CAS 2010/A/2041 Yuliya Chepalova v. Fédération Internationale de Ski (FIS)

ARBITRAL AWARD

delivered by the

COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President: Prof. Luigi **Fumagalli**, Attorney-at-law, Milan, Italy

Arbitrators: Ms Maidie E. **Oliveau**, Attorney-at-law, Los Angeles, United States
Mr Quentin **Byrne-Sutton**, Attorney-at-law, Geneva, Switzerland

between

Yuliya Chepalova, Russia
Represented by Mr Claude Ramoni, Attorney-at-law, Lausanne, Switzerland

as Appellant

and

Fédération Internationale de Ski (FIS), Switzerland
Represented by Mr Jean-Pierre Morand, Attorney-at-law, Lausanne, Switzerland

as Respondent

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1. BACKGROUND

1.1 The Parties

1. Ms Yuliya Chepalova (hereinafter also referred to as "Chepalova" or the "Appellant") is an international-level cross-country skier of Russian nationality, born on 23 December 1976, member of the Russian Ski Federation (hereinafter referred to as the "RSF").

2. The Fédération Internationale de Ski (hereinafter also referred to as the "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.

1.2 The Dispute between the Parties

3. 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.

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

5. The A sample (code A2368648) provided by Chepalova was analysed by the Institute of Doping Analysis and Sports Biochemistry of Dresden, Germany (hereinafter also referred to as "IDAS" or the "Dresden Laboratory"), a laboratory accredited by the World Anti-Doping Agency (hereinafter also referred to as the "WADA"). On 14 August 2009 IDAS reported the presence of recombinant erythropoietin (hereinafter also referred to as "rEPO"), a prohibited substance under the FIS anti-doping rules, in the sample (identified by IDAS with the internal code 90014) provided by Chepalova. This analytical finding (hereinafter also referred to as the "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 (hereinafter also referred to as the "Barcelona Laboratory").

6. On 21 August 2009 the FIS advised the RSF of the Adverse Analytical Finding and imposed a provisional suspension on Chepalova pursuant to Article 7.6 of the FIS Anti-Doping Rules, 2009 Edition (hereinafter also referred to as the "FIS ADR").

7. In an email message of 25 August 2009 the RSF informed the FIS that the case of Chepalova "*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 Chepalova.

8. That notwithstanding, on 3 September 2009 Chepalova requested the analysis of the B sample.

9. On 27-30 September 2009 the B sample (code B2368648) was analysed at IDAS.

10. On 29 September 2009, Chepalova, 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:

"*27-29 September 2009 wurden die Athletin Julija Tschepalowa und Aleksej Schpak ins Institut für Dopinganalytik und Sportbiochemie Dresden eingeladen, um die Probe B2368648 zu öffnen. Während der Analyse der Probe B2368 wurden die exogenen Formen EPO analysiert. Während der Durchführung der Analyse der Probe B2368648, die auf dem technischen Dokument TD 2009 EPO beruht hat, wurde die Verteilung von Isoformen des Erythropoetins auf 2 Gels (normal und groß) durchgeführt. Das große Gel wurde zwecks des genaueren Ergebnisses verwendet. Während der Analyse haben wir dieses Gel und seine Auftragung auf die Proben gesehen.*

Uns wurden die Ergebnisse präsentiert, die mit Hilfe des Standardgels entstanden sind. Man hat alle unseren Fragen beantwortet. Wir haben gebeten, die Ergebnisse vom großen Gel zu zeigen, aber das Labor hat streng abgesagt. Da nur die Hälfte von Analysenergebnissen präsentiert wurde, ist dieser Moment die der Auswertung von Analysenergebnissen kritisch geworden.

Mehrmals haben wir gebeten die Analysenergebnisse oder das Computerbild zu zeigen. Man hat geantwortet, dass es 30 Minuten lang in Anspruch nimmt und das Labor dafür keine Zeit hat. Man hat uns vorgeschlagen, das Dokumentenpaket zu fordern. Laut den internationalen Regeln verpflichtet sich das Labor nicht, das zweite Gel zur Verfügung zu stellen, das das zuverlässigere Ergebnis gibt.

Die einzige mögliche Lösung für die obenerwähnten Umstände ist die Tatsache, dass das große Gel vielleicht das negative Ergebnis der Dopinganalyse, das Nichtvorhandensein von rekombinanten Formen des Erythropoetins gezeigt hat.

Während der Analyse der Probe B2368648 waren die Ziele unserer Anwesenheit die Ganzheitsprüfung der Probe B368648, die Kontrolle des Verlaufs der technischen Prozedur und das Informieren über die entstandenen Ergebnisse.

Es gab keine Möglichkeiten uns über die Ergebnisse der Analyse vom großen Gel zu informieren. Dadurch werden alle internationalen Standards und Normen verletzt. Dadurch wird das Recht des Sportlers verletz, eine objektive Information über die Analysenergebnisse zu kriegen.

Da die Ergebnisse der Analyse der Probe B2368648 absichtlich verheimlicht wurden, halten wir es für unmöglich, den Dopingfall als positiv zu betrachten.

Hiermit informieren wir das Labor über unsere Meinung".

11. The counter-analysis' report issued on 14 October 2009 confirmed the Adverse Analytical Finding also with respect to the B sample as follows:

"*The data obtained from the EPO analysis of sample B2368648 (female, urine) fulfil the acceptance and stability criteria described in the WADA Technical Document TD2009EPO. The isoform profile complies with the identification criteria for an Adverse Analytical Finding of recombinant erythropoietin. This evaluation was supported by a second opinion pronounced by Dr José A. Pascual (IMIM, Barcelona)*".

12. 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 Chepalova would be heard by the Doping Panel of the FIS (hereinafter also referred to as the "Doping Panel").

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

14. On 22 December 2009, the Doping Panel issued a decision (hereinafter also referred to as the "Decision") in which it held (at its §§ 73-77) 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, Julija Tchepalova, 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 21st August 2009 (which means 21st August 2009 - 20th 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".

15. 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*!).

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

2. THE ARBITRAL PROCEEDINGS

2.1 The CAS Proceedings

17. On 12 January 2010, Chepalova filed a statement of appeal with the Court of Arbitration for Sport (hereinafter also referred to as the "CAS"), pursuant to the Code of Sports-related

Arbitration (hereinafter also referred to as the "Code"), to challenge the Decision. The statement of appeal contained the appointment of Ms Maidie E. Oliveau as arbitrator and had attached 5 exhibits (A1 to A5).

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

19. On 20 January 2010 the Respondent appointed Mr Quentin Byrne-Sutton as arbitrator.

20. In a letter dated 28 January 2010 the Respondent noted, with regard to Chepalova'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*".

21. In a letter dated 28 January 2010, the Appellant confirmed her request to be provided with the information.

22. 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*".

23. By communication dated 8 February 2010, the CAS Court Office informed the parties, on behalf of the President of the CAS Appeals Arbitration Division, that the Panel had been constituted as follows: Prof. Luigi Fumagalli, President of the Panel; Ms Maidie E. Oliveau and Mr Quentin Byrne-Sutton, arbitrators.

24. 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.

25. 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.

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

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

28. On 31 March 2010 the Panel issued procedural directions.

29. On the basis of the Panel's directions, on 16 April 2010 the Respondent filed its answer, with 8 exhibits (R1 to R8), seeking the dismissal of the appeal.

30. 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)*".

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

32. On 3 May 2010 the Respondent filed the documents requested.

33. On the basis of the Panel's directions:

    i. on 19 May 2010 the Appellant filed her reply brief, with 17 exhibits (A15 to A31), 2 additional expert opinions and 1 additional witness statement (E7 to E9); and

    ii. on 9 June 2010 the Respondent filed its second response with 5 exhibits (R9 to R13).

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

35. Following the letter of 10 June 2010 sent by the CAS Court Office on behalf of the President of the Panel, the parties summarized on 11 June 2010 the issues to be discussed by the experts at the hearing, as follows:

    i. as to the Appellant:

    "*1. The lack of reliability / inaccuracy of the results obtained using the IEF-DB Method*
    a. The excessive proteination of the sample
    b. "effort" urine
    c. Degradation of urine
    d. Changes in the different pictures of the appellant's sample / the disappearance of bands
    e. Effect of changes in the urine preparation on the results
    f. Lack of validation of the method used in order to establish the percentage of bands in the basic area
    g. Lack of positive reference sample
    h. Uncertainty in the calculation of the 85% threshold
    i. Uncertainty resulting from the use of GASepo software
    2. The relevance of the SDS PAGE Method.
    3. The failure by IDAS to comply with "procedural" rules provided for under the ISL (mainly in connection with the "second confirmation" performed in the Seibersdorf Laboratory and the B-sample analysis)".

    ii. as to the Respondent:

    "- *The SDS PAGE analysis. …;*
    - *The "effort" urine;*
    - *The alleged degradation of the urine;*
    - *The uncertainty;*
    - *The preparation of the sample (dilution, immunoaffinity, etc…);*
    - *The interpretation of the results*".

36. A hearing was held on 14 June 2010 on the basis of the notice given to the parties in the letter of the CAS Court Office dated 23 April 2010. The Panel was assisted at the hearing by Ms Andrea Zimmermann, Counsel to the CAS.

The following persons attended the hearing:

i. for the Appellant: by Mr Claude Ramoni, Mr Dmitry Baboshin and Mr Maxim A. Kosarev, counsel, and the Appellant in person;

ii. for the Respondent: by Mr Jean-Pierre Morand, counsel.

37. At the hearing, the following expert witnesses were heard by way of witness conferencing: Dr Paul Scott and Dr Ivan Boldyrev (called by the Appellant), Dr Martial Saugy and Dr Detlev Thieme (called by the Respondent). The witness conference was intended to clarify several issues, with specific regard to those mentioned in the parties' letters dated 11 June 2010 (§ 35 above).

38. In the course of the hearing, the Respondent insisted that the Appellant's sample contained an unknown form of biosimilar rEPO behaving as endogenous EPO when analysed with the SDS-PAGE method (the "*Sodium Dodecyl Sulphate – PolyAcrylamide Gel Electrophoresis method*": referred to in this award as the "SDS-PAGE Method"). As an example of this situation, FIS made reference to another sample, provided by a different athlete, mentioned in the laboratory documentation package concerning Chepalova's A sample under reference code 90008 (hereinafter referred to as the "Sample 90008"), which was reported positive: Sample 90008 contained rEPO, as evidenced by the application of the IEF-DB method (the "*Isoelectric Focussing and Double Blotting method*: referred to in this award as the "IEF-DB Method"), the behaviour of which could not be distinguished from endogenous EPO when applying the SDS-PAGE Method.

39. At the conclusion of the hearing, Chepalova made a declaration. The parties, then, confirmed that they had no objections in respect of their right to be heard and to be treated equally in the arbitration proceedings. However, the Appellant insisted to be granted the opportunity to comment in writing, after the hearing, on a specific issue raised by the Respondent during the hearing (§ 38 above).

40. As a result, 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*".

41. On the basis of such directions:

i. on 21 June 2010 the Appellant filed her additional submission; and

ii. on 26 June 2010 the Respondent filed its answer to the Appellant's additional submission.

2.2 The Position of the Parties

42. The following outline of the parties' positions is illustrative only and does not necessarily comprise every contention put forward by the parties. The Panel, indeed, has carefully considered all the submissions made by the parties, even if there is no specific reference to those submissions in the following summary.

a. The Position of the Appellant

43. In its statement of appeal, the Appellant requested that CAS "*rules as follows:*

    1. The decision issued on 22 December 2009 by the FIS Doping Panel in the matter of Ms Yuliya Chepalova is set aside.

    2. Ms Yuliya Chepalova is cleared from all charges brought against her in connection with the anti-doping test which took place on 2 January 2009.

    3. All the arbitration costs, if any, shall be borne by the International Ski Federation, which will in any event reimburse the minimum court office fee of CHF 500 to Ms Yuliya Chepalova.

    4. The International Ski Federation is ordered to pay to Ms Yuliya Chepalova a contribution towards her legal and other costs relating to these proceedings, in an amount to be determined at the discretion of the Panel".

44. The relief so sought was confirmed in the appeal brief dated 1 March 2010.

45. In other words, the Appellant criticizes the Decision, which she asks the Panel to set aside, alleging that IDAS reported a "*false positive*" and that in consequence no sanction should be imposed on her.

46. In her submissions in this arbitration, the Appellant preliminarily underlines that she never accepted the results reported by IDAS, which constitute the only evidence supporting her "*purported*" anti-doping rule violation.

47. With respect to the "*applicable law*", the Appellant acknowledges the application of the FIS ADR, and, for the purposes of Article 6.4 of the FIS ADR (§ 71(vi) below), of the International Standard for Laboratories, version 6.0, in force since 1 January 2009 (hereinafter also referred to as the "ISL").

48. At the same time, Chepalova points out that, in connection with the ISL, technical documents have been issued by WADA with respect to EPO tests conducted by the accredited laboratories:

    i. TD2009EPO version 1.0 [*Harmonization of the method for the identification of recombinant erythropoietins (i.e. epoetins) and analogues (i.e. darbepoetin and methoxypolyethylene glycol-epoetin beta)*] was published on 1 April 2009 and entered into force on 31 May 2009 (hereinafter also referred to as "TD2009EPO"), replacing

    ii. TD2007EPO, version 2.0 issued on 5 April 2007 and in force since 31 May 2007 [*Harmonization of the method for the identification of epoetin alfa and beta (rEPO) and darbepoetin alfa (NESP) by IEF-double blotting and chemiluminescent detection*] (hereinafter also referred to as "TD2007EPO").

    In that relation, she asserts that TD2007EPO was, for the purposes of Clause 1.0, third paragraph ISL, the "*Technical Document whose effective date most recently precede[d] that of Sample receipt date*" (January 2009).

49. The Appellant, then, submits that

    i. "*the report issued by the IDAS Laboratory does not demonstrate the presence of exogenous r-EPO in her body. On the contrary, the SDS PAGE Method applied by the IDAS Laboratory confirmed the endogenous origin of the EPO found in her body*"; and

    ii. "*numerous departures from the ISL and/or ISO norms (including mistakes made in the course of the analytical procedures and breach of rules of evaluation of identification criteria) invalidate the adverse analytical finding reported by the IDAS Laboratory*".

50. With respect to the first point, the Appellant preliminarily explains that, in order to make a distinction between rEPO (exogenous EPO) and endogenous EPO (hereinafter referred hereto as "uEPO") according to TD2007EPO, the so-called "IEF-DB Method" had to be applied, and that under TD2007EPO the percentage of the bands in the basic area was considered not to be discriminating enough. On the other hand, TD2009EPO, while confirming the application of the IEF-DB Method, "*reintroduces the criteria of the percentage of bands in the basic area, which was expressly excluded by the TD2007EPO*". In fact, under the new document, for the identification of rEPO, "*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*". However, in order to minimise the risk of false positive results, the TD2009EPO provides for the application of the so-called "SDS-PAGE Method" to confirm the exogenous or endogenous origin of a finding.

51. In light of the foregoing, the Appellant submits that the report issued by the Dresden Laboratory does not demonstrate the presence of rEPO in her body: on the contrary, the application of the SDS-PAGE Method "*resulted in the Appellant's sample being compliant with uEPO*". Therefore, FIS has not discharged the burden to prove the presence of rEPO in the Appellant's sample. In this respect, the Appellant submits that:

    i. the presumption that accredited laboratories have conducted sample analysis and followed custodial procedures in accordance with the ISL does not apply to the interpretation of the results;

    ii. the analysis performed under the SDS-PAGE Method demonstrates the endogenous origin of the EPO found in the urine of the Appellant, because the results of the application of the SDS-PAGE Method on a sample containing exogenous EPO will never be compliant with endogenous EPO;

    iii. the SDS-PAGE Method gives more reliable results than the IEF-DB Method in her case, and the issue is not whether the application of the SDS-PAGE Method was required under TD2009EPO: "*fact is that the SDS-PAGE Method [was] applied*" and that it "*did not confirm the exogenous origin of the finding by the IEF-DB Method and confirmed the endogenous origin of the EPO found in [her] sample*";

    iv. in view of the SDS-PAGE Method confirming the endogenous origin of the EPO found, the shift of the bands into the basic area can only be explained as a consequence of effort, of a degradation of the urine sample, or of the preparation of the sample by the laboratory: in this framework, "*the only reliable scientific explanation for the shift of the bands in the Appellant's sample to the basic area while performing the IEF-DB Method resulting in a fully normal analysis is a degradation of the Appellant's sample between the date of collection and the date of the analysis. Elevated temperatures is the most likely explanation for this phenomenon*";

v. the IEF-DB Method applied to the Appellant by IDAS is "*not conclusive*", because this method has been "*conducted … in breach of the ISL and the WADA Technical Documents. Such IEF-DB Method does not demonstrate that the Appellant's sample contained exogenous r-EPO, in particular as the SDS PAGE Method resulted in the Appellant's sample behaving as endogenous EPO. Furthermore, the results reported by the laboratory raise serious doubts as to the reliability and accuracy of the analysis, inasmuch as it has not been confirmed by the SDS-PAGE Method*":

a. the new method adopted by IDAS under TD2009EPO has not been validated (Clause 4.4.10 and 5.4.4.2 of the ISL);

b. the IEF-DB Method is affected by "*external factors*", which are reasonable explanations for the shift of the bands in the basic area or the percentage of bands in the basic area in view of the results of the SDS-PAGE Method, such as

- ✓ degradation of the sample, "*due to unstable peptides*", not detected by the "stability test" performed in accordance with TD2007EPO or TD2009EPO,
- ✓ intense background and/or "*artefactual less intense lines*" between bands, which affected the densitometry analysis and can be observed also in the control samples (so that "*increased background is … not a characteristic of alleged biosimilar EPO purportedly detected in the Appellant's sample*", but an indication of the poor quality of the results obtained on the basis of the IEF-DB Method and of the need to apply the SDS-PAGE Method),
- ✓ changes to sample preparation, which, if not properly validated, "*may affect the isoform distribution of the bands*", and therefore be the source of the shift of the bands under the IEF-DB Method. Indeed, IDAS "*confessed having applied several techniques with regard to the Appellant's sample*", including dilution: the dilution of the sample (with the aim of suppressing excess of proteins) may be the cause of the Adverse Analytical Finding, since it "*caused bands in the endogenous area to disappear*",
- ✓ effort, which affects the analysis performed by the IEF-DB Method: contrary to the indications contained in the laboratory documentation packages, the urine sample was provided by Chepalova in-competition, after the Appellant had participated to the "Ladies 10km Classic Mass Start" at Val di Fiemme,
- ✓ excess of protein concentration in the Appellant's sample ("*proteinuria*"), shown by the "*screening analysis of her urine*", which may cause "*false positive*" results: in order to avoid proteinuria or eliminate the masking effect of non specific proteins in the course of the identification of the endogenous or exogenous origin of EPO, IDAS "*chose to dilute the sample*". In so doing, IDAS followed a method not provided in TD2007EPO or TD2009EPO and not validated – which affects the isoform distribution of the sample and has therefore an effect on the application of the identification criteria provided for in TD2007EPO and TD2009EPO,
- ✓ consideration of bands (8 and 9), which are not EPO, in the analysis of the undiluted Appellant's A sample performed in the course of the screening test to estimate the percentage of bands: this shows that the only undiluted sample (if bands 8 and 9 are not considered) does not meet the 85% threshold provided for under TD2009EPO,

- ✓ set-up of the GASEPO software: the "*analyses of the "raw data" show that the percentage of bands in the basic area calculated with the GASEPO software is not reliable*", since the meeting of "*the 85% threshold also depends on how the GASEPO software has been set-up*"; and in the absence of a positive reference sample, it is impossible to draw any conclusion from the results obtained using the GASEPO software;

c. a departure from Clause 5.4.7.3 ISL and TD2009EPO took place, since the positive control samples did not satisfy the identification criteria (85% of the bands in the basic area) required by TD2009EPO, and "*the Appellant's sample behaved in the same way as the negative reference sample*": departing from the ISL, 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*;

d. "*uncertainty*" and "*lack of robustness*" of the IEF-DB Method, in contrast with Clause 5.4.4.2.1, third bullet point ISL, is confirmed by the fact that the application of the same method to identical samples lead to dissimilar results. The IEF-DB Method "*does not meet the criteria provided for under article 5.4.4.3.2.2 for the evaluation of the threshold of approximately 85% of the bands in the basic area provided for under article 3.2.2 TD2009EPO*". On the contrary, the SDS-PAGE Method is "*more robust and Fit-for-purpose*";

vi. some issues affect the second opinion issued by Dr Pascual (with respect to the A sample analysis): IDAS' first attempt to obtain a second opinion resulted in "*inconclusive results*"; Dr Pascual, before issuing his second opinion, appears to have "*inquired whether he had to report a positive or negative case*".

52. With respect to the second point, the Appellant submits that "*other departures from the ISL and the Technical Documents*", as well as "*further violations of the Appellant's rights*", have occurred. Specifically, the following can be identified:

i. assessment of the results by IDAS with reference to suggestions of the FIS: "*numerous contacts occurred between the Respondent and the IDAS Laboratory to decide whether the IDAS Laboratory should report an "atypical" result or a "positive" result*". In other words, IDAS did not decide independently whether the Appellant's sample had to be reported positive: "*the Respondent took an active part in the analytical procedure, trying to "help" the IDAS Laboratory to report an adverse analytical finding in the case of Appellant … by providing data and suggesting that the Appellant used a prohibited substance*" while it was "*aware of the identity of the Appellant*";

ii. violation of Clause 5.2.4.3.1.4 ISL: "*the IDAS Laboratory performed a second confirmation analysis for the A sample of the Appellant using the same aliquots as for the screening and the first confirmation*";

iii. violation of Clause 5.3.5 ISL, of the TD2009LCOC (the technical document issued by WADA with respect to the Laboratory Internal Chain of Custody, in force since 1 January 2009) and of the TD2009LDOC (the technical document issued by WADA concerning the Laboratory Documentation Packages, in force since 1 January 2009) with regard to the "*specified complement analyses*" carried out at the WADA accredited laboratory of Seibersdorf, Austria (hereinafter also referred to as the "Seibersdorf Laboratory"): this "*cooperative analysis*" was performed in breach of the rules relating to the chain of custody and the authorizations, since no mention is made in the analysis documentation package of the name of the operator who performed at the Seibersdorf

Laboratory some operations on the Appellant's sample, and no mention is made of any authorization given by WADA to transfer the sample. "*As … IDAS … chose to report the purported adverse analytical finding only after receipt of the analysis performed in Seibersdorf, it is proven that such departure may have caused the adverse analytical finding*". In addition, the contacts with the Seibersdorf Laboratory confirm that IDAS "*was of the opinion that the analyses it performed were not sufficient to demonstrate an adverse analytical finding in the case of the Appellant*";

iv. violation of Clause 5.3.9 ISL: the "*improved modification of the technique*" applied in cooperation with the Seibersdorf Laboratory does not comply with IDAS set procedures and there is no record documenting it, where "*any departure from … accredited and validated methods … can be the origin of the adverse analytical finding*";

v. violation of the Appellant's right to attend the full analysis of the B sample (Article 7.1.4 FIS ADR and Clause 5.2.4.3.2.6 ISL): "*IDAS … strongly refused to let*" the Appellant and her representative "*attend all steps of the B Sample analysis, namely the testing of the "extended gel"... . … IDAS … chose to show some parts of the analysis, hiding other aspects despite the Appellant's protestations*", and this leads to the invalidation of the full analysis;

vi. violation of Clause 5.2.6.5 ISL: 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. At least, this delay should be taken into account, under Article 10.9.1 FIS ADR, to decide the starting date of any ineligibility period.

53. Finally, the Appellant rebuts the Respondent's statement, made at the hearing (§ 38 above), that Sample 90008 constitutes an illustration of a sample containing an unknown form of biosimilar rEPO behaving as endogenous EPO when analysed under the SDS-PAGE Method. In the Appellant's opinion, such statement is "*inaccurate*": Sample 90008 "*is not an example of a very specific type of biosimilar rEPO with the same molecular weight as endogenous uEPO*". In such respect the Appellant submits that Sample 90008 did not fulfil the identification criteria set by TD2009EPO for other epoetins, since none of the analyses performed had resulted in a percentage of bands in the basic area reaching the required 85% threshold. As a result, it should be assumed that IDAS, in order to report Sample 90008 as positive, considered that the identification criteria for "known" forms of rEPO (EPO alpha or beta) had been met, even though the application of the SDS-PAGE Method should have detected the presence of such forms of rEPO.

b. The Position of the Respondent

54. In the answer dated 16 April 2010, FIS requested that:

"*1. The Appeal of Ms Yuliya Chepalova be dismissed.*

2. The Appellant Ms Yuliya Chepalova be ordered to pay the Respondent's costs and expenses arising out of this arbitration in an amount to be determined by the CAS Panel".

55. FIS, in other words, asks this Panel to dismiss the appeal brought by Chepalova and to confirm the sanction imposed by the Decision, since the analyses performed of the Appellant's samples "*establish a clear positive case*" and "*show convincingly that … Chepalova committed an anti-doping rule violation*".

56. In its submissions before this Panel, the Respondent made some preliminary observations with respect to the "*Applicable Law and [the] Technical Documents*", pointing out that:

    i. the FIS ADR apply;

    ii. the ISL applies;

    iii. "*it was fully appropriate*" for IDAS "*to wait until the adoption of the TD2009EPO to evaluate the results*" under the criteria set forth in the new document, pursuant to the "*most recent state of art technology and knowledge*". TD2007EPO, in fact, applies only to the identification of epoetin alpha and beta and NESP, and cannot be applied to new forms of EPO. In such respect, the Appellant emphasizes that the application of the method to detect rEPO has not changed from TD2007EPO to TD2009EPO: "*only the evaluation and interpretation criteria have changed as those mentioned in TD2007EPO … were … not adequate anymore to identify newer variations of EPO*";

    iv. the three identification criteria set by TD2009EPO for other epoetins are fulfilled. In any case, the 85% threshold is not an absolute value: a percentage slightly under 85% is not relevant, since the third identification condition of other epoetins under TD2009EPO refers to the intensity of the bands in the basic area accounting for "*approximately 85% or more*" (underlining by the Respondent) of the total band intensity.

57. The Respondent, then, challenges the arguments raised by the Appellant and submits that they are "*without merit*". The Respondent's contentions are the following:

    i. with respect to the "*SDS-PAGE Method*": "*contrary to the allegations of the Appellant, the SDS-PAGE method does not establish the endogenous origin of the EPO found in her sample. This analysis only shows that the rEPO taken by the athlete has a similar molecular weight as uEPO … . In other words, the SDS-PAGE analysis is not conclusive as to the endogenous character … when rEPO has a similar weight as uEPO*". Therefore, in the Appellant's case, "*the only conclusion which can be drawn from the SDS-PAGE Method is that the rEPO present in the urine of the athlete does not differ significantly in molecular weight from the endogenous urinary EPO*". In addition, the SDS-PAGE Method is only "*a complementary technique … and not a required confirmation technique when the main criteria are sufficient to draw a conclusion*";

    ii. with respect to the "*Effort Urine*": the identification criteria of TD2009EPO take into account "*proteinuria*". In any case, in the Appellant's sample no sign of "*proteinuria*" was observed, the complete disappearance of the endogenous bands is not consistent with effort urine, and the percentage of the basic bands over 85% of the band intensity excludes effort urine;

    iii. with respect to the "*alleged degradation of the urine*": "*there is not the slightest indication that the Appellant's samples were at any time [exposed] to high temperature and/or could have been degraded during transportation*"; quite to the contrary, the documents regarding the chain of custody establish that the samples have been kept under "*proper and secure*" conditions from collection to delivery to the laboratory. In addition, degradation is excluded by the results of the stability test, by the pH of the Appellant's urine (lower than 6.0) and by the results of the application of the SDS-PAGE Method;

iv. with respect to the "*results of the IEF Method*", challenged by the Appellant:

a. as to the "*validation of the method*": a new validation was not necessary, since the analytical procedures remained unchanged under TD2009EPO; in fact, only the evaluation and interpretation criteria have been amended in TD2009EPO;

b. as to the "*external factors*":

- ✓ the "*degradation of the urine*" has to be excluded, since no sign of it was shown by the stability test performed at IDAS, and the chain of custody documents confirm that the sample was kept under secure conditions. In addition, there is "*absolutely no support*" to the argument that degradation could result in producing a profile fully consistent with the use of biosimilar rEPO,
- ✓ the "*background*" did not affect the interpretation of the images, which clearly show an adverse analytical finding,
- ✓ the "*sample preparation*" did not affect the results: dilution may be essential to avoid protein overloading and is generally acknowledged by the technical documents; in addition, the direct comparison of the undiluted sample and the diluted samples reveals no significant difference between them. At the same time, the immunoaffinity process, useful for the concentration or the cleanup of samples, was not required since in the Appellant's sample no further concentration was needed. On the contrary, dilution was adequate and "*did not significantly affect the percentage of basic bands*";
- ✓ the "*bands in the upper basic area*" were not attributed, in the confirmations for the A and the B samples, to EPO isoforms: therefore, they did not affect the basic band ratio;
- ✓ "*effort*" is not a factor which can explain the shift of the bands;
- ✓ "*manipulation of the data with GASEPO*" software: the Appellant's experts did not properly handle and evaluate the raw data; the Appellant's submissions, therefore, deserve "*no credit*";

c. as to the "*alleged departures from ISL and TD2009EPO*" with respect to the positive control samples: IDAS used for the positive control samples an "*excretions study*" consisting in epoetin alpha, and in the analysis of the A sample and of the B sample of the Appellant the control samples were clearly positive pursuant to the identification criteria of epoetin alpha and beta. Under TD2009EPO it is not necessary that the EPO on the positive control sample be the same as that discovered in the athlete sample: an equivalent substance is sufficient. In fact, "*the so-called biosimilars of epoietin are numerous on the market … and they have not all been identified and referenced so far. Consequently, it cannot be requested from laboratories to have all of them available*": since IDAS used an equivalent substance, no departure can be found;

d. as to "*uncertainty*": the method covers the "*uncertainty*" factor, since the 85% limit accounts for individual variations; in any case, "*the data from the 6fold repetition of IEF experiments during the B-sample confirmation show a certainty level greater than 99.9%*". In addition, the "*mixture BRP*", used as a qualitative reference to define the borderline of the acidic and basic range for each individual gel, is prepared by IDAS on each working day: therefore, "*statistical evaluations*

of long-term reproducibility -referring to slightly different mixtures- are pointless";

v. with respect to the "*other alleged departures*":

a. as to the "*assessment of the results by IDAS*": most of the discussions between FIS and IDAS related to the adoption of TD2009EPO. In agreement with FIS, IDAS decided to wait until TD2009EPO entered into force to evaluate the results under the new identification criteria: "*such decision is not contrary to the rules*";

b. as to the "*violation of art. 5.2.4.3.1.4 ISL*": according to this provision, a laboratory shall repeat confirmation analyses only when there are "*technical insufficiencies*", such as batch quality control failure; "*in the case at hand, there was no insufficiency and all data from the first confirmation were compliant with the relevant documents*";

c. as to the "*violation of art. 5.3.5 ISL, of the TD2009LCOC and TD2009LDOC*": the analysis of the A sample under the SDS-PAGE Method was performed at the Seibersdorf Laboratory after the sample had been analysed pursuant to the IEF-DB Method at IDAS and the Adverse Analytical Finding was reported only on the basis of the results of the IEF-DB Method. As a result, the handling of the sample between the two laboratories is irrelevant, and the mere fact that the SDS-PAGE Method was applied at the Seibersdorf Laboratory did not affect the Adverse Analytical Finding, since the results of this test were not considered for the determination of the positive result;

d. as to the "*violation of art. 5.3.9 ISL*": any violation relating to the conduct of the SDS-PAGE Method is irrelevant, since this test "*did not serve*" in the determination process of the Adverse Analytical Finding;

e. as to the "*violation of the right to attend the B sample analysis*": the Appellant was granted the right to attend, together with a representative, to the opening and the analysis of the B sample. The Appellant's complaint that her rights have been violated because she could not attend the testing of the "*extended gel*" is without merit, since only the analysis of the "*normal gel*" is mandatory and the Appellant was able to attend it without restriction;

f. as to the "*violation of art. 5.2.6.5 ISL*": the 10-day deadline set in such provision is not mandatory, since it may be changed by agreement between the laboratory and the anti-doping organization, and in the Appellant's case FIS and IDAS decided to wait until TD2009EPO had entered into force to evaluate the analysis results. In any case, the alleged violation of the 10-day deadline "*cannot cause an adverse analytical finding*". As to the beginning of the sanction, the period of ineligibility shall start from the day of the provisional suspension (i.e., from 21 August 2009), since no substantial delays have occurred in the results' management or in the disciplinary procedure.

58. In summary, the Respondent submits that an anti-doping rule violation has been committed by Chepalova: in her urine, a new kind of biosimilar rEPO, having a molecular weight consistent with uEPO, was found. In this respect, the Appellant submits that "*when … Chepalova was caught, several other doping cases based on biosimilar substances arose, many of which including Russian athletes*". In addition, the Respondent indicated at the hearing (§ 38 above) that Sample 90008 offers an example of an unknown form of biosimilar rEPO behaving as endogenous EPO when applying the SDS-PAGE Method.

3. LEGAL ANALYSIS

3.1 Jurisdiction

59. CAS has jurisdiction to decide the present dispute between the parties.

60. 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.

61. 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.

3.2 Appeal Proceedings

62. 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.

3.3 Admissibility of the Appeal

63. 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.

3.4 Scope of the Panel's Review

64. 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.

3.5 Applicable Law

65. The law applicable in the present arbitration is identified by the Panel in accordance with Article R58 of the Code.

66. 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*".

67. 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 Chepalova.

68. 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.

69. 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, rendered on 5 January 1995, *UCI and CONI*), do not apply retroactively to facts that occurred prior to their entry into force, but only for the future (CAS 2000/A/274, *S. v/ FINA*, award of 19 October 2000).

70. 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.

71. 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.

72. The analyses of the A and B samples provided by Chepalova were conducted in 2009. As a result, the Panel finds, in agreement with the parties (§§ 47 and 56(i) above), 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.

73. 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.

74. 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, *Iourieva & Akhatova v/ IBU*, at §§ 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.

3.6 The Dispute

75. The appeal brought by Chepalova 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.

76. As a result of the Appellant's submissions and petitions, there are two main questions that the Panel has to examine:

    i. the first is whether Chepalova 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;

    ii. the second, to be addressed in the event Chepalova 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.

77. The Panel shall consider each of said questions separately.

i. Can Chepalova be found to have committed an anti-doping rule violation?

A. Introduction

78. 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 (§ 71(iv) 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 Chepalova 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 § 14 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.

79. The presence of rEPO in the sample provided by Chepalova 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, *UCI v/ H.*; award of 28 January 2002, CAS 2001/A/345, *M. v/ Swiss Cycling*;

award of 29 November 2002, CAS 2002/A/370, *L. v/ IOC*; award of 24 January 2003, CAS 2002/A/374, *M. v/ IOC*; award of 19 November 2003, CAS 2001/A/452, *IAAF v/ B.*; award of 13 April 2005, CAS 2004/O/679, *USADA v/ B.*; award of 5 May 2006, CAS 2001/A/831, *IAAF v/ H.* 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*" (award of 12 November 2009, CAS 2009/A/1931, *Iourieva & Akhatova v/ IBU*).

80. 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.

81. 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.

82. The possibility, then, to declare a sample positive is based on the evaluation of the image obtained, taking into account:

    i. acceptance criteria, which define the requisites that the image has to fulfil to allow the application of the identification criteria (TD2009EPO, Section 3.1);

    ii. identification criteria, which define the requisites that the image has to fulfil to find the presence of rEPO (TD2009EPO, Section 3.2);

    iii. stability criteria, which are to confirm that no interference has affected the adverse analytical finding (TD2009EPO, Section 3.3).

83. 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 … . […]

84. 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.

85. 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.

86. 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.

87. 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:

    i. 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;

    ii. Section 3.2.5 of TD2009EPO uses "permissive" language: the SDS-PAGE Method "*can*" be used;

    iii. 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)*".

88. In the Panel's opinion, the above:

    i. confirms that the IEF-DB Method is the primary method for the rEPO detection;

    ii. 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;

    iii. 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.

89. 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.

90. 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".

91. 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?*

92. 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.

B.1 The relevance of the SDS-PAGE Method.

93. 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.

94. With respect to such submission, the Panel underlines the complementary nature, as well as the characteristics, of the SDS-PAGE Method, mentioned above (§§ 88-89). 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.

95. 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 Chepalova'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.

96. 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.

B.2 The reliability of the IEF-DB Method, as applied in the Appellant's case.

Validation

97. 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.

98. 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.

99. The Panel does not agree with this submission.

100. 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.

101. 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 § 79 above), the Panel concludes that the application of the new identification criteria under TD2009EPO did not require a new validation .

Effort

102. According to the Appellant, one of the reasons for the "*non typical endogenous EPO expression*" of Chepalova's banding pattern could be "effort", which affects the isoelectric behaviour of urinary EPO.

103. The Panel is not convinced by this explanation that the Appellant is offering only as a mere possibility, without any further substantiation.

104. 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 Chepalova'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 Isoeletric Patterns of Erythrpoietin*, Clin. J. Sport

Med., 19(4), 311-315; Voss et al., *Effects of High Intensity Exercise on Isoeletric Profiles and SDS-PAGE Mobility of Erythopoietin*, Int. J. Sports Med., 2010) .

105. 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

106. Excess of protein concentration ("*proteinuria*") in the Appellant's sample is invoked by Chepalova 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.

107. The Panel notes that protein concentration was properly (§§ 112-117 below) dealt with by dilution, and that all profiles (diluted or not, including the screening analysis) satisfied the identification criteria set by TD2009EPO.

108. 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

109. 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 (positive: B sample analysis documentation package, p. 22 table 5.6.4, p. 33 table 5.8.4; and negative: A sample analysis documentation package, p. 17 table 5.5.3, p. 17 table 6.5.7; B sample analysis documentation package, p. 21 table 5.6.3, p. 32 table 5.8.3).

110. Contrary to the Appellant's contentions:

i. 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 that 85% of the total signal;

ii. 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;

iii. the positive control samples indicated by the Appellant satisfy all identification criteria for epoetin alpha without any background preventing such conclusion;

iv. all the negative control samples invoked by the Appellant have a profile which is clearly incompatible with rEPO findings.

111. 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

112. The Appellant submits that IDAS applied several techniques with regard to Chepalova'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 1/3rd to 1/4th 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.

113. 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.

114. 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 (A Sample: Exhibit A6; B Sample: Exhibit A7) are the following:

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

B Sample	*Position*	***Ratio (%)***	*Table*	*Page*	*Date*
Gel 1					
Sample undiluted	Lane 19	**88.5**	5.6.8	25	29 Nov 09
Sample diluted 1:1	Lane 6	**87.2**	5.6.8	26	29 Nov 09
	Lane 11	**86.9**	5.6.8	26	
Sample diluted 1:3	Lane 9	**88.0**	5.6.8	27	29 Nov 09
	Lane 16	**89.2**	5.6.8	27	
	Lane 21	**86.9**	5.6.8	28	

Gel 2					
Sample diluted 1:1	Lane 4	**89.4**	5.8.8	35	29 Nov 09
	Lane 12	**90.7**	5.8.8	36	
Sample diluted 1:3	Lane 6	**89.4**	5.8.8	36	29 Nov 09

115. 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.

116. 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 (Exhibit R6, sub L4) covered dilution experiments comparing 7 concentration levels of reference samples which indicated that banding patterns had not been affected by dilution.

117. 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

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

119. 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 Chepalova'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).

120. 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

121. 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.

122. 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.

123. 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

124. 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.

125. 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.

126. 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

127. 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.

128. First, the Appellant submits that the positive control samples used (for the first confirmation analysis of the A sample: A sample analysis documentation package, p. 23 table 6.5.4; for the analysis of gel 1 of the B sample: B sample analysis documentation package, p. 22 table 5.6.4; and for the analysis of gel 2 of the B sample: B sample analysis documentation package, p. 33 table 5.8.4) 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.*

129. 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 or data or Sample from a validated Reference Collection [i.e., a collection of samples of known origin] is acceptable*".

130. 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)*".

131. 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.

132. 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.

133. 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.

134. 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.

<u>*Uncertainty and Lack of Robustness*</u>

135. 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*".

136. 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*".

137. 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.

138. 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.

139. 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 (§ 79 above).

140. Concerning the "Robustness" of the IEF-DB Method in testing the Appellant's sample, the Panel notes the absolute consistency of the isoeletric profiles shown by the various analyses performed on the A and the B samples provided by Chepalova; confirming the "Robustness" of the Method in a satisfactory manner for the Panel.

141. "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.

142. 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.

143. 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

144. 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.

145. 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.

146. 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?

147. 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.

The contacts between IDAS and the Respondent

148. The Appellant criticizes the analysis procedures, by submitting that they were somehow affected by "improper" contacts between IDAS and FIS.

149. 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.

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

Choice of aliquots

151. 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.

152. 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*".

153. 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.

154. 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.

155. 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.

The cooperation between IDAS and the Seibersdorf Laboratory

156. 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.

157. 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*".

158. In light of the foregoing, the Panel finds the Appellant's submissions are:

    i. 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

ii. 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.

159. 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.

The departures from validated procedures

160. 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.

161. The Panel, in light of the observations of the set out above (§ 158), 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.

162. The Panel therefore finds that the Adverse Analytical Finding was not affected by any departures from validated procedures.

The violation of the Appellant's right to attend the B sample analysis

163. 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".

164. 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*".

165. 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"*".

166. 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.

167. 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.

168. 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 Chepalova and her representative attended the opening of the B sample and the conduct of the analysis on the "normal gel".

169. The Panel finds the Appellant's submissions on this point to be:

    i. 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

    ii. without merit, since the performance of the additional test was not required to confirm the initial adverse analytical finding.

170. 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.

The delay in the reporting of the analysis' results

171. 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.

172. 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*".

173. The Panel finds that the deadline for the reporting of the A sample analysis' results is not strictly mandatory, since it can be extended by an agreement between the laboratory in charge of the analysis (in this case, IDAS) and the organization responsible for the sample testing and the management of the test results (in this case, FIS). At the same time, the Panel notes that FIS and IDAS agreed on the waiver of such deadline: FIS authorized the "cooperative analysis" with the Seibersdorf Laboratory; FIS and IDAS agreed to wait until the entry into force on 31 May 2009 of the (then) new TD2009EPO, in order to apply the identification criteria set forth therein.

174. The Panel therefore finds that the no breach of Clause 5.2.6.5 ISL has been committed.

D. Conclusion

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 (§ 89 above) and (iii) the Adverse Analytical Finding is not invalid for any procedural reasons.

175. Consequently and given the detection of rEPO in her urine, Chepalova is to be found in violation of the anti-doping rule constituted by Article 2.1 of the FIS ADR.

ii. What is the appropriate sanction to be imposed on Chepalova?

176. The conclusion that Chepalova 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 Chepalova 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 Chepalova ineligible to compete for two years is therefore correct.

177. 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.

178. 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.

179. 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.

180. In light of the foregoing, the Panel confirms that the ineligibility period imposed on Chepalova started on 21 August 2009.

3.8 Conclusion

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

182. (...)

ON THESE GROUNDS

The Court of Arbitration for Sport rules that:

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

2. (...)

Lausanne, 1 October 2010

THE COURT OF ARBITRATION FOR SPORT

Luigi **Fumagalli**
President of the Panel

Maidie E. **Oliveau**
Arbitrator

Quentin **Byrne-Sutton**
Arbitrator