Arbitration CAS 2009/A/1931 E. & A. v. International Biathlon Union (IBU), award of 12 November 2009

Panel: Prof. Richard McLaren (Canada), President; Mr Efraim Barak (Israel); Mr Dirk-Reiner Martens (Germany)

Biathlon
Doping (recombinant EPO)
Definition of the International Standards for Laboratories (ISL)
Use of the most recent state of the art technology and knowledge
Duty of the accredited laboratories in applying the standards
No more requirement that a different analyst perform the analytical procedures
Principle of lex mitior

1. **The ISL is a mandatory level 2 International Standard developed as part of the World Anti-Doping Code (WADAC). The ISL includes requirements for WADA accreditation of doping laboratories, operating standards for laboratory performance and description of the accreditation process. Its main purpose is to ensure laboratory production of valid test results and evidentiary data. It is also intended to ensure that the accredited laboratories achieve uniform and harmonized results and reporting thereon. The ISL, including all Annexes and Technical Documents, is mandatory for all Signatories to the WADAC. The ISL is therefore not directly applicable to athletes but rather to the signatories to the WADAC.**

2. **The laboratories must always use the most recent state of the art technology and knowledge to identify prohibited substances and methods. The ISL is intended also to ensure that the accredited laboratories achieve uniform and harmonized results and reporting thereon. Therefore, the ISL ought to indicate that the use of the most recent state of the art technology and knowledge will be used in testing, particularly in a transitional period between use of an existing and effective TD and a replacing one.**

3. **It is the duty of the accredited WADA laboratories to be strict in meeting the requirements of the ISL and applying the standards.**

4. **The 2009 ISL removed the requirement that a different analyst perform the analytical procedures. The only requirement of article 5.2.4.3.2.2 in the 2009 ISL is that the "B" sample confirmation shall be performed in the same laboratory as the "A" sample confirmation.**

5. **The principle of *lex mitior* is generally understood to mean that, if the law relevant to the offence of the accused has been amended, the less severe law should be applied. Therefore, the principle of *lex mitior* relates more specifically to the applicable**

sanction and is not applicable to the technical rules underlying the scientific basis of the evidence.

The Appellants E. and A. (the "Athlete(s)" or the "Appellant(s)") are two international-level Russian biathletes, who are members of the national biathlon team of Russia.

The Respondent, the International Biathlon Union (IBU; the "Respondent") is the international federation governing the sport of biathlon.

The Appellants competed in December 2008 at the IBU Worldcup competitions held in Oestersund, Sweden. E. underwent an in-competition anti-doping test on 4 December 2008. She again underwent an out-of-competition anti-doping test, as did A. on 5 December 2008.

The "A" Samples were analysed in December of 2008. Adverse Analytical Findings ("AAF") for recombinant EPO ("rEPO") from the above tests were reported to the IBU on 28 January 2009 by the WADA-accredited laboratory in Lausanne (the "Lab"). A second opinion had been given by the director of the WADA-accredited laboratory in Vienna (the "Vienna Lab"), Dr. G. Gmeiner on 13 January 2009 and confirmed the presence of rEPO for each Athlete's sample. The Athletes requested the analysis of their "B" samples. Opening of the "B" samples took place on 10 February 2009 and on 12 February the Lab confirmed the presence of rEPO in all "B" samples. The reports for both the "A" and "B" samples state that: *"the isoelectric profile of this sample shows the presence of recombinant EPO"*.

The "A" sample analyses were performed by Ms Lamon, an analyst at the Lab. She also prepared the retentates extraction for the "B" samples analysis; as well as immunoaffinity urine purification. These procedures in the Lab involve several direct interactions to be carried out with an open sample aliquot.

The IBU imposed provisional suspensions on each athlete on 4 February 2009. Both matters were referred by the IBU to its Doping Hearing Panel (the "DHP").

Lab documentation packages for the "A" and "B" samples were released on 10 March and 3 March 2009 respectively. On 6 May 2009, the Lab sent a letter to the IBU informing it of a mistake within the laboratory documentation packages of various samples. An *"erratum"* to the Lab documentation packages for the "A" samples was enclosed in a letter of 6 May 2009 from the Lab.

The hearings before the DHP were held on 8 May 2009. A separate decision was issued in each athlete's case on 11 August 2009. Both Athletes were found to have committed a doping offence and two year suspensions were imposed on each commencing on the date of the tests.

The DHP applied the 2006 IBU Disciplinary Rules as amended in September 2008 (the "2006 DR") and the 2006 IBU Anti-Doping Rules as amended in September 2008 (the "2006 ADR"). The

parties' counsels agree that the 2006 rules are the applicable ones in force at the time of the taking of the samples. Therefore, the 2006 DR and 2006 ADR are the rules applied in this appeal.

The IBU has initiated a blood testing program to *"safeguard athletes' health and ensure fair competition"*. The program consists, amongst other things, of pre-race testing for athletes with the possibility of suspension from competition for those athletes whose haematocrit values exceed 52% for males and 48% for females. The blood profiles of each athlete as taken from the IBU data bank were compiled in chart format and filed with the Panel.

On 13 August 2009, the Athletes filed their Statement of Appeal with the Court of Arbitration for Sport (CAS) and on 1 September 2009 filed their Appeal brief. The Appeal is therefore timely. The Athletes request the following relief:

i) The decision issued on 11 August 2009 by the IBU Doping Hearing Panel in the matter of E. is set aside;

ii) The decision issued on 11 August 2009 by the IBU Doping Hearing Panel in the matter of A. is set aside;

iii) E. and A. are cleared from all charges brought against them in connection with the anti-doping tests, which took place on 4 and 5 December 2008;

iv) All the arbitration costs, if any, shall be borne by the International Biathlon Union, which shall in any event reimburse the Court Office fee of CHF 500 to E. and A.; and

v) The International Biathlon Union is ordered to pay to the Appellants E. and A. a contribution towards their legal and other costs relating to these proceedings, in an amount to be determined at the discretion of the Panel.

On 22 September 2009, the Respondent IBU filed its Response Brief requesting that:

i) the Appeal shall be dismissed in its entirety; and

ii) the Appellants shall bear the costs of this arbitral proceeding and contribute an amount to the legal costs of the Respondent according to article R64.5 of the Code of Sports Related Arbitration.

On 15 October 2009 a hearing was held at the CAS offices in Lausanne, Switzerland.

In addition to their written submissions, the parties examined and cross-examined the expert witnesses by way of a witness conference. The witness conferences served to clarify many issues for the Panel. In that respect, the Panel finds it important to point out the following:

- It was agreed by all experts and parties that the blood profiles submitted by the Respondent as an exhibit could not be used as evidence of a doping violation, but rather could only be used in support of a decision to target test the Appellants.
- The laboratory documentation package that was provided to the Appellants and the Panel was insufficient, in terms of its inclusion of the criteria used to interrupt the images produced and support the conclusion of an AAF.

- Dr. Saugy and Dr. Gmeiner testified that there was no need to undergo further testing of the samples, or to demonstrate how the lab identified the bands, because all the bands were in the basic area and when compared to the positive and negative controls, it is very clear that the substance was of exogenous origin. Dr. de Boer did not deny this salient fact.

LAW

Jurisdiction of the CAS

1. Article R47 of the Code of Sports-related Arbitration (the "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.

   An appeal may be filed with the CAS against an award rendered by the CAS acting as a first instance tribunal if such appeal has been expressly provided by the rules applicable to the procedure of first instance".

2. The parties agree that the decision of the DHP, who replaced the Executive Board of the Respondent as the responsible body for imposing sanctions in doping matters, had jurisdiction to hear the disputes at first instance and issue the decisions appealed in this matter.

3. The jurisdiction of CAS to hear these appeals is not contested by either Party.

Admissibility

4. The parties through their counsel agree that the appeal is admissible. No issue is taken as to the admissibility of the appeal.

Applicable Law

5. Article R58 of the 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. The parties agree that the date of the taking of the sample is decisive of which rules shall apply to the matter and as such, the 2006 DR as amended and the 2006 ADR as amended are applicable to this appeal. The parties disagree as to which International Standards for Laboratories (ISL) and as to which WADA Technical Document on EPO are to be applied. They also disagree as to the application, if at all, of the principle of *lex mitior*. In that regard, it is submitted by the Appellants that: if the 2009 ADR contains rules more favourable to the Appellants than the ones provided for under the 2006 DR and the 2006 ADR; then, the Panel should apply the more favourable rules in determining the case at hand.

7. Article 6.1 of the 2006 ADR provides that only WADA accredited laboratories are to perform analysis of samples under the IBU doping controls. It further provides that: *"these Laboratories will analyze Doping Control Samples in conformity with the current International Standard for Laboratories Analysis (with revisions published by WADA on a continuous basis) and report the results accordingly"* (underlining is that of the Panel). The ISL is a mandatory level 2 International Standard developed as part of the World Anti-Doping Code (WADAC). The ISL includes requirements for WADA accreditation of doping laboratories, operating standards for laboratory performance and description of the accreditation process. Its main purpose is to ensure laboratory production of valid test results and evidentiary data. It is also intended to ensure that the accredited laboratories achieve uniform and harmonized results and reporting thereon. The ISL, including all Annexes and Technical Documents, is mandatory for all *Signatories* to the WADAC. The ISL is therefore not directly applicable to athletes but rather to the signatories to the WADAC defined as:

"Those entities signing the Code and agreeing to comply with the Code, including the International Olympic Committee, International Federations, International Paralympic Committee, National Olympic Committees, National Paralympic Committees, Major Event Organizations, National Anti-Doping Organizations, and WADA".

8. The IBU is a signatory to the WADAC. As a signatory, it is required to comply with the ISL which by its anti-doping rules in Article 6.1 of the 2006 ADR the IBU indicates it will do. This entire structure and process was further elaborated upon in the testimony and exhibit of Dr. Olivier Rabin, Science Director for WADA.

9. The samples that are the subject of this award were all obtained in 2008. As stated above, the date of the taking of the samples is decisive for the determination of the anti-doping rules and for regulations applicable to the athletes, such as the Prohibited List. The "A" samples were analysed in December 2008. Accordingly, Article 6.1 of the 2006 ADR made the ISL 2008

applicable to the analysis of the "A" sample. The "B" samples were analysed in February 2009. By that time, version 6 of the ISL known as ISL 2009 had been issued by WADA with effect from 1 January 2009. Given the dynamic provisions of Article 6.1 of the 2006 ADR ISL 2009 is to be applied by the laboratories immediately on taking effect.

10. The ISL 2009 represents a revision published by WADA and is within the bracketed and underlined wording of Article 6.1 of the 2006 ADR outlined above. Therefore, the ISL 2009 is the applicable ISL for the "B" sample analysis carried out by the Lab, contrary to the submissions of the Appellants. No case was provided by the Appellants that the outdated version ought to be applied because the ISL 2009 introduced a technical change, which in the words of Dr. Rabin, *"… may affect the consistency of the analysis method and therefore the comparability of the results* [in this case of the "A" & "B" samples] *may be influenced"*.

11. The International Standards bring with them companion documents known as Technical Documents (TD) which are relevant to the laboratories in the fight against doping. The WADA accredited laboratories are constantly adjusting to take the most recent developments and product into account when designing and applying the analytical procedure for the detection of Prohibited Substances. EPO has been on the Prohibited List for some years and the initial TD for EPO was based on analysis and reporting of EPO-α, EPO-β and NESP. The TD applicable to the analysis of these substances was reflected in TD2007EPO. The expiration of the patents for these substances brought with it a rapid development of new products and methods. The Panel is advised that there are presently some 80 different variations of this substance available on the market many of which are not produced by the regulated pharmaceutical industry. These developments necessitated the writing of a new TD.

12. The rEPO alleged to be in the samples in this case is a biosimilar form of EPO. For these newer variations of the substance, a technical document TD2009EPO was issued dated 1 April 2009 with effect from 31 May 2009. That document had been in the development stages for all of 2008 and Dr. Saugy, the Director of the Lab and Dr. Gmeiner, an expert for the Respondent and provider of the second opinion, were instrumental in developing the analytical techniques and writing the TD. They were therefore well versed in its contents both in the draft stage and in its published form. The accredited laboratories were in transition from the use of TD2007EPO to TD2009EPO at the time of testing the Athletes' samples in this case. But TD2009EPO had not become effective when the "A" samples were analysed in December 2008; nor, when the "B" samples were analysed in February 2009. The TD2009EPO is not applicable because its effective date is after the "B" sample was analysed. However, it was Dr. Rabin's opinion in his testimony that the laboratories must always use the most recent state of the art technology and knowledge to identify prohibited substances and methods. As a result of the involvement of Dr. Saugy and Dr. Gmeiner in the drafting of the TD, the Lab and the Vienna Lab were very familiar with the contents of what ultimately became TD2009EPO even though it had not come into effect at the December 2008 and February 2009 dates of analysis. The ISL is intended also to ensure that the accredited laboratories achieve uniform and harmonized results and reporting thereon. Therefore, it is the opinion of this Panel that the ISL ought to indicate that the use of the most recent state of

the art technology and knowledge will be used in testing, particularly in a transitional period between use of an existing and effective TD and a replacing one.

Merits of the Appeal

13. This is the first case of biosimilar EPO to have been heard and decided by the CAS. From the witness conference, the Panel learned that the application of the method to detect rEPO has not changed from TD2007EPO to TD2009EPO. The direct urinary test description of the method in the two TDs is substantially the same. The method involves four procedures: sample preparation; isoelectric focusing; double blotting; and chemiluminescent detection. Therefore, the description of the laboratory method as described in CAS 2002/A/397, CAS 2002/A/370 and CAS 2002/A/374 cases with the refinements discussed in CAS 2005/A/679 are still applicable. The test for rEPO is valid and reliable there being no change regarding the application of the method for rEPO in comparison to the test when used for the detection of other forms of EPO such as darbepoetin (Aranesp).

14. The challenge for biosimilar EPO detection comes in the *"Evaluation and Interpretation of Results"*. TD2007EPO provides that the evaluation of the image obtained by the method is based upon the consecutive application of the following criteria: *"acceptance, identification and stability"*. It is the identification criterion that is provided for in the TD2009EPO by reference to 3.2.2. *"Other Epoetins"* which is new and relates to biosimilar rEPO. That section of the document reads as follows:

> *"1. In the basic area (as defined in Figure 1) there must be at least 3 acceptable, consecutive bands;*
>
> *2. The 2 most intense bands measured by densitometry in the basic area must be consecutive;*
>
> *3. The sum of the intensity of all bands in the basic area, must account for approximately 85% or more of the total intensity of the bands within the window of the sample lane; or,*
>
> *Additional Evidence, as described in the section 3.2.5 below, must be obtained confirming the presence of an exogenously produced EPO".*

15. Each of the three criteria listed must be satisfied. The problem in the confirmation of biosimilar EPOs is the lack of reference materials. There is no "standard" available to compare the signal of a suspect sample with that of a "reference positive" one. In this particular case, the rEPO that was detected was unknown to the laboratory and as such, they were only able to compare it with other more well-known forms of biosimilar EPO. In this case, Dr. Gmeiner stated in his second opinion that the profiles significantly departed from the profile known to be of endogenous origin and that the results correspond with profiles known from biosimilar forms of recombinant erythropoietin deriving e.g. from BHK cells (BHK is an abbreviation of Baby Hamster Kidneys) or "Chinese Erythropoietin".

16. Dr. De Boer makes the point that as an independent observer he cannot judge the images based merely on the TD requirements. He claims to be a "competent analyst" and asserts that the Lab documentation and reporting does not meet the requirement of article 5.2.6.1 of the ISL 2008 in that the record provided by the Lab does not enable a competent analyst to

"… evaluate what test had been performed and interpret the data". He is not privy to the WADA accredited laboratories internal discussions which assist Dr. Saugy in making his identification.

17. Dr. Gmeiner stated there was sufficient data that *"it gave a picture that is complete enough"*. He testified that his laboratory published in January 2009 information comparing different types of biosimilar EPOs. That publication could be downloaded from the internet and was available for an experienced person to use as a comparison in interpreting the data in the Lab Report. Both Dr. Gmeiner and Dr. Saugy agreed that the reference criteria applied could have been included. The Panel notes that there is room for improvement in the future in the aspect of meeting the "Documentation and Reporting" aspects of the ISL. It is not only expected but it is the duty of the accredited WADA laboratories to be strict in meeting the requirements of the ISL and applying the standards. However, in the specific circumstances of this case, that, by itself, is no reason to find that there is not an AAF.

18. During the witness conference when examining the images produced by the Lab, Dr. Gmeiner examined various images on the screen in the hearing room and observed that *"there is no endogenous EPO visible and the endogenous bands are available only very faint in other profiles"*. Dr. Saugy confirmed this interpretation. Dr. Gmeiner in his second opinion analysed the raw data from the Lab and confirmed the conclusion reached by the Lab with print outs on his own computer. The Panel is satisfied that the isoelectric profiles of the samples reveal the presence of rEPO; and, therefore, there was an AAF in respect of all samples. The presence of rEPO in the samples is established.

19. The Panel's conclusion that an AAF has been established means that there is a violation of the 2006 ADR in s. 1.2.2 in that the Athletes had a Prohibited Substance in their urine specimen. That conclusion means there is a doping infraction under the 2006 ADR unless there are any other defenses set out below that either upset or alter this conclusion.

20. The foregoing conclusion answers the core of the Appellants submissions on appeal and in particular that the Lab failed to analyse and report in conformity with the 2008 ISL and related TDs. The Appellant also make the following arguments in this matter:

    A. There were several departures from 2008 ISL in three areas:
        - Violation of article 5.2.4.3.2.2 of 2008 ISL,
        - Failure to apply criteria provided under TD2007EPO and related violation of article 5.4.4.1.1 of 2008 ISL,
        - A mixing up of samples by the Lab.

    B. Other departures from the ISL and the TDs:
        - Violation of article 5.3.9 of 2008 ISL and TD2003LDOC,
        - Violation of article 5.2.6.5 of the 2008ISL,
        - Violation of TD2007EPO- lack of clarity of the results,
        - Violation of TD2003LDOC- lack of data related to "positive" control samples,
        - Violation of article 5.4.6.1 of the 2008 ISL,
        - Further Issues.

A. Departures from 2008 ISL in three areas

a) Article 5.2.4.3.2.2

21. The Appellants assert that the same analyst cannot perform sample analytical procedures in the "A" and "B" sample analysis. The Respondent does not contest that this occurred. See the discussion of the Factual Background above.

22. Article 5.2.4.3.2.2 of the 2008 ISL provided that a different analyst than the "A" sample analyst must perform the analytical procedures on the "B" sample during the period when the sample is open and accessible. In this situation had that rule been in effect, there may have been a violation. However, the "B" sample was not analyzed until February 10 through 12, 2009. As a consequence, the 2009 ISL standard applied to the "B" sample analysis. As prescribed by Article 6.1 of the 2006 ADR, the accredited laboratories are obliged to apply the standards currently in force at the time of the analytical procedure to be performed on a sample. As discussed in the Applicable Law section of this award, the 2006 ADR also required the application of the ISL 2009 because of the dynamic reference in Article 6.1. The 2009 ISL removed the requirement that a different analyst perform the analytical procedures. The evidence of Dr. Rabin provided that *"… experience has demonstrated that the separation of staff did not add to the correctness and accuracy of the analysis, as well as to adhere to rules in force in other international accreditation bodies"*. It was also his opinion that the separation of staff was not a technical change which might have required the application of the ISL 2008. The only requirement of article 5.2.4.3.2.2 in the 2009 ISL is that the "B" sample confirmation shall be performed in the same laboratory as the "A" sample confirmation. That obligation is complied with. Therefore, there is no violation of the applicable ISL.

23. The Athletes have therefore failed to establish that there was a violation of the 2009 ISL. For the reasons stated above, there is no need to determine whether the 2008 ISL was violated as it was not the applicable document for the "B" sample analysis. It is further noted that the case law cited (TAS 2006/A/1119; AAA 30 190 0019907 and FINA Doping Panel 1/07) being applicable to the language in the ISL in 2008 and earlier is no longer applicable to the issue under the 2009 ISL.

24. Furthermore, the submission that the principle of *lex mitior* applies to the two ISLs is unfounded. Firstly, the Panel finds that this principle relates more specifically to the applicable sanction and not the technical rules underlying the scientific basis of the evidence. The principle of *lex mitior* is generally understood to mean that, if the law relevant to the offence of the accused has been amended, the less severe law should be applied. However, even if the principle did apply to more than the sanction, it would be impossible here to determine which is the more favourable ISL. In this case, the rules of the 2008 ISL provide the Appellants with a basis on which to argue that the ISL was breached but if the 2009 ISL is applied there is no basis for the same argument. Such a situation does not make the 2008 ISL more favourable. The 2009 ISL was not breached. It simply cannot be the intent that this rule would allow an

accused to afford itself of the more favourable science. Applying such an argument to a criminal case would be tantamount to requiring the court to find an accused innocent of a crime, even if the DNA proves the accused is the culprit simply because the crime was committed prior to the availability of DNA testing. This Panel finds that this simply cannot be the case.

b) Failure to apply criteria under TD2007EPO and article 5.4.4.1.1 of 2008 ISL

25. A technical document on erythropoietin ("EPO") was published by WADA in the form of TD2007EPO. The purpose of technical documents ("TD") is to ensure harmonization of the methods for identification, reporting and analyzing within WADA accredited laboratories. In the EPO TD, the purpose is to establish a uniform or harmonized method for the identification of recombinant erythropoietins and analogues. It is submitted on behalf of the Appellants that the samples do not meet the identification criteria provided by that TD. The Respondent asserts that the referenced TD is not the correct one.

26. TD2007EPO which the Appellants seek to rely upon does not deal with the most recent mutations of the Prohibited Substance rEPO and how to test for them. TD2007EPO applies only to the identification of epoetin alfa and beta and darbepoetin alfa (NESP). The prohibited substance that is the subject matter of this hearing is not one of those substances. As such, the Panel finds that TD2007EPO is not, and simply cannot be applicable. Dr. Rabin also testified to this fact in his testimony at the hearing.

27. At the time the samples were received and analysed by the Lab, WADA was in the midst of developing new testing procedures for biosimilar EPO. At the forefront of drafting those developments was Dr. Saugy, the Lab Director in Lausanne, and Dr. Gmeiner, the Director of the Vienna Lab. They were two of the six authors of what would become TD2009EPO. Thus, the Lab used its special knowledge of the forth coming but as yet unpublished details of TD2009EPO to test the samples.

28. WADA requires that a second opinion be provided by one of the authors of the EPO TD before any AAF for rEPO or one of its analogues is reported. The Vienna Lab provided this opinion. Dr. Gmeiner, equally familiar with the evolving technical document, took the Lab raw data and reproduced the results to determine if there was an AAF. The Vienna Lab confirmed the findings. Therefore, the Lab fulfilled its mandate to apply the most recent state of the art technology to its analytical work in detecting rEPO. It should be noted that the original EPO cases that arose out of the Salt Lake City Winter Olympics had no TD because the substance was being discovered and how to test for it was evolving during the games. See discussion in CAS 2002/A/370, CAS 2002/A/374 & CAS 2002/A/400.

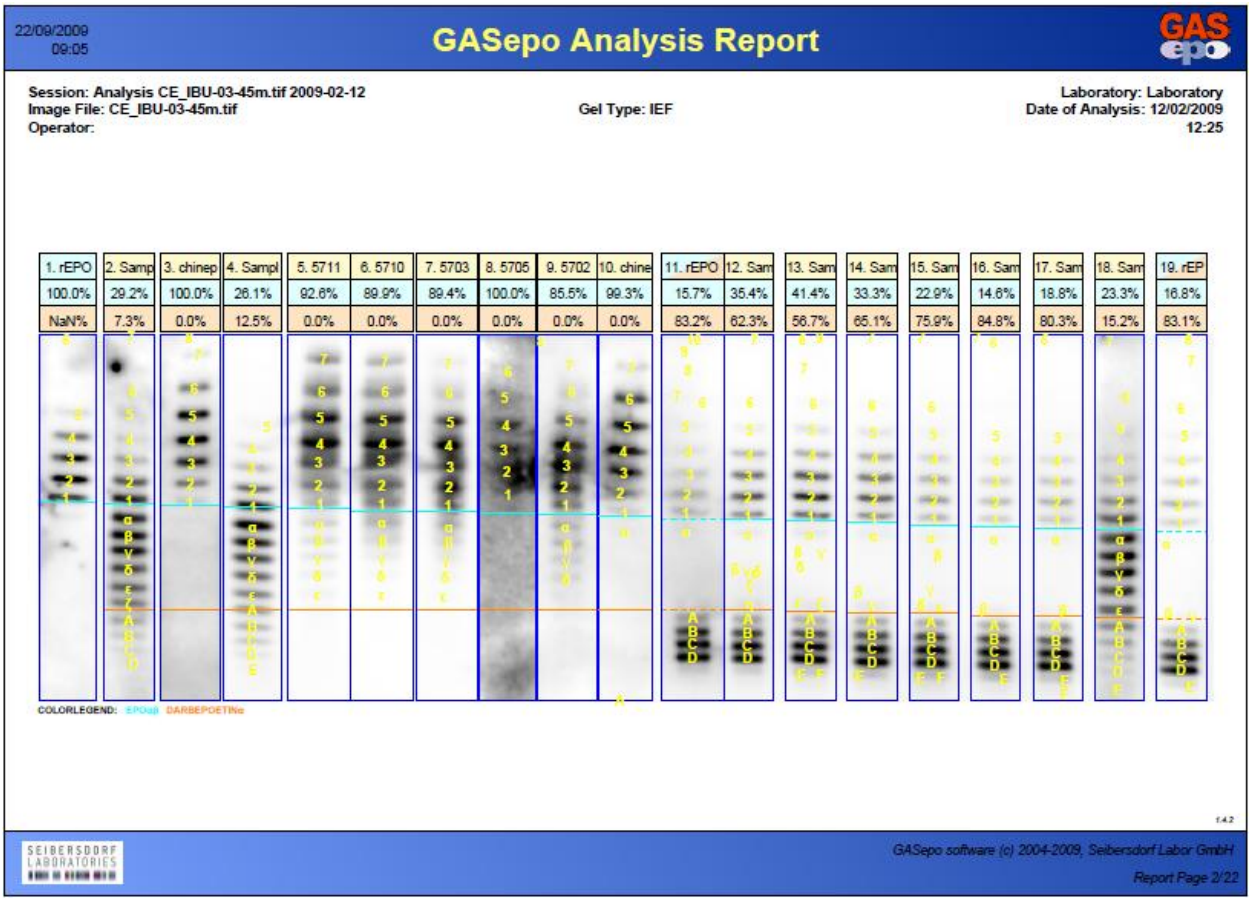
29. Despite the fact that TD2009EPO had not been proclaimed into effect, the Panel was able at the time of the hearing to ask the experts to apply that document to the various exhibits provided. The result is undeniably an AAF. The criteria for *"Other Epoetins"* are set out at section 3.2.2 as referenced above.

30. The exhibit submitted and reviewed in its electronic format at the hearing with the assistance of the parties' experts clearly establishes that 100% of the bands are in the basic zone on the isoelectric profile. The third criterion requiring merely 85% is thus overwhelmingly met. Dr. Saugy is of the view that such an image is not in conformity with endogenous EPO. Dr. Gmeiner opines that if another of the criteria is not completely met, it does not make the sample a negative one. Both Dr. Gmeiner and Dr. Saugy testified that as long as the global image fits the criteria that is sufficient. As described by the experts at this hearing, this also clearly establishes that the rEPO detected was exogenous. Dr. de Boer provided no evidence to the contrary. Thus, even though the second criteria, namely that the two most intense bands measured by densitometry in the basic area must be consecutive, is not completely met, such circumstance does not prevent the Panel to rely on the convincing evidence provided by Dr. Saugy and Dr. Gmeiner to conclude that the samples of the Athletes clearly establish an AAF.

31. The issue to be determined is whether the results reported reveal the presence of a prohibited substance, namely, exogenous EPO. The results did not demonstrate the presence of a classical 'first generation EPO' as discussed in TD2007EPO, but rather a copy EPO form molecule (biosimilar) that corresponds to a standard form of Chinese origin in terms of bands distribution and intensity. Because they were unknown at the time, this new molecule, as well as many other new copy-EPOs, had not been taken into account when the original TD2007EPO was drafted.

32. TD2009EPO is the replacement technical document for TD2007EPO and represents the state of the art at the time of publication of the testing for the wide variety of erythropoietin known as recombinant rEPO, a generic term. The second opinion provided by Dr. Gmeiner confirms the Lab's finding of rEPO. In his first opinion of the "A" samples, Dr. Gmeiner states that the samples *"significantly depart from the profiles known to be of endogenous origin. It* [the sample] *corresponds with profiles known from biosimlar forms of recombinant erythropoietin deriving e.g. from BHK cells"*. Dr. Gmeiner, in his second opinion of the "B" samples finds that they confirm the results of the "A" sample testing, as the profiles again *"significantly depart from the profiles known to be of endogenous origin"*. He further elaborates that *"the profiles of all samples correspond to the profiles of biosimilar forms of recombinant erythropoietin deriving e.g. from «Chinese Erythropoietin»"*.

33. The AAF is best demonstrated by placing the supporting *"GASepo Analysis Report"* of the Vienna Lab in this award. Below is the information clearly establishing that there is no ambiguity about the analytical results establishing that the rEPO is exogenous being 100 % in the basic area.



34. The sample numbers attributed to the Athletes are 5710 (lane 6), 5703 (lane 7) and 5705 (lane 8). From the above image it can be seen that they are remarkably similar to the reference band for Chinese EPO (lane 10).

35. The Athletes submit that the reference in the Lab documentation and second opinion documentation indicating a finding of rEPO is misleading because the only published criteria is TD2007EPO which has identification for what might be described as "classical" EPO but not biosimilar rEPO. Indeed a better description of the analytical finding might have been undertaken, and the notes of the Panel above in paragraph 17 are also applicable to this insufficient description. However, it does not affect the conclusion that the Lab found a Prohibited Substance. To the extent that the Appellants' expert found the Lab documentation deficient or lacking in explanation, he had through the counsel, the power to obtain production of other information. This power was never exercised. Rather, Dr. de Boer comes to the hearing stating he cannot confirm the final conclusion because of a deficiency in the Lab package. While admitted by both experts for the Respondent that sufficient information to support the finding was not included in the laboratory documentation package provided to Dr. de Boer, the Panel finds that this did not affect the chemical analytical conclusions nor cause the AAF this case. The argument is therefore rejected.

c) Mixing-up of the Samples

36. The Appellants challenge the chain of custody within the laboratory as it is identified in the laboratory documentation packages. The fundamental purpose of this stringent requirement is to ensure that the sample analysed is that of the athlete accused of having committed a doping infraction. There is no breach of the chain of custody up to the arrival of the sample at the Lab.

37. The Appellants seek to rely on a letter dated 6 May 2009, written by the Lab to the IBU to clarify what the Lab stated was an *"unfortunate mistake"*. At page 30 of the laboratory documentation package, the marking of the lanes of routine samples was not properly done. The Lab therefore sent a corrected version, stating that the mistake had no impact on the results obtained, and that it was merely a typographical error.

38. The Appellants state that they could have accepted this error had it not been for the fact that the amendments included by the Lab in this package remained inconsistent with other pages of the "A" sample documentation packages. However, they point to the fact that lane 10 of the gel that was identified as sample 5706, was identified in the previous laboratory documentation as 5766. For several reasons, the Panel dismisses this argument in its entirety.

39. Firstly, the Panel finds, contrary to the Appellants position, there was no mixing up of the samples. The error was in fact merely typographical and was confirmed by Dr. Gmeiner. Secondly, the Panel does not find that any other errors contributed to the overall reliability of the results. The Panel finds that while the 5706 may look like 5766, this is simply a case of poor handwriting and the number is in fact 5706. Furthermore, sample 5706 is attributable to neither Appellant in this case and as such cannot but used to create a false argument as to the reliability of the results.

40. The Appellants pointed to several other alleged departures from the ISL and the technical documents in support of their argument that the results of the laboratory should not be relied upon.

B. Other Alleged Departures

41. Article 5.3.9. of the 2008 ISL and of the TD2003LDOC provides that *"[i]f the gels are prepared the same day, let them polymerise for at least 2 hours at room temp"*. It is the position of the Appellants that the lab documentation packages demonstrate that the gels were not prepared in accordance with this requirement. However, upon careful examination of the laboratory documentation, the Panel finds that it is clear that the polymerization of the gels lasted at least 2.25 hours. As pointed out by the Respondent, what in fact happened earlier were simply the unfreezing and the preparation of both retentates and standards which related to the samples and standards only, and not the gels.

42. The Appellants argue that the Lab was in violation of Article 5.2.6.5 of the 2008 ISL which provides that the reporting of the "A" sample results *"should occur within (10) ten working days of receipt of the Sample"*. The report on the "A" sample from the Lab took more than 30 working days. The Panel finds however that the language in this section is permissive and that while it may be ideal to have the results reported within that timeframe, it is not always possible, or even advisable. There is, therefore, no departure from the 2008 ISL, such that it could have caused the AAF, or even contributed to it.

43. The Appellants also assert a violation of TD2007EPO due to a lack of clarity of the results. In particular, the Appellants point to five (5) different examples where the image of the sample is unclear. While the Panel agrees that the photocopies of the exhibits are in fact unclear, and would appear to perhaps be in violation of the relevant technical document, these images are merely photocopies and it is not the photocopies which form the basis of the Lab's or the Vienna Lab's conclusions. It was for this reason that the parties were requested to bring the electronic copies of the images to the hearing for all to see and examine on a large screen during the witness conference.

44. The Panel also dismisses the Appellants arguments that the Lab was in violation of TD2003LDOC due to a lack of data related to "positive" control samples. The fact of the matter is, rEPO was detected in the Appellants' systems, by a reliable testing mechanism. Unfortunately, in this case rEPO is a new biosimilar form of EPO that is neither recognized nor approved by the Food and Drug Administration in the United States, nor by the European regulatory authorities. As such, at this stage, there is no viable mechanism available to generate positive controls-excretion studies. The testimony of Dr. Gmeiner was truly helpful in demonstrating the similarities between rEPO of exogenous origin and EPO of endogenous origin. Dr. Gmeiner testified that identification of the sample as exogenous is only possible at this time by way of comparison to other known biosimilar forms.

45. Likewise, the Panel rejects the Appellants' argument that there was a violation of article 5.4.5.1 of the 2008 ISL regarding the certification of the reference materials. This was not a classical form of rEPO. However, as clearly demonstrated in the exhibit reproduced above at paragraph 33, the profile of the Appellants' "A" and "B" samples so clearly resembled a standard form EPO, that there was no need for further testing, and in fact there was no way to further identify the substance.

46. Lastly, the Panel discards the Appellants position that the laboratory should have provided information with regard to the time which elapsed between the moment the Appellants ceased to perform in the competition and the time of sample collection. If the Appellants wished to demonstrate that there is some relevance to this issue, and its relation to the reliability of the results, they should have provided this information to the Panel. The burden is on the Appellants to demonstrate that the positive findings in their cases were due to or attributable to their recent physical efforts. No evidence was provided to the Panel to enable it to make any assessment of this argument. As such, it must fail.

47. Finally, the Panel cannot accept the Appellants argument relating to the freezing of the samples. The Appellants fail to provide any source for this assertion. It is, insofar as the submissions of the Appellants, unfounded and not supported by any scientific publication.

Conclusion

48. In summary, the Panel concludes that there have been no departures from the applicable ISL and its accompanying technical documents. Without diminishing the importance of improvement in the future the aspect of meeting the "Documentation and Reporting" aspects of the ISL and the description of the analytical finding (see paragraphs 17 and 36 above), the AAF of the Lab in this case can be fully relied upon by the sanctioning and reviewing bodies.

49. It is found that the Appellants' samples contain rEPO, a prohibited substance. For all of the foregoing reasons the IBU DHP panel's conclusions in both Athletes' cases were correct and these appeals are dismissed.

The Court of Arbitration for Sport rules:

1. The Appeal of E. and A. is dismissed.

(…).