



**Arbitration CAS 2010/A/2041 Y. v. Fédération Internationale de Ski (FIS), award of 1 October 2010**

Panel: Prof. Luigi Fumagalli (Italy), President; Ms Maidie E. Oliveau (United States); Mr Quentin Byrne-Sutton (Switzerland)

*Cross country skiing*

*Doping (rEPO)*

*Validity of the method to find the presence of rEPO in a urine sample*

*Validity of the adverse analytical finding*

*Extent of the right to attend the B sample “opening and analysis”*

*Sanction*

1. Considering that the IEF-DB Method which is a “direct detection method” codified by TD2007EPO and TD2009EPO (Technical Document issued by WADA) has been applied for years to detect the presence of rEPO in the sample provided by the athlete and has also been repeatedly validated by the CAS jurisprudence, the application of the new identification criteria under TD2009EPO to address, as “Other Epoetins”, the new types of EPOs does not require a new validation. The application of the SDS-PAGE Method cannot be considered to be a mandatory supplement to the IEF-DB Method under TD2009EPO in every case. If a doubt exists as to the origin of the EPO found in a sample not showing a typical endogenous profile, the SDS-PAGE Method can be applied (as additional evidence) to discriminate between forms of EPO on the basis of a different, compared to the IEF-DB Method, principle: not the acidity of the molecules, but their mass.
2. As long as (i) the results shown by the IEF-DB Method, indicating that the identification criteria for “Other Epoetins” are clearly met, are reliable and are sufficient to support the Adverse Analytical Finding, (ii) the results of the SDS-PAGE Method cannot be deemed to exclude the positive finding based on the IEF-DB Method and (iii) there is no evidence invalidating the Adverse Analytical Finding for any procedural reasons, then the detection of rEPO in the athlete's urine is established and the athlete is to be found in violation of the anti-doping rule constituted by Article 2.1 of the FIS ADR.
3. The opportunity for the athlete and/or his/her representative to attend the B sample “opening and analysis” is indeed a basic right in doping-control proceedings, since it reflects the need that an athlete is heard before an adverse analytical finding is finally reported and provides the possibility for the athlete to verify that the procedures intended to confirm the initial adverse analytical finding are properly conducted. However this right does not necessarily extend to the right to attend the performance of those analyses which are not required to confirm the initial adverse analytical

**finding like the attendance of the performance of the analysis performed on the “extended gel”.**

- 4. An athlete who has violated an anti-doping rule (presence of a prohibited substance in his/her urine sample – Article 2.1 of the FIS ADR) is to be sanctioned with two years’ ineligibility pursuant to Article 10.2 of the FIS ADR.**

Y. (“the “Appellant”) is an international-level cross-country skier of Russian nationality, born in 1976, member of the Russian Ski Federation (RSF).

The Fédération Internationale de Ski (FIS or the “Respondent”) is the international governing body in all matters concerning the sport of skiing. It has its registered seat in Oberhofen, Switzerland.

The circumstances stated below are a summary of the main relevant facts, as submitted by the parties in their written pleadings or in the evidence offered in the course of the proceedings. Additional facts may be set out, where relevant, in connection with the legal discussion which follows.

On 2 January 2009 Y. took part in a cross-country event in Val di Fiemme, Italy. After the competition, Y. underwent an anti-doping control.

The A sample (code A2368648) provided by Y. was analysed by the Institute of Doping Analysis and Sports Biochemistry of Dresden, Germany (“IDAS” or the “Dresden Laboratory”), a laboratory accredited by the World Anti-Doping Agency (WADA). On 14 August 2009 IDAS reported the presence of recombinant erythropoietin (“rEPO”), a prohibited substance under the FIS anti-doping rules, in the sample (identified by IDAS with the internal code 90014) provided by Y. This analytical finding (“Adverse Analytical Finding”) was confirmed, in a double reading of the results of the A sample analysis, by Dr José A. Pascual of the WADA accredited laboratory of Barcelona, Spain (the “Barcelona Laboratory”).

On 21 August 2009 the FIS advised the RSF of the Adverse Analytical Finding and imposed a provisional suspension on Y. pursuant to Article 7.6 of the FIS Anti-Doping Rules, 2009 Edition (the “FIS ADR”).

In an email message of 25 August 2009 the RSF informed the FIS that the case of Y. “*could be closed*” because the athlete had decided to retire. In fact, on 3 September 2009, the FIS received the official retirement form signed by Y.

That notwithstanding, on 3 September 2009 Y. requested the analysis of the B sample. On 27-30 September 2009 the B sample (code B2368648) was analysed at IDAS.

On 29 September 2009, Y., after discussions regarding the availability of, and her possibility to review, the results of the analysis performed on the “extended gel”, submitted to IDAS the following written declaration, whereby, in essence, she claimed that she had been denied the opportunity to attend the entire analysis of the B sample

The counter-analysis’ report issued on 14 October 2009 confirmed the Adverse Analytical Finding also with respect to the B sample.

In a letter dated 19 October 2009, the FIS informed the RSF of the results of the analysis of the B sample and that the case of Y. would be heard by the Doping Panel of the FIS (the “Doping Panel”).

The hearing concerning Y. took place before the Doping Panel on 13 November 2009.

On 22 December 2009, the Doping Panel issued a decision (the “Decision”) in which it held the following:

*“ In view of the admission of the athlete and the adverse analytical finding in both the A and B sample for the substance recombinant EPO, which is identified on the WADA Prohibited List 2009 in Class S2 Hormone and Related Substances, the Panel finds that the athlete, Y., has committed an anti-doping rule violation, contrary to Article 2.1 of the FIS Anti-Doping rules and is declared ineligible from participating from any FIS sanctioned events for a period of two (2) years.*

*. The Panel finds no reason to either decrease or increase the period of ineligibility.*

*. In accordance with Article 10.9, there being no substantial delay in conducting the hearing process, the period of ineligibility shall commence on the date of this hearing decision with credit given, pursuant to Article 10.9.3, for the period of the provisional suspension which was communicated to the athlete by FIS by letter dated 21<sup>st</sup> August 2009 (which means 21<sup>st</sup> August 2009 - 20<sup>th</sup> August 2011).*

*. Pursuant to Article 10.8, in addition to the automatic disqualification of the results in the competition which produced the positive sample, all other competitive results from the date that the positive sample was obtained are disqualified, along with the forfeiture of any medals, points and prizes.*

*. The Panel has determined that no costs are to be awarded in these circumstances”.*

In support of its Decision, the Doping Panel in summary considered that:

*“ The presence of a Prohibited substance in the athlete’s sample is established based on analytical reports issued by a WADA accredited laboratory.*

*. The profile of the athlete’s sample is clearly different from an endogenous profile.*

*. Based on the evaluation criteria set forth in the applicable technical document (TD2009EPO), the conclusions of the laboratory, supported in this case by a second opinion issued by another WADA accredited laboratory, are clear and establish the presence of a Prohibited Substance (rEPO).*

*. Finally, the Panel finds that the argument based on the SDS-page analysis is also without merit. The positive findings are supported by the application of the main criteria set forth in TD2009EPO.*

*. In light of the presumption set forth in the FIS ADR, as a general rule, the Panel will rely on the analysis of an approved WADA accredited laboratory unless the arguments and evidence brought by an athlete is scientifically valid and reliable which in this case they are not” (sic).*

The Decision was notified by the FIS to the RSF on 22 December 2009. Y. was immediately informed of the Decision.

On 12 January 2010, Y. filed a statement of appeal with the Court of Arbitration for Sport (CAS), pursuant to the Code of Sports-related Arbitration (the “Code”), to challenge the Decision.

On 19 January 2010 the Appellant filed a request for the production by IDAS of additional information.

In a letter dated 28 January 2010 the Respondent noted, with regard to Y.’s request for additional information, that in its opinion *“the Appellant seems to be fishing for elements rather than having solid reasons to appeal”*, but that it had *“contacted the IDAS laboratory which will provide a statement responding to the extent adequate to the requests of information / questions raised”*.

On 5 February 2010 the Respondent filed with the CAS *“a document established by the laboratory answering the questions raised by the Appellant to the extent appropriate”*, and noted that *“the answers have been provided on a voluntary basis within the relevant regulations”*.

On 1 March 2010 the Appellant filed her appeal brief. The appeal brief had 9 exhibits attached (A6 to A14), 2 expert reports and 4 witness statements (E1 to E6), and contained a request for the production of additional information and documents.

In a letter dated 9 March 2010, as supplemented on 11 March 2010, the Panel invited the Respondent to comment on the Appellant’s request or to file the documents requested.

On 18 March 2010 the Respondent filed a letter from IDAS, with attachments, intended to provide the additional information requested.

In letters dated 24 and 26 March 2010 the Appellant submitted that the Respondent had not provided all requested information.

On 31 March 2010 the Panel issued procedural directions.

On the basis of the Panel’s directions, on 16 April 2010 the Respondent filed its answer seeking the dismissal of the appeal.

In a letter of 21 April 2010 the Appellant insisted on her request for the production of information by the Respondent, asking the Panel to issue *“an order, inviting IDAS/FIS to provide all initial (original) images of all gels for the A and B samples made under all exposure intervals and initial (original) images in the GASEpo format both before and after any correction or processing of all gels in the A and B samples, both as print out (pdf) copies and in the electronic versions (in the GASEpo format)”*.

On 23 April 2010 the Panel directed the Respondent to provide the documents so requested by the Appellant.

On 3 May 2010 the Respondent filed the documents requested.

On the basis of the Panel's directions:

1. on 19 May 2010 the Appellant filed her reply brief; and
2. on 9 June 2010 the Respondent filed its second response.

On 9 June 2010, the CAS Court Office, on behalf of the President of the Panel, issued an order of procedure (the "Order of Procedure"), which was accepted and countersigned by the parties.

A hearing was held on 14 June 2010.

By letter dated 15 June 2010 the Panel allowed the parties to file short submissions "*strictly limited to comment on the analytical results of the sample under reference Code 90008 as described in pages 21, 22, 28, 29 and 30 of Laboratory Documentation Package (Sample A 2368648), Exhibit A6*".

On the basis of such directions:

1. on 21 June 2010 the Appellant filed her additional submission; and
2. on 26 June 2010 the Respondent filed its answer to the Appellant's additional submission.

## LAW

### Jurisdiction

1. CAS has jurisdiction to decide the present dispute between the parties.
2. The jurisdiction of CAS is not disputed and has been confirmed by the signing of the Order of Procedure. In addition, it is contemplated, pursuant to Article R47 of the Code, by Articles 8.1.9 and 13 of the FIS ADR.
3. More specifically, the provisions contained in the FIS ADR which are relevant to that effect in these proceedings are the following:  
*8.1.9 Decisions of the FIS Doping Panel may be appealed to Court of Arbitration for Sport as provided in Article 13.*

### *13.1 Decisions Subject to Appeal*

*Decisions made under these Anti-Doping Rules may be appealed as set forth below in Article 13.2 through 13.4 or as otherwise provided in these Anti-Doping Rules. Such decisions shall remain in effect while under appeal unless the appellate body orders otherwise. Before an appeal is commenced, any post-decision review authorized in these rules must be exhausted (except as provided in Article 13.1.1).*

### *13.2 Appeals from Decisions Regarding Anti-Doping Rule Violations, Consequences, and Provisional Suspensions*

*A decision that an anti-doping rule violation was committed, a decision imposing Consequences for an anti-doping rule violation, or a decision that no anti-doping rule violation was committed ... may be appealed exclusively as provided in this Article 13.2. ...*

#### *13.2.1 Appeals Involving International-Level Athletes*

*In cases arising from competition in an International Event or in cases involving International-Level Athletes, the decision may be appealed exclusively to CAS in accordance with the provisions applicable before such court.*

#### *13.2.3 Persons Entitled to Appeal*

*In cases under Article 13.2.1, the following parties shall have the right to appeal to CAS: (a) the Athlete or other Person who is the subject of the decision being appealed ...*

### *13.6 Time for Filing Appeals*

*The time to file an appeal to CAS shall be twenty-one (21) days from the date of receipt of the decision by the appealing party.*

## **Appeal Proceedings**

4. As these proceedings involve an appeal against a decision regarding an international level athlete in a disciplinary matter brought against FIS on the basis of rules providing for an appeal to the CAS, they are considered and treated as appeal arbitration proceedings in a disciplinary case of international nature, in the meaning and for the purposes of the Code.

## **Admissibility of the Appeal**

5. The statement of appeal was filed within the deadline set in Article 13.6 of the FIS ADR. No further recourse against the Decision is available to the Appellant within the structure of FIS. Accordingly, the appeal is admissible.

### Scope of the Panel's Review

6. According to Article R57 of the Code, the Panel has full power to review the facts and the law of the case. Furthermore, the Panel may issue a new decision which replaces the decision challenged, or may annul the decision and refer the case back to the previous instance.

### Applicable Law

7. The law applicable in the present arbitration is identified by the Panel in accordance with Article R58 of the Code.
8. Pursuant to Article R58 of the Code, the Panel is required to 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"*.
9. The FIS body that rendered the appealed Decision did so on the basis of the FIS Anti-Doping Rules ("FIS ADR") when determining whether an anti-doping rule violation had been committed and when setting the sanction to be imposed on Y.
10. The Panel also considers that the FIS ADR are the "applicable regulations" for the purposes of Article R58 of the Code. Swiss law, being the law of the country in which the FIS is domiciled, applies subsidiarily.
11. The Panel identifies the applicable substantive rules by reference to the principle "*tempus regit actum*": in order to determine whether an act constitutes an anti-doping rule infringement, the Panel applies the law in force at the time the act was committed. In other words, new regulations, unless they are more favourable for the athlete ("*lex mitior*" principle: advisory opinion CAS 94/128), do not apply retroactively to facts that occurred prior to their entry into force, but only for the future (CAS 2000/A/274).
12. In light of the above, in order to establish an anti-doping rule violation and its consequences, the Panel shall apply the FIS ADR in force in 2009.
13. The provisions set in the FIS ADR which are relevant in this arbitration include the following:
  - i. Article 2 [Anti-Doping Rule Violations]:  
*Athletes and 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:*
    - 2.1 *The presence of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample*

- 2.1.1 *It is each Athlete's personal duty to ensure that no Prohibited Substance enters his or her 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 violation under Article 2.1.*
- 2.1.2 *Sufficient proof of an anti-doping rule violation under Article 2.1 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.*
- 2.1.3 *Excepting those 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.*
- 2.1.4 *As an exception to the general rule of Article 2.1, the Prohibited List or International Standards may establish special criteria for the evaluation of Prohibited Substances that can also be produced endogenously.*

ii. Definition of "Prohibited Substance":

*Any substance so described on the Prohibited List.*

iii. Article 4 [The Prohibited List]:

*These Anti-Doping Rules incorporate the Prohibited List which is published and revised by WADA as described in Article 4.1 of the Code [the WADC].*

iv. Class S2 [Hormones and related substances] of the 2009 Prohibited List:

*The following substances and their releasing factors, are prohibited:*

1. *Erythropoiesis-Stimulating Agents (e.g. erythropoietin (EPO), darbepoietin (dEPO), hematide); ...*

*and other substances with similar chemical structure or similar biological effect(s).*

*[Comment to class S2: ... If a laboratory reports, using a reliable analytical method, that the Prohibited Substance is of exogenous origin, the Sample will be deemed to contain a Prohibited Substance and shall be reported as an Adverse Analytical Finding]*

v. Article 3 [Proof of Doping]:

3.1 *Burdens and Standards of Proof*

*FIS and its National Ski Associations shall have the burden of establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether FIS or its National Ski Association has established an anti-doping rule violation to the comfortable satisfaction of the 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. Where these Rules place the burden of proof upon the Athlete or other Person alleged to have committed an anti-doping rule 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 Articles 10.4 and 10.6, where the Athlete must satisfy a higher burden of proof.*

3.2 *Methods of Establishing Facts and Presumptions*

*Facts related to anti-doping rule violations may be established by any reliable means, including admissions. The following rules of proof shall be applicable in doping cases:*

3.2.1 *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 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 occurred which could reasonably have caused the Adverse Analytical Finding, then FIS or its National Ski Association shall have the burden to establish that such departure did not cause the Adverse Analytical Finding.*

3.2.2 *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 which could reasonably have caused the Adverse Analytical Finding or other anti-doping rule violation occurred, then FIS or its National Ski Association shall have the burden to establish that such a departure did not cause the Adverse Analytical Finding or the factual basis for the anti-doping rule violation.*

vi. Article 6.4 [Standards for Sample Analysis and Reporting]:

*Laboratories shall analyse Doping Control Samples and report results in conformity with the International Standard for Laboratories.*

vii. Definition of "International Standard":

*A standard adopted by WADA in support of the Code. Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the International Standard were performed properly. International Standards shall include any Technical Documents issued pursuant to the International Standard.*

viii. Article 10 [Sanctions on Individuals]:

10.1 *Disqualification of Results in Event During which an Anti-Doping Rule Violation Occurs*

*An Anti-Doping Rule violation occurring during or in connection with an Event may lead to Disqualification of all of the Athlete's individual results obtained in that Event with all consequences, including forfeiture of all medals, points and prizes, except as provided in Article 10.1.1.*

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

*The period of Ineligibility imposed for a violation of Article 2.1 (Presence of Prohibited Substance or its Metabolites or Markers), Article 2.2 (Use or Attempted Use of Prohibited Substance or Prohibited Method) or Article 2.6 (Possession of Prohibited Substances and*

*Methods) shall be as follows, unless the conditions for eliminating or reducing the period of Ineligibility, as provided in Articles 10.4 and 10.5, or the conditions for increasing the period of Ineligibility, as provided in Article 10.6, are met:*

*First violation: Two (2) years' Ineligibility.*

#### *10.9 Commencement of Ineligibility Period*

*Except as provided below, the period of Ineligibility shall start on the date of the hearing decision providing for Ineligibility or, if the hearing is waived, on the date Ineligibility is accepted or otherwise imposed.*

##### *10.9.1 Delays Not Attributable to the Athlete or other Person*

*Where there have been substantial delays in the hearing process or other aspects of Doping Control not attributable to the Athlete or other Person, the FIS or Anti-Doping Organisation imposing the sanction may start the period of Ineligibility at an earlier date commencing as early as the date of Sample collection or the date on which another anti-doping rule violation last occurred.*

*10.9.3 If a Provisional Suspension is imposed and respected by the Athlete, then the Athlete shall receive a credit for such period of Provisional Suspension against any period of Ineligibility which may ultimately be imposed.*

14. The analyses of the A and B samples provided by Y. were conducted in 2009. As a result, the Panel finds, in agreement with the parties that, for the purposes of Articles 3.2 and 6.4 of the FIS ADR, the International Standard for Laboratories (ISL) applies in the present case.
15. In connection with the ISL, the TD2009EPO, issued by WADA with respect to EPO tests conducted by accredited laboratories, is also relevant for the purposes of resolving the issues in dispute in these proceedings.
16. The Panel notes that since TD2009EPO was published on 1 April 2009 and entered into force on 31 May 2009, in replacement of TD2007EPO, in force since 31 May 2007, the latter was in January 2009, for the purposes of Section 1.0 of the ISL, the “*Technical Document whose effective date most recently precede[d] that of Sample receipt date*”. Nevertheless, the Panel agrees with the award issued on 12 November 2009 by another CAS panel (CAS 2009/A/1931 §§ 7.7-7.8) that TD2009EPO did not set new rules for the definition of anti-doping rule violations, but only reflected an improved scientific method for the interpretation of the results of the analytical procedures (which did not change from TD2007EPO to TD2009EPO). In this respect, the Panel emphasizes that laboratories must always use the most recent state of the art and technology and knowledge to identify prohibited substances. As a result, the Panel is satisfied that TD2009EPO could be used by IDAS to interpret the results of the A and B sample analyses and to report the Adverse Analytical Finding.

## **Merits**

17. The appeal brought by Y. against the Decision raises many issues, which the Panel has to consider. In support of her request to be cleared from all charges brought against her, because

her case “*is one of those cases of so-called false-positive*”, the Appellant is in fact advancing two main submissions: the first is that the analyses performed on her samples do not support the Adverse Analytical Finding reported by IDAS and sanctioned by the Doping Panel; the second is that the Adverse Analytical Finding is to be invalidated because of procedural reasons. Both main submissions, then, are developed in several directions. The first main submission is based on the relevance of the SDS-PAGE Method to explain that the EPO detected in the Appellant’s sample has an endogenous origin, and involves issues relating to the reliability of the IEF-DB Method, as allegedly affected, in the Appellant’s case, by numerous factors (absence of validation, effort, “*proteinuria*”, degradation, background, changes to sample preparation, dilution, consideration of non-EPO bands, software set-up, absence of positive control samples, uncertainty and lack of robustness, unreliability of the second opinion). The second main submission stands on the allegation of a variety of departures from the provisions set by the ISL or the relevant technical documents with respect to the analysis procedure and refers to: “improper” contacts between IDAS and the Respondent; the choice of aliquots; the cooperation between IDAS and the Seibersdorf Laboratory; departures from validated procedures; the violation of the Appellant’s right to attend the B sample analysis; the delay in the reporting of the analysis’ results.

18. As a result of the Appellant’s submissions and petitions, there are two main questions that the Panel has to examine:
  - A. the first is whether Y. can be found to have committed an anti-doping rule violation. In this respect, the numerous issues raised by the Appellant with regard to the Adverse Analytical Finding are to be examined;
  - B. the second, to be addressed in the event Y. is found to have committed an anti-doping rule violation, concerns the sanction to be imposed on her, with respect to its duration and starting date.
  
19. The Panel shall consider each of said questions separately.
  - A. *Can Y. be found to have committed an anti-doping rule violation?*
    - a) Introduction
  
20. The first question relates to the analyses of the A sample and of the B sample, which were found to be positive for the presence of a prohibited substance (rEPO). In fact, all synthetic forms of EPO are substances prohibited by FIS (above). Therefore, the confirmed presence, to the comfortable satisfaction of the Panel and on the basis of the analytical results, of rEPO in the urine of Y. would constitute an anti-doping rule violation under Article 2.1 of the FIS ADR. Contrary to an indication in the holding of the Decision (see above), the Appellant never admitted to the use of a prohibited substance: hence the necessity to verify whether the reporting of the Adverse Analytical Finding was correct.
  
21. The presence of rEPO in the sample provided by Y. was established on the basis of the IEF-DB Method, as a “direct detection method” codified by TD2007EPO and TD2009EPO and

validated by CAS in several decisions: award of 28 January 2002, CAS 2001/A/343, CAS 2001/A/345, CAS 2002/A/370, CAS 2002/A/374, CAS 2001/A/452, CAS 2004/O/679, CAS 2001/A/831. The precedents in the CAS jurisprudence allow the Panel to confirm the reliability of the IEF-DB Method to find the presence of rEPO in a urine sample. And this conclusion can be made with respect to the IEF-DB Method under TD2009EPO, since “*the method to detect rEPO has not changed from TD2007EPO to TD2009EPO*” (CAS 2009/A/1931).

22. Such method relies upon the fact that EPO and rEPO, because of their components, have different electrical charges. This means that EPO and rEPO respond differently when placed in an electric field: because rEPO has predominantly positive charges, it will move to the more basic area of a pH field, while endogenous EPO, having a majority of negative charges, will move predominantly to the acidic area of the pH field.
23. To test a urine sample for rEPO, a multi-staged laboratory process is conducted, in which the EPO hormones from the sample are preserved, concentrated and applied to a gel, which operates as an electric field once cathodes are attached. The resulting distribution of the EPO hormones through the electric field is specially photographed and developed as a computer image.
24. The possibility, then, to declare a sample positive is based on the evaluation of the image obtained, taking into account:
  - acceptance criteria, which define the requisites that the image has to fulfil to allow the application of the identification criteria (TD2009EPO, Section 3.1);
  - identification criteria, which define the requisites that the image has to fulfil to find the presence of rEPO (TD2009EPO, Section 3.2);
  - stability criteria, which are to confirm that no interference has affected the adverse analytical finding (TD2009EPO, Section 3.3).
25. With specific reference to the identification criteria, TD2009EPO provides the following:

#### 3.2.1 EPOETIN ALPHA AND BETA

1. *In the basic area ... there must be at least 3 acceptable, consecutive bands assigned as “1”, “2”, and “3” in the corresponding reference preparation;*
2. *The 2 most intense bands measured by densitometry shall be in the basic area, shall be consecutive and shall be bands “1” and “2” or “2” and “3”;*
3. *Each of the two most intense bands in the basic area must be more intense (approximately twice or more) than any band in the endogenous area, as measured by densitometry.*

*or*

*Additional Evidence, as described in the section 3.2.5 below, must be obtained confirming the presence of an exogenously produced EPO.*

#### 3.2.2 OTHER EPOETINS

1. *In the basic area ... 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.*

### 3.2.3 DARBEPOETIN ALPHA (NESP)

1. *In the acidic area ... there must be at least 3 acceptable, consecutive bands assigned as "B", "C" and "D" in the corresponding reference preparation;*
2. *The most intense band measured by densitometry must be "C" or "D";*
3. *Both bands "C" or "D" must be more intense than band "B".*

### 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.*

### 3.2.5 ADDITIONAL EVIDENCE

*When the profile departs from a typical endogenous profile (as referenced by the uEPO NIBSC standard) but does not fulfil the strict criteria defined in the above section 3.2.1 to 3.2.4, it may be due to other biosimilar rEPOs ... or a combination of substances. Thus the most intense bands may be other than "1", "2" or "3" or may show some intense band in the endogenous area (e.g. epoetin delta - DYNEPO™) ..., or be an atypical profile (shifted towards the basic area) ..., etc. In such cases, additional scientific evidence may be needed to arrive to a final conclusion. The application of an electrophoretic SDS-PAGE procedure or equivalent where protein separation is based on a different principle (i.e. apparent molecular mass or hydrodynamic volume) can be used complementarily to the IEF method for the purpose of helping to confirm the exogenous or endogenous origin of the finding ... .  
[...]*

26. In such respect, TD2009EPO, replacing TD2007EPO, introduced (in its Section 3.2.2) new criteria to identify an adverse analytical finding corresponding to the presence of "Other Epoetins" in an urine sample. It is in fact common ground between the parties that the scope of application of TD2007EPO was limited to the forms of EPO commercially existing at the time of the document's release: the identification criteria it established, therefore, were considered by WADA not to be adapted to identify the newer forms of EPO (biosimilars or copies), which appeared on the market after the release of TD2007EPO. As a result, while the application of the IEF-DB Method did not change from TD2007EPO to TD2009EPO, new evaluation criteria were included in TD2009EPO to address, as "Other Epoetins", the new types of EPOs. In this regard, the peculiarity of the identification criteria for "Other Epoetins" refers to the relevance given to the relative amount of the basic band areas: an adverse analytical finding for "Other Epoetins" can be reported if the sum of the intensity of all bands in the basic area account for "approximately 85% or more" of the total intensity of the bands within the window of the sample lane.

27. The Panel notes that, according to TD2009EPO and with respect to “Epoetins Alpha and Beta” and “Other Epoetins”, in addition to the abovementioned identification criteria, “Additional Evidence”, as described in Section 3.2.5, is deemed relevant in confirming the presence of exogenously produced EPO in samples not showing a typical endogenous profile. In other words, while the satisfaction of the identification criteria (set in Section 3.2.2) is sufficient to allow the reporting of the presence of rEPO as one of the “Other Epoetins” in a sample, an adverse analytical finding for “Other Epoetins” is justified also in the event those criteria (e.g., if for instance the intensity of bands in the basic area accounts for less than “*approximately 85%*” of the total intensity of the bands) are not satisfied, if additional evidence allows this conclusion. The rule is in line with the “non-quantitative” nature of an anti-doping rule violation linked to the detected presence of rEPO in an athlete’s sample. The relative amount (approximately 85%) of the basic band areas does not constitute the “threshold” past which an offence can be found: it only gives evidence of the presence in a sample of a prohibited substance, whose mere detection is considered an anti-doping rule violation. As a result, “Additional Evidence” can be adduced to confirm the presence of rEPO in a sample, even though, for instance, the condition concerning the relative amount of the basic band areas is not satisfied.
28. In the context of the “Additional Evidence”, Section 3.2.5 of TD2009EPO mentions the SDS-PAGE Method as a method which “*can*” be used “*complementarily*” to the IEF-DB Method for the purpose of “*helping*” to confirm the exogenous or endogenous origin of the finding.
29. With respect to the role of the SDS-PAGE Method in the framework of the identification criteria for “other Epoetins”, the Panel notes three points:
- Section 3.2.5 of TD2009EPO refers to the SDS-PAGE Method as “*additional evidence*”, whose use is “*complementary*” to the IEF-DB Method for the purpose of “*helping*” to confirm the nature of a finding;
  - Section 3.2.5 of TD2009EPO uses “permissive” language: the SDS-PAGE Method “*can*” be used;
  - the use of the SDS-PAGE Method is indicated “*where protein separation is based on a different principle (i.e. apparent molecular mass or hydrodynamic volume)*”.
30. In the Panel’s opinion, the above:
- confirms that the IEF-DB Method is the primary method for the rEPO detection;
  - means that the laboratory conducting the sample’s analysis is authorized to (“*can*”) use the SDS-PAGE Method with respect to samples not showing a typical endogenous profile, if the primary method does not allow a final conclusion on the basis of the identification criteria used with such method;
  - indicates that the application of the SDS-PAGE Method is proper when the exogenous rEPO at stake allows a distinction with respect to the uEPO normally found in a sample based on specific peculiarities, such as molecular mass.

31. As a result, in the Panel's opinion, the application of the SDS-PAGE Method cannot be considered to be a mandatory supplement to the IEF-DB Method under TD2009EPO in every case: if a doubt exists as to the origin of the EPO found in a sample not showing a typical endogenous profile, the SDS-PAGE Method can be applied (as additional evidence) to discriminate between forms of EPO on the basis of a different, compared to the IEF-DB Method, principle: not the acidity of the molecules, but their mass. The SDS-PAGE Method, therefore, does not discriminate between rEPO and uEPO in every single instance: the SDS-PAGE Method cannot distinguish between rEPO and uEPO sharing the same characteristics in terms of molecular mass, i.e. does not exclude that EPO molecules having the same mass as uEPO may have an exogenous origin. This explains why the SDS-PAGE Method is only "complementary" to the IEF-DB Method and why to deem the SDS-PAGE Method as being adequate for systematically discriminating between rEPO and uEPO would give this method a primary role, which it does not have under TD2009EPO.
32. Based on the above, and chiefly on the basis of the identification criteria for "Other Epoetins" set in TD2009EPO, the Dresden Laboratory reported, both with respect to the A sample and the B sample, adverse analytical findings for the presence of rEPO. Such conclusions were confirmed by Dr Pascual, in his "second opinions".
33. The above findings are disputed by the Appellant. As mentioned, the Appellant's submissions can be grouped into two main categories. The Panel shall consider them separately, in order to draw an overall conclusion.
  - b) The first group of submissions: is the Adverse Analytical Finding supported by the analysis performed on the Appellant's sample?
34. The first main group of submission is based on the alleged relevance of the SDS-PAGE Method to explain that the EPO detected in the Appellant's sample has an endogenous origin and involves issues relating to the reliability of the IEF-DB Method, as allegedly affected, in the Appellant's case, by numerous factors.
  - ba) The relevance of the SDS-PAGE Method
35. The Appellant submits that the application of the SDS-PAGE Method confirmed the endogenous origin of the EPO found in her A sample, and that IDAS applied this method because the IEF-DB Method, primarily followed, could not support, due to several reasons, the reporting of an adverse analytical finding.
36. With respect to such submission, the Panel underlines the complementary nature, as well as the characteristics, of the SDS-PAGE Method, mentioned above. Therefore, in the event that, following the application of the IEF-DB Method, the identification criteria for rEPO are satisfied, an adverse analytical finding is to be declared and the application of the SDS-PAGE Method becomes irrelevant; the SDS-PAGE Method, in fact, even if applied, cannot

contradict the adverse analytical finding to be reported with respect to a sample fulfilling the identification criteria. The existence of (new) forms of rEPO sharing the same molecular mass as uEPO (which therefore cannot be detected by the SDS-PAGE Method), in fact, has been convincingly sustained in this arbitration by the Respondent's experts (and not excluded by the Appellant's experts): the lack of abnormality of a pattern shown by the SDS-PAGE Method does not contradict a positive finding under the IEF-DB Method.

37. In light of the foregoing, the Panel finds that the indication, reported by IDAS, that the SDS-PAGE Method found the Appellant's sample was entirely consistent with endogenous EPO, would become relevant only in the event the profile of Y.'s samples is found not to fulfil the identification criteria for "Other Epoetins" (Section 3.2.2 of TD2009EPO). Only in such a situation would the results of the analysis under the SDS-PAGE Method be pertinent and preclude the report of an adverse analytical finding. On the contrary, the conclusion that the identification criteria under Section 3.2.2 of TD2009EPO are satisfied would render immaterial the findings of the SDS-PAGE Method.

38. Thus, the Panel has to examine whether the application of the IEF-DB Method leads to an adverse analytical finding and turn to the SDS-PAGE Method only in the event the identification criteria are not satisfied.

bb) The reliability of the IEF-DB Method, as applied in the Appellant's case.

- Validation

39. It is a basic principle that methods for the detection of prohibited substances need to be validated: only methods which are scientifically "Fit-for-purpose" can be applied to analyse samples in the fight against doping. The validation of the method is indeed a guarantee for the athlete and only the adherence by the laboratory to the validated method can justify an anti-doping rule violation based on the detected presence of a prohibited substance in an athlete's sample. The factors to be investigated to demonstrate that a method is "Fit-for-purpose" for the detection of non-threshold substances (such as rEPO) are listed in Clause 5.4.4.2.1 ISL.

40. In this respect, the Appellant contends that the new method adopted by IDAS under TD2009EPO has not been validated: therefore, the results shown by the IEF-DB Method cannot form the basis for an adverse analytical finding.

41. The Panel does not agree with this submission.

42. As already pointed out, in relation to TD2007EPO the adoption of TD2009EPO only modified the identification criteria, by providing specific conditions for the reporting of an adverse analytical finding for "Other Epoetins" on the basis of the interpretation of the EPO profiles produced in application of the IEF-DB Method. No new method is used. On the other hand, all analytical procedures remained unaffected: according to the unchallenged statement of the Respondent's experts, the IDAS' Standard Operating Procedures did not



change, and the method for the measurement of the intensities of the chemiluminescence signal, or for the definition of the position of the bands in a lane, remained the same.

43. In light of the above, and considering that the IEF-DB Method has been applied for years and has also been repeatedly validated by the CAS jurisprudence (see above), the Panel concludes that the application of the new identification criteria under TD2009EPO did not require a new validation.

- Effort

44. According to the Appellant, one of the reasons for the “*non typical endogenous EPO expression*” of Y.’s banding pattern could be “effort”, which affects the isoelectric behaviour of urinary EPO.
45. The Panel is not convinced by this explanation that the Appellant is offering only as a mere possibility, without any further substantiation.
46. Contrary to the Appellant’s submission, it is noteworthy that one of her own experts, Dr Scott, conceded that “*most well characterized “exercise” urines do not result in such an extreme shift [as the shift found in the Y.’s banding pattern] such that almost no EPO is expressed in the endogenous region*”. This assertion is confirmed by Dr Saugy. Dr Saugy admits that exercise can induce a shift of the endogenous bands towards the basic field, but underlines that in effort urine profiles: the endogenous bands never completely disappear from the profile; and the percentage in the basic bands observed are never over 85% of the total band intensities. This point is supported in scientific literature showing examples of observed “effort urines” not meeting the established WADA identification criteria for rEPO (LAMON ET AL., *Effects of Exercise on the Isoelectric Patterns of Erythropoietin*, Clin. J. Sport Med., 19(4), 311-315; VOSS ET AL., *Effects of High Intensity Exercise on Isoelectric Profiles and SDS-PAGE Mobility of Erythropoietin*, Int. J. Sports Med., 2010) .
47. The Panel therefore finds that effort did not affect the reliability of the results shown by the IEF-DB Method on the Appellant’s sample.

- Excess of Protein Concentration

48. Excess of protein concentration (“*proteinuria*”) in the Appellant’s sample is invoked by Y. as a possible cause of “*false positive*” results. According to her, such excess is shown by the “*screening analysis of her urine*”, with the consequence that the analysis results are unreliable and cannot support an adverse analytical finding.
49. The Panel notes that protein concentration was properly (see below) dealt with by dilution, and that all profiles (diluted or not, including the screening analysis) satisfied the identification criteria set by TD2009EPO.

50. The Panel therefore finds that excessive protein concentration did not affect the reliability of the results shown by the IEF-DB Method on the Appellant's sample.

- Background

51. According to the Appellant, one of the reasons indicating the "poor quality" of the analysis performed under the IEF-DB Method is the intense background and/or the "artefactual less intense lines" between bands, which can be observed also in the control samples.

52. Contrary to the Appellant's contentions:

- as indicated by Dr Pascual in his second opinions,
  - a. the gels for the screening, first and second confirmation of the A sample analysis, as well as the gels of the B sample analysis, complied with the acceptance criteria set by TD2009EPO, "having a (clean) uniform background and allowing unequivocal assignment of the bands (of rEPO) as compared to the reference samples", and
  - b. the background which affected the densitometric analysis still allowed the identification of the presence of rEPO with an intensity in the basic area accounting for more than 85% of the total signal;
- according to TD2009EPO (Section 2, first paragraph), the quality, identification and stability criteria therein described (including the absence of areas of excessive background producing a significant interference), need to be satisfied by the results derived from the "Confirmation Procedure": areas of background shown in the images obtained in the "Initial Testing Procedure" are not necessarily relevant;
- the positive control samples indicated by the Appellant satisfy all identification criteria for epoetin alpha without any background preventing such conclusion;
- all the negative control samples invoked by the Appellant have a profile which is clearly incompatible with rEPO findings.

53. The Panel therefore finds that background did not affect the reliability of the results shown by the IEF-DB Method on the Appellant's sample.

- Changes to Sample Preparation: Dilution

54. The Appellant submits that IDAS applied several techniques with regard to Y.'s sample. In this context, it is the Appellant's opinion that the dilution of the sample might be the cause of the Adverse Analytical Finding. Dr Scott submits that "diluting the sample to 1/3<sup>rd</sup> to 1/4<sup>th</sup> its original concentration would account for the endogenous bands disappearing in the subsequent analyses", affecting "the 85% criterion". In any case, dilution had not been validated as a step in the sample preparation.

55. The Panel notes that, contrary to the Appellant's submissions, the dilution of the sample does not appear to have affected the basic band ratio.

56. The basic band ratio (i.e., the percentage of the total intensity of the bands represented by the bands in the basic area) of the analyses performed on the Appellant's sample, as shown by the relevant laboratory documentation packages are the following:

<b>A Sample</b>	<i>Position</i>	<i>Ratio (%)</i>	<i>Table</i>	<i>Page</i>	<i>Date</i>
Gel Image Screening (Processed)	Lane 8	<b>85.3</b>	5.5.5	18	10 Feb 09
	First Confirmation	Lane 10	<b>89.4</b>	6.5.8	25
	Lane 20	<b>88.2</b>	6.5.8	26	
Second Confirmation	Gel 1 Lane 10	<b>89.8</b>	8.5.8	42	17 Apr 09
	Gel 2 Lane 13	<b>94.4</b>	8.5.8	43	17 Apr 09

<b>B Sample</b>	<i>Position</i>	<i>Ratio (%)</i>	<i>Table</i>	<i>Page</i>	<i>Date</i>
<u>Gel 1</u>					
Sample undiluted	Lane 19	<b>88.5</b>	5.6.8	25	29 Nov 09
Sample diluted 1:1	Lane 6	<b>87.2</b>	5.6.8	26	29 Nov 09
	Lane 11	<b>86.9</b>	5.6.8	26	
Sample diluted 1:3	Lane 9	<b>88.0</b>	5.6.8	27	29 Nov 09
	Lane 16	<b>89.2</b>	5.6.8	27	
	Lane 21	<b>86.9</b>	5.6.8	28	
<u>Gel 2</u>					
Sample diluted 1:1	Lane 4	<b>89.4</b>	5.8.8	35	29 Nov 09
	Lane 12	<b>90.7</b>	5.8.8	36	
Sample diluted 1:3	Lane 6	<b>89.4</b>	5.8.8	36	29 Nov 09

57. The above (and chiefly the results of the B sample analysis – Gel 1) shows that the application of 3 different dilution ratios did not affect significantly the basic band ratio, ranging from 86.9% to 89.2%, with the undiluted sample showing a ratio of 88.5, i.e. higher than most of

the ratios of the diluted samples. Those results, in addition, do not materially depart from the results of the analysis of the A sample. Dilution by an inert solvent, indeed, equally affects all isoforms and does not lead (as made clear by the abovementioned results) to the selective suppression of certain bands.

58. In addition to the foregoing, the Panel notes that the (positive and negative) reference standards are prepared and applied to the gel for the application of the IEF-DB Method in the same concentration level as the athlete's sample and that the validation data of the EPO analyses conducted at IDAS covered dilution experiments comparing 7 concentration levels of reference samples which indicated that banding patterns had not been affected by dilution.

59. The Panel therefore finds that dilution did not affect the reliability of the results shown by the IEF-DB Method on the Appellant's sample.

- Degradation

60. According to the Appellant, another reason for the "*non typical endogenous EPO expression*" of Y.'s banding pattern could be the "*degradation*" of the sample.

61. The Panel notes however that no signs of sample degradation were observed in the analyses performed: on one hand, the Respondent's experts indicated that several factors (pH value, steroid profile, stability test, molecular weight) allow the conclusion that Y.'s sample was not degraded; on the other hand, one of the Appellant's experts (Dr Scott) conceded that, since "*the activity tests ... were all negative, ... it is likely that no bacterial or enzymatic contamination exist[ed]*", and that the discovery that the sample temperature remained "*uncontrolled or unknown*" only for "*hours rather than days ... reduces the probability that temperature based degradation was the cause of the AAF*" (Adverse Analytical Finding).

62. The Panel therefore finds that the results shown by the application of the IEF-DB Method on the Appellant's sample were not affected by degradation.

- Consideration of non-EPO bands

63. The Appellant contends that in the analysis of the undiluted A sample performed in the course of the screening test the software took into consideration also some bands (8 and 9), which are not EPO.

64. The Panel is not convinced by such submission and remarks that in the confirmation analyses for the A and the B samples the bands in the upper basic area were not attributed to EPO isoforms: therefore, they did not affect the basic band ratio and still the "85% condition" set as one of the identification criteria for "Other Epoetins" was satisfied.

65. The Panel therefore finds that the results shown by the application of the IEF-DB Method on the Appellant's sample were not affected by the consideration of non-EPO bands.

- Software set-up

66. According to the Appellant, the set-up of the GASEPO software used in the framework of the IEF-DB Method affects the evaluation of the basic band ratio. In order to substantiate her allegation, the Appellant re-analyzed the “raw data” provided by the Respondent to show that the detected concentration of the bands in the basic area depends on how the software is set up.
67. The Panel finds this submission to be speculative and unsubstantiated. Indeed, the Appellant alleges that the results of the analyses under the IEF-DB Method may be affected by a “peculiar” use of the software used for their processing. She did not submit, nor adduced any evidence, that the specific results of the analyses performed on her sample have been altered through an improper use of the software. Quite to the contrary, the Respondent indicated specifically that in the re-analyses conducted on the “raw data” by the Appellant, to show the possible impact of the software setup, deviations from data processing principles can be identified.
68. The Panel therefore finds that no evidence has been submitted to prove that the results shown by the application of the IEF-DB Method on the Appellant’s sample were affected by the GASEPO software setup.

- Positive Control Samples

69. The Appellant challenges the Adverse Analytical Finding also by alleging some departures from the applicable provisions governing the laboratory procedures with respect to the positive control samples applied in the A and B sample analyses.
70. First, the Appellant submits that the positive control samples used did not satisfy the identification criteria (85% of the bands in the basic area) required by TD2009EPO. In addition, the Appellant contends that IDAS did not compare the Appellant’s sample with another reference sample supposed to fulfil the same identification criteria, but applied the criteria under TD2009EPO *in abstracto*.
71. With respect to the positive control samples the Panel notes that the ISL provides the following:
- at Clause 5.7.3 (in the framework of the monitoring of analytical performance), first bullet point, that “*the range of quality control activities should include: Positive and negative controls analyzed in the same analytical run as the Presumptive Analytical Finding Sample*”;
  - at Clause 5.4.4.2.1 (as a factor to be investigated to demonstrate that a method is Fit-for-purpose), sixth bullet point: “*Standards. Reference Materials should be used for identification, if available. If there is no reference sample available, the use of data or Sample from a validated Reference Collection [i.e., a collection of samples of known origin] is acceptable*”.

72. TD2009EPO, in its documentation and reporting section, requires, for both the Initial Testing Procedure Data and the Confirmation Procedure Data, inter alia, images corresponding to lanes representing “*standard of the suspected or equivalent substance (e.g., epoetins, darbepoetin, CERA)*”.
73. In light of the foregoing, the Panel finds that IDAS was not obliged to use, as a positive reference sample, the very same substance detected in the Appellant’s sample. The ISL as well as TD2009EPO contemplate the possibility that a reference sample corresponding exactly may not be available to the laboratory. In this event, the use of an equivalent is allowed.
74. In that relation, the record indicates that positive control samples were used for all the confirmation gels. Failing referenced standards for all biosimilar or copy EPO available on the market, IDAS used an equivalent positive control substance, namely epoetin alpha.
75. As a result, the positive control samples used in the analyses of the Appellant’s samples have to be evaluated to verify whether they satisfy the identification criteria set by TD2009EPO, not pursuant to Clause 3.2.2 (applicable to “Other Epoetins”), but under Clause 3.2.1 (concerning “Epoetin Alpha and Beta”). It is clear that the identification criteria therein are satisfied.
76. The Panel therefore finds that no departure from the applicable provisions has taken place with respect to the positive control samples applied in the Appellant’s A and B sample analyses. The results of the IEF-DB are therefore not affected.

- Uncertainty and Lack of Robustness

77. Clause 5.4.4.2.1, third bullet point ISL indicates “*Robustness*” as a factor to be investigated to demonstrate that a method is Fit-for-purpose:

*“The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible tests shall be controlled”.*

78. The issue of “*Uncertainty*” is addressed by the ISL as follows:

*“5.4.4.3 Estimate of Uncertainty of Method*

*In most cases an identification of a Prohibited Substance, its Metabolite(s) or Marker(s), is sufficient to report an Adverse Analytical Finding.*

*5.4.4.3.1 Uncertainty in identification*

*The appropriate analytical characteristics shall be documented for a particular assay. The Laboratory shall establish criteria for identification of a compound at least as rigorous as stated in the relevant Technical Document.*

*5.4.4.3.2 Uncertainty in establishing that a substance exceeds a threshold.*

*The purpose of threshold reporting is to establish that the Prohibited Substance or its Metabolite(s) or Marker(s) are present at a concentration/ratio of measured analytical values greater than the threshold taking into consideration the applicable uncertainty. The*

*method, including selection of standards and controls, and estimation of uncertainty shall be Fit-for-purpose.*

*5.4.4.3.2.1 Uncertainty of quantitative results, particularly at the threshold value, shall be addressed during the validation of the assay.*

*5.4.4.3.2.2 The expression of uncertainty shall use the expanded uncertainty using a coverage factor,  $k$ , to reflect a level of confidence of 95 %.*

*5.4.4.3.2.3 Uncertainty may be further addressed in Technical Documents in order to reflect the purpose of analysis for the specific substances”.*

79. Robustness of a method means that the method must be capable of providing the reliable repetition of results at different times and with different operators performing the range of sample analyses to be conducted on the sample's aliquots.
80. In this connection, the Panel notes that the issue of “Robustness” can be dealt with from two different perspectives: generally, the “Robustness” of the IEF-DB Method as such can be discussed; specifically, the “Robustness” of the analyses performed on the Appellant's sample can be evaluated.
81. With respect to the validity of the method, the Panel recalls that the IEF-DB Method has been recognized several times by the CAS jurisprudence (see above).
82. Concerning the “Robustness” of the IEF-DB Method in testing the Appellant's sample, the Panel notes the absolute consistency of the isoelectric profiles shown by the various analyses performed on the A and the B samples provided by Y; confirming the “Robustness” of the Method in a satisfactory manner for the Panel.
83. “Uncertainty”, on the other hand, describes the relative indeterminacy of every scientific measurement. As a result, ISL provides that *“in establishing whether a substance exceeds a threshold”* an estimation of uncertainty is to be included, to reflect a certain level of confidence.
84. In this respect, the Panel has two observations. The first is that rEPO is not a “threshold substance”: as a result, the mere identification of the substance is sufficient to report an adverse analytical finding. The second is that, to the extent some measurements are necessary, for instance in order to determine the basic band ratio, TD2009EPO takes into account “Uncertainty”: in fact, the third identification condition for “Other Epoetins” refers to a ratio of “approximately” 85% between the intensity of the bands in the basic area and the total intensity of the bands. This means that applying the “Uncertainty” factor (reflecting a confidence of 95%: Clause 5.4.4.3.2.3 ISL) to profiles, such as the Appellant's, exceeding (even though slightly) the ratio prescribed by the TD2009EPO for “Other Epoetins”, the identification condition is nevertheless satisfied.
85. The Panel therefore finds that the results of the IEF-DB Method, *per se* and/or as applied to the Appellant's sample, are not affected by “Uncertainty” or lack of “Robustness”.

- Unreliability of the Second Opinion

86. The Appellant, then, criticizes the procedure that led to the issuance of the second opinion by Dr Pascual with respect to the A sample analysis: the Appellant reads the correspondence exchanged between IDAS and the Barcelona Laboratory as an indication that IDAS was requesting an opinion confirming its findings.
  87. The Panel does not agree with the Appellant's reading of such correspondence. The Panel understands from it that IDAS transmitted the analytical data, with certain observations, relating to several samples (including those of the Appellant) to the members of the EPO group entitled to issue "second opinions" (as provided by TD2009EPO, p. 8, last paragraph), and that, after a response from Dr Pascual who inquired whether he had to issue a formal "second opinion", IDAS confirmed the request to obtain a "*defensible conclusion*", be it positive or negative.
  88. The Panel therefore finds that no evidence has been brought by the Appellant that puts into question the reliability of the second opinion issued by Dr Pascual with respect to the Appellant's A sample.
- c) The second group of submissions: is the Adverse Analytical Finding to be invalidated because of departures from set procedures or of violations of the Appellant's rights?
89. The second main group of submissions refers to the allegation of a variety of violations of the Appellant's rights and/or of departures from the provisions set by the ISL or by the relevant technical documents with respect to the analysis procedure.
    - ca) The contacts between IDAS and the Respondent
  90. The Appellant criticizes the analysis procedures, by submitting that they were somehow affected by "improper" contacts between IDAS and FIS.
  91. The Panel does not agree with the Appellant's submission. In fact, the correspondence exchanged between FIS and IDAS, which forms the basis for the Appellant's contention, does not support the conclusion that IDAS did not decide independently whether the Appellant's sample had to be reported positive. Such correspondence, actually, referred only to the possibility for IDAS to perform analyses in cooperation with the Seibersdorf Laboratory, and to the "timing" of the reporting by IDAS of the analyses results: discussions took place, in fact, with respect to the application of the (then upcoming) TD2009EPO to several analytical results looking "*rather similar*"; and IDAS accepted the FIS' suggestion. Such exchange cannot be held to have improperly affected the evaluation of the Athlete's banding pattern on the merits under the applicable rules: IDAS independently decided to report the Adverse Analytical Finding after a careful analysis of the results of the application of the IEF-DB Method, without being influenced by FIS.



92. The Panel therefore finds that the Adverse Analytical Finding was not affected by “improper” contacts between IDAS and FIS.

cb) Choice of aliquots

93. In the Appellant’s opinion, IDAS breached Clause 5.2.4.3.1.4 ISL, because it performed a second confirmation analysis for the Appellant’s A sample using the same aliquots as for the screening and the first confirmation analyses.

94. Clause 5.2.4.3.1.4 ISL provides that *“the Laboratory shall have a policy to define those circumstances where the Confirmation Procedure for an “A” Sample may be repeated (e.g., batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and be completed on a new Aliquot of the “A” Sample”*.

95. The Panel notes that, with respect to the A sample, after a screening test, two confirmation analyses under the IEF-DB Method and an analysis pursuant to the SDS-PAGE Method were performed: according to the A sample analysis documentation package, the first confirmation analysis under the IEF-DB Method and the analysis under the SDS-PAGE Method were carried out at IDAS, while the second confirmation analysis was performed at the Seibersdorf Laboratory.

96. The Panel finds, however, contrary to the Appellant’s submissions, that the second confirmation analysis (as well as the SDS-PAGE Method) was not carried out as a “repetition” of the first confirmation analysis: no technical problems had arisen, demanding the nullification and the repetition of the first analysis, whose results are clearly intelligible and support *per se* the Adverse Analytical Finding. As a result, the performance of the additional analyses fell outside the scope of application of Clause 5.2.4.3.1.4 ISL. The choice of the aliquots for these additional analyses is therefore irrelevant.

97. The Panel in light of the above finds that the Adverse Analytical Finding was not affected by a departure from Clause 5.2.4.3.1.4 ISL.

cc) The cooperation between IDAS and the Seibersdorf Laboratory

98. The Appellant submits that violations of Clause 5.3.5 ISL, as well as of provisions of the TD2009LCOC and of the TD2009LDOC, were committed by IDAS with regard to the *“specified complement analyses”* carried out at the Seibersdorf Laboratory: more specifically, this *“cooperative analysis”* was performed in breach of the rules relating to the chain of custody and the authorizations.

99. On the basis of the documents contained in the A sample analysis documentation package, the Panel observes that, after a screening test, a confirmation analysis under the IEF-DB

Method and an analysis pursuant to the SDS-PAGE Method performed at IDAS (respectively on 10 February 2009, 13 February 2009 and 27 February 2009), a second confirmation analysis was carried out at the Seibersdorf Laboratory on 17 April 2009, after FIS had authorized on 2 April 2009 the “*carrying out [of] cooperative analyses*”.

100. In light of the foregoing, the Panel finds the Appellant’s submissions are:
- irrelevant, since they refer to a confirmation analysis (the second), which adds nothing to the results shown by the first confirmation analysis, sufficient in itself, according to TD2009EPO, to justify the Adverse Analytical Finding; meaning that even if the results of the tests performed at the Seibersdorf Laboratory were considered void, because of the problems claimed to exist by the Appellant, the Adverse Analytical Finding, based on the results of the application of the IEF-DB Method at IDAS, would not be nullified; and
  - without merit, since the performance of additional tests at the Seibersdorf Laboratory had been duly authorized, and the results shown (entirely consistent with those obtained at IDAS) indicate that the analyses were not affected by hypothetical problems caused by transport conditions.
101. The Panel therefore finds that with regard to the cooperation between IDAS and the Seibersdorf Laboratory the Adverse Analytical Finding was not affected by any violations of Clause 5.3.5 ISL or of the provisions of the TD2009LCOC or of the TD2009LDOC.
- cd) The departures from validated procedures
102. In the Appellant’s opinion, IDAS breached Clause 5.3.9 ISL with respect to the “*improved modification of the technique*” applied in cooperation with the Seibersdorf Laboratory, held not to comply with IDAS set procedures, without any record documenting it.
103. The Panel, in light of the observations of the set out above, finds the Appellant’s submissions also in this respect to be irrelevant. As mentioned, even if the results of the tests performed at the Seibersdorf Laboratory were considered void because of the problems claimed to exist by the Appellant, the Adverse Analytical Finding, based on the results of the application of the IEF-DB Method at IDAS, would stand.
104. The Panel therefore finds that the Adverse Analytical Finding was not affected by any departures from validated procedures.
- ce) The violation of the Appellant’s right to attend the B sample analysis
105. The Appellant submits that IDAS breached Article 7.1.4 FIS ADR and Clause 5.2.4.3.2.6 ISL, because it did not allow her to attend the full analysis of the B sample, namely the testing of the “extended gel”.

106. Article 7.1.4 FIS ADR provides the following:

*“If the initial review of an Adverse Analytical Finding under Article 7.1.2 does not reveal an applicable TUE, or departure from the International Standard for Testing or the International Standard for Laboratories that caused the Adverse Analytical Finding, FIS shall promptly notify the Athlete of: (a) the Adverse Analytical Finding; (b) the anti-doping rule violated; (c) the Athlete’s right to promptly request the analysis of the B Sample or, failing such request, that the B Sample analysis may be deemed waived; (d) the scheduled date, time and place for the B Sample analysis (which shall be within the time period specified in the International Standard for Laboratories) if the Athlete or FIS chooses to request an analysis of the B Sample; (e) the opportunity for the Athlete and/or the Athlete’s representative to attend the B Sample opening and analysis at the scheduled date, time and place if such analysis is requested; and (f) the Athlete’s right to request copies of the A and B Sample laboratory documentation package which includes information as required by the International Standard for Laboratories. FIS shall also notify the Athlete’s National Anti-Doping Organisation and WADA. If FIS decides not to bring forward the Adverse Analytical Finding as an anti-doping rule violation, it shall so notify the Athlete, the Athlete’s National Anti-Doping Organisation and WADA”.*

107. Clause 5.2.4.3.2.6 ISL provides:

*“The Athlete and/or his/her representative, a representative of the entity responsible for Sample collection or results management, a representative of the National Olympic Committee, National Sport Federation, International Federation, and a translator shall be authorized to attend the “B” confirmation.*

*If the Athlete declines to be present or the Athlete’s representative does not respond to the invitation or if the Athlete or the Athlete’s representative continuously claim not to be available on the date of the opening, despite reasonable attempts by the Laboratory to accommodate their dates, over a period not to exceed 7 working days, the Testing Authority or the Laboratory shall proceed regardless and appoint an independent witness to verify that the “B” Sample container shows no signs of Tampering and that the identifying numbers match that on the collection documentation. At a minimum, the Laboratory Director or representative and the Athlete or his/her representative or the independent witness shall sign Laboratory documentation attesting to the above.*

*The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations.*

*The Laboratory Director may remove, or have removed by proper authority, any Athlete or representative(s) interfering with the testing process. Any behavior resulting in removal shall be reported to the Testing Authority and may be considered an anti-doping rule violation in accordance with Article 2.5 of the Code, ‘Tampering, or Attempting to tamper, with any part of Doping Control’”.*

108. The Panel considers the opportunity for the athlete and/or his/her representative to be given the opportunity to attend the B sample “*opening and analysis*” is indeed a basic right in doping-control proceedings, since it reflects the need that an athlete is heard before an adverse analytical finding is finally reported and provides the possibility for the athlete to verify that the procedures intended to confirm the initial adverse analytical finding are properly conducted.

109. The Panel however finds that the purpose of the athlete’s right to attend the B sample “*opening and analysis*” also defines its limits: in other words, the athlete does not necessarily have the

right to attend the performance of those analyses which are not required to confirm the initial adverse analytical finding.

110. In the present case, the Appellant submits that she had not been given the possibility to attend the performance of the analysis performed on the “extended gel”. It is in fact not disputed that Y. and her representative attended the opening of the B sample and the conduct of the analysis on the “normal gel”.
111. The Panel finds the Appellant’s submissions on this point to be:
- irrelevant, since they refer to an analysis that was not required and which adds nothing to the results shown by the analysis performed on the “normal gel”, sufficient in itself to confirm the Adverse Analytical Finding; meaning that even if the results of the tests performed on the “extended gel” were considered void, because of a violation of the Appellant’s rights, the Adverse Analytical Finding, as confirmed by the analysis of the “normal gel” would not be nullified; and
  - without merit, since the performance of the additional test was not required to confirm the initial adverse analytical finding.
112. The Panel therefore finds that Adverse Analytical Finding was not affected by a violation of the Appellant’s right to attend the B sample analysis.
- cf) The delay in the reporting of the analysis’ results
113. In the Appellant’s opinion, IDAS breached Clause 5.2.6.5 ISL: an undue delay occurred between the receipt of the sample (8 January 2009) and the report of the results (14 August 2009) by IDAS, and also with respect to the issuance of the second opinion.
114. According to Clause 5.2.6.5 ISL, *“reporting of “A” sample results should occur within ten (10) working days of receipt of the Sample. . . . The reporting time may be altered by agreement between the Laboratory and the Testing Authority”*.
115. 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.
116. The Panel therefore finds that the no breach of Clause 5.2.6.5 ISL has been committed.

d) Conclusion

117. All the above demonstrates, in the Panel's opinion, that (i) the results shown by the IEF-DB Method, indicating that the identification criteria for "Other Epoetins" are clearly met, are reliable and are sufficient to support the Adverse Analytical Finding, (ii) the results of the SDS-PAGE Method cannot be deemed to exclude the positive finding based on the IEF-DB Method and (iii) the Adverse Analytical Finding is not invalid for any procedural reasons.
118. Consequently and given the detection of rEPO in her urine, Y. is to be found in violation of the anti-doping rule constituted by Article 2.1 of the FIS ADR.

C. *What is the appropriate sanction to be imposed on Y.?*

119. The conclusion that Y. has violated an anti-doping rule pursuant to Article 2.1 of the FIS ADR (presence of a prohibited substance in her urine sample) dictates that Y. is to be sanctioned with two years' ineligibility pursuant to Article 10.2 of the FIS ADR. No reasons for the elimination or reduction of such a sanction have been invoked or exist. The Decision that declared Y. ineligible to compete for two years is therefore correct.
120. The Decision held that in the calculation of the ineligibility period imposed on the Appellant credit had to be given for the period of the provisional suspension, which was applied on 21 August 2009. In substance, the ineligibility imposed was declared to start on 21 August 2009.
121. The Appellant, however, invokes the alleged delays in the reporting of the positive results of the A sample to request, pursuant to Article 10.9.1 FIS ADR, that the period of ineligibility be set to start at the date of the sample collection.
122. The Panel does not agree with the Appellant's submission. No substantial delays in hearing process or in other aspects of the doping control appear to have occurred: indeed the complexity of the analyses (and the time taken for their completion) seems to be linked to the nature of the substance found in the Appellant's sample. No reason therefore exists to set the starting date of the ineligibility period at a date earlier than the date of the Appellant's provisional suspension.
123. In light of the foregoing, the Panel confirms that the ineligibility period imposed on Y. started on 21 August 2009.

**Conclusion**

124. The Panel holds that the appeal brought by Y. is to be dismissed, and that the Decision is to be confirmed. Furthermore, the Panel holds that all other prayers for relief are dismissed.

**The Court of Arbitration for Sport rules that:**

1. The appeal filed by Y. against the decision issued on 22 December 2009 by the Doping Panel of the Fédération Internationale de Ski is dismissed.

(...)

4. All other prayers for relief are dismissed.