images.
- 8.10 The experts for the Athlete submitted that “corresponding” meant in the science world identical. The Panel accepts that the definition of corresponding in TD2009EPO may not be what is the generally accepted definition of corresponding in the scientific community. However, the Panel accepts Dr. Rabin’s, Dr. Gmeiner’s and Dr. Lasne’s testimony as uncontradicted and that the definition of corresponding in TD2009EPO is “*in the area of*” the CERA reference substance for the analysis in question. Furthermore, TD2009EPO is clear that for CERA it is not necessary that the bands be corresponding with the assigned lanes, as is required for the detection of rEPO or NESP for example, rather it requires that there be correspondence in the “area” of the CERA reference substance.
- 8.11 The Athlete argues that the GasEPO analysis report was manipulated by the Rome Lab. The above images, which the Panel has reproduced is the raw data from the gel images.

Accordingly, the Panel finds that, even without the assistance of the GasEPO software, it is established that there is CERA in the Appellant's sample.

- 8.12 The Panel found the Appellant's experts' evidence on the SDS Page generally informative. However, it does not find that it is relevant in this case. What is relevant is the requirements in the applicable technical document (TD2009EPO). TD2009EPO provides that an SDS Page analysis may be performed when the profile is not consistent with a typical endogenous profile but does not fulfill the strict criteria defined in the TD2009EPO.
- 8.13 The evidence of the Respondents' experts is that an SDS Page for CERA would rarely be of use. Therefore, to the extent the SDS Page either did or did not confirm the presence of CERA, it is not determinative of whether or not CERA was present in the sample. By the Code the lab is bound to follow and apply, and the panel must apply the technical document which only requires SDS Page analysis in exceptional cases.
- 8.14 What does matter for the purposes of this case is what the TD2009EPO requires, whether it was followed, and whether the Appellant's sample met the requirements under the TD2009EPO. In this respect the Panel agrees with recent CAS jurisprudence which confirmed that once the identification criteria for exogenous EPO is satisfied "*following the application of the IEF-DB Method [...], an adverse analytical finding is to be declared and the application of the SDS Page Method becomes irrelevant, in fact even if applied, cannot contradict the adverse analytical finding to be reported with respect to a sample fulfilling the identification criteria.*"¹ The Panel finds that the acceptance criteria, the identification criteria, and the stability criteria are all met in this case.
- 8.15 Regarding the Appellant's general allegations that the IEF method for detection of CERA is not valid and is unspecific, the Panel find that the evidence submitted by the Respondents establishes that the IEF method is both valid and has a high degree of specificity. In making this finding the Panel relies on the evidence of Dr. Lasne regarding the extensive work that went in to establishing the test, and the steps taken to ensure the method was specific for CERA. Dr. Lasne's statement that no sample ever returned a positive finding for CERA where there was no CERA is compelling, as is the fact that prior to the development of CERA no analysis of a sample ever had results where bands appeared in the basic area of the CERA reference.

¹ CAS 2010/A/2041 *Yuliya Chepalova v. Federation Internationale de Ski*

8.16 Dr. Franke and Heid's evidence about the possibility of cross-reacting proteins from the IEF double blotting method cannot at this stage be considered reliable evidence. The Appellant's experts cannot point to one scientific study generally accepted within the applicable scientific peer group supporting this theory. For this reason, the Panel must reject this theory as implausible.

b. Did the Appellant's iron injection cause the adverse analytical finding?

8.17 The evidence of the Appellant's experts is not supported by any reliable evidence at this stage. The Appellant's experts have postulated a theory which, in their minds, could account for Tysse's adverse analytical finding but they have not even performed an IEF analysis on the Athlete's sample. Furthermore, it does not help the Athlete's argument in this regard that, given that he has been taking iron injections for many years, up to this point there has never been an adverse analytical finding resembling CERA in his samples provided in the past. As the Panel understands the Appellant's sister, who has the same medical condition, has received iron injections and has been an international race walker like her brother, has never tested positive in a doping test.

8.18 The Panel further finds that the medical records show no direct evidence that Tysse suffers from any kidney condition.

c. Are there any other issues which ought to nullify the results obtained in this case?

i. The second opinion:

8.19 Regarding the Appellant's arguments that the second opinion ought to include another lab performing a second analysis, the Panel rejects this argument. The Panel is not a drafter of rules. The job of this Panel is to review the accepted rules and regulations of WADA and the IAAF regarding doping violations and to apply them. This Panel is not the legislature and shall not take on this role. The TD2009EPO has been accepted by the doping community at large, and until it is shown that this document is in error, the Panel ought to consider it valid and reliable.

ii. Breach of International Standard 5.2.6.5:

8.20 The International Standard for Laboratories stipulates that the reporting of the A sample "should" occur within ten working days of receipt of the sample. Given the language of the document, this Panel finds that it is not a requirement. Furthermore, even if it were,

the burden is on the Athlete to establish, on the balance of probabilities that the departure from the International Standard could reasonably have caused the adverse analytical finding. The Panel does not find the Athlete has established this (see also the panel's statement in CAS 2010/A/2041 C. v/FIS, para. 173-174: "173. *The Panel finds that the deadline for the reporting of the A sample analysis' results is not strictly mandatory, since it can be extended by an agreement between the laboratory in charge of the analysis (in this case, IDAS) and the organization responsible for the sample testing and the management of the test results (in this case, FIS). At the same time, the Panel notes that FIS and IDAS agreed on the waiver of such deadline: FIS authorized the "cooperative analysis" with the Seibersdorf Laboratory; FIS and IDAS agreed to wait until the entry into force on 31 May 2009 of the (then) new TD2009EPO, in order to apply the identification criteria set forth therein. 174. The Panel therefore finds that the no breach of Clause 5.2.6.5 ISL has been committed"*

iii. Breach of International Standard 5.2.4.3.1.4

8.21 Regarding the alleged breach of section 5.2.4.3.1.4 of the ISL, the Panel accepts the argument of the IAAF that this section relates to a repeat of the A sample confirmation procedure and has nothing to do with the initial testing. As stated by the IAAF, the relevant section of the ISL regarding the initial testing procedure on urine is section 5.2.4.2 and that section contains no provision concerning a repeat of the initial screening from a new aliquot of the A sample.

iv. Sample storage

8.22 The Panel accepts the evidence of Prof. Botrè in this respect and finds that the internal chain of custody of the sample is intact and in compliance with the Standards for Laboratories. According to Prof. Botrè's uncontradicted statement, the only time that the samples or aliquots were at room temperature was during the routine preparatory steps such as aliquoting or loading of the test tubes for ultracentrifugation.

8.23 The Panel also accepts the evidence and finds as a fact that the stability tests conducted on the A and B samples gave clear results that excluded any evidence of instability.

8.24 Lastly, given that the Panel heard no evidence that sample degradation could lead to an adverse analytical finding, and in fact heard to the contrary from the Respondents' experts, the Panel rejects this argument.

- v. Poor Quality Control:
 - 8.25 The Appellant's general statement regarding poor quality control employed by the Rome Lab must be rejected. The Appellant does not particularize this claim, but rather makes a general accusatory statement in this regard.
 - 8.26 In response to this statement the Respondents' witness, Prof. Botrè, provides a detailed account of all procedures conducted on the Appellant's sample at the Rome Lab. Furthermore, Dr. Gmeiner, and Dr. Lasne, both having had an opportunity to review the laboratory documentation, confirm that the analyses were conducted in accordance with the applicable International Standards for Laboratories.
 - 8.27 In conclusion, and regarding any alleged breaches or departures in general, the Panel also notes that Rule 33.2 of the IAAF Rules provides that the laboratory is presumed to have conducted the analysis in accordance with the International Standards for Testing. The athlete may of course rebut this presumption, but must do so on the balance of probabilities. In each case, the Panel finds that the Appellant has failed to establish any departure on the balance of probabilities.
- vi. The strict liability standard in the IAAF Rules for doping violations is unlawful according to the European Convention for Human Rights
 - 8.28 The Panel finds that even if it were applicable, there is no violation of the European Convention for Human Rights. The No fault and No Significant Fault provisions in both the WADA Code and the IAAF Rules protect the athlete against any violation in this respect.
 - 8.29 In making this statement, the Panel further notes that the Appellant agreed at the end of this hearing that procedurally, his rights were heard.
- 9. (...)

ON THESE GROUNDS

The Court of Arbitration for Sport rules that:

- (1) The appeal filed by the Appellant Mr Erik Tysse on 16 February 2011 is dismissed.
- (2) The decision of the NAF Tribunal dated 31 January 2011 is hereby confirmed.
- (3) (...)

Lausanne, 29 August 2011

THE COURT OF ARBITRATION FOR SPORT

Dr Martin **Schimke**

President of the Panel

Prof. Richard H. **McLaren**

Arbitrator

Mr Lars **Halgreen**

Arbitrator

Ms. Erin **McDermid**

Ad hoc clerk