

**IN THE MATTER OF DISCIPLINARY PROCEEDINGS BEFORE AN INDEPENDENT TRIBUNAL UNDER THE TENNIS ANTI-DOPING PROGRAMME 2022**

Before:

Mr Nicholas Stewart KC (Chair)

Professor Peter Sever

Ms Amani Khalifa

**BETWEEN:**

**INTERNATIONAL TENNIS INTEGRITY AGENCY**

**Anti-Doping Organisation**

**and**

**SIMONA HALEP**

**Respondent**

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**DECISION ON LIABILITY AND SANCTIONS**

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**A. INTRODUCTION**

1. This is the unanimous reasoned decision of this Independent Tribunal on liability and sanctions on charges against Ms Simona Halep of Anti-Doping Rule Violations (“**ADRVs**”) under the Tennis Anti-Doping Programme 2022

**THE INDEPENDENT EXPERTS**

(the “**TADP**”). It follows a two-day hearing in London on 28 and 29 June 2023, where both parties were represented by lawyers. Ms Halep was present throughout and gave evidence. As explained in section H below, the Tribunal is inviting submissions on costs in the light of this decision. We shall then incorporate our decision on costs in a single final decision.

2. Ms Halep (also referred to as the “**Player**”) is a 31-year-old Romanian national, currently based in France. She is a professional tennis player of international standing and has achieved great success. She has twice been ranked world number 1 in women’s singles tennis, in 2017 and 2019. Her 24 singles titles include the 2018 French Open and the 2019 Wimbledon Championships.
3. Ms Halep has undergone numerous doping tests since 2013. Until a positive test on 29 August 2022 during the US Open, all had been negative, and she had never been charged with any doping offence or (as far as we are aware) any disciplinary offence at all.
4. These charges are brought by the International Tennis Integrity Agency (the “**ITIA**”). All aspects of doping control under the TADP are delegated to the ITIA by the International Tennis Federation (the “**ITF**”), which is the international governing body for tennis. The ITF is a signatory to the World Anti-Doping Code (“**WADA Code**”) and the TADP contains anti-doping rules in accordance with the WADA Code.
5. Ms Halep accepts that she has been bound by the TADP at all relevant times and does not dispute the jurisdiction of this Independent Tribunal over these charges against her.
6. There are two separate sets of charges against Ms Halep, which have been consolidated so that they are all to be resolved by this same Independent Tribunal (also referred to as the “**Tribunal**”) in one set of proceedings.

7. Under article 1.3 of the Procedural Rules Governing TADP Proceedings Before an Independent Tribunal (the “**Procedural Rules**”) the proceedings before the Tribunal constitute arbitration proceedings with a seat or legal place in London, England, to which the Arbitration Act 1996 applies. However, no specific reference to provisions of that Act is needed in this decision.
8. By TADP Article 1.1.4, the TADP must be interpreted as an independent and autonomous text. Article 1.1.5 then provides that, subject to Article 1.1.4, the TADP is governed by English law.

## **B. CHARGES AGAINST THE PLAYER**

9. The first charges (the “**Roxadustat Charges**”) brought by the ITIA against Ms Halep arise from an In-Competition doping test on 29 August 2022 during the US Open, which had started on that day and ran to 11 September 2022. Ms Halep had played and lost her first-round singles match on the first day of the event, 29 August. Later that same day, she was required to give a urine sample, which she did fully cooperatively. On testing at the Doping Control Laboratory in Montreal (the “**Montreal laboratory**”) accredited by the World Anti-Doping Agency (“**WADA**”), her urine was found to contain Roxadustat (also called FG-4592), which is a Prohibited Substance under the WADA Code and also specifically under the TADP.
10. Roxadustat is legitimately used for medical treatment of anaemia but in the sporting context is prohibited because it is a blood doping agent, which increases haemoglobin and the production of red blood cells. Roxadustat thereby increases the available oxygen in an athlete’s body.
11. Ms Halep does not contend that there was any irregularity in the testing procedure and accepts the validity of the finding that her urine sample given on 29 August 2022 (the “**29 August Sample**”) contained Roxadustat. That sample had been split into A and B samples in accordance with the standard

rules and procedures. On testing by the Montreal laboratory, Roxadustat had been found in the A Sample. Ms Halep exercised her right to have the B Sample analysed. That was done by the Montreal laboratory, which found Roxadustat in the B Sample as well. Ms Halep did not have a Therapeutic Use Exemption (“**TUE**”) allowing her to use Roxadustat.

12. By a charge letter dated 31 October 2022 (the “**Roxadustat Charge Letter**”), the ITIA brought the Roxadustat Charges against Ms Halep. As explained later in this decision, Ms Halep admits that under the strict terms of the TADP, she has committed an ADRV. However, she says that she is innocent of any knowing ingestion or use of the banned Roxadustat. Ms Halep claims that the presence of Roxadustat in her body was caused by contamination of a collagen supplement she was using in late August 2022, which she says was neither known nor could reasonably have been suspected by her or any of her support team.
13. Ms Halep had been provisionally suspended from all tennis competition since 7 October 2022 and has remained suspended pending the issue of this decision on the Roxadustat Charges. The seriousness of that suspension for Ms Halep is obvious.
14. While the case against Ms Halep on the Roxadustat charges was proceeding before this tribunal – though it had not yet come to a hearing – issues arose in relation to Ms Halep’s position under the Athlete Biological Passport (“**ABP**”) Programme. That led to a further charge of breach of the TADP (the “**ABP Charge**”).
15. The ABP Programme, which is used in several major sports including tennis and, for example, athletics, has applied to Ms Halep since at least 2013. It involves regular blood tests which establish an individual profile of an athlete’s blood. As explained more fully below, a blood test result identified by a computerised algorithm as significantly out of line with that athlete’s profile on specific key elements may be referred to a panel of experts. If their

opinion is that the likely cause of the result is illicit blood doping, that opinion forms the basis of a charge of breach of the TADP.

16. The potential for Ms Halep to be charged with a breach of the TADP based on her ABP had been triggered by a blood test on 22 September 2022. There was then a process which led to Ms Halep eventually being charged by the ITIA by letter dated 19 May 2023 (the “**ABP Charge Letter**”).
17. The practical effect of the gap between Ms Halep’s 22 September 2022 blood test and the ABP Charge being brought on 19 May 2023 was that the hearing on the Roxadustat Charges was deferred to await the position following expert review of her blood test results against her ABP, as it was apparent that there might then be further charges laid against her by the ITIA (as did happen). Following the ABP Charge Letter, the Independent Tribunal imposed a quite demanding timetable on the parties and their lawyers to achieve the earliest feasible hearing date on all the charges against Ms Halep. We appreciate the hard work and cooperation from both sides which enabled us to hold the hearing on 28 and 29 June 2023.
18. The ITIA was represented by counsel Mr Richard Liddell KC and by Mr Chris Lavey and his colleagues at Bird & Bird LLP, London, UK. Ms Halep was represented by the Law Offices of Howard L. Jacobs, Westlake Village, California, led by Mr Jacobs. The consistently high quality of legal representation on both sides has helped the Tribunal enormously on this complex case.
19. Although the Roxadustat Charges and the ABP Charges are now all to be resolved together in consolidated proceedings, it is useful first to set the scene on each separately.

#### **Roxadustat Charge: Applicable rules, burden and standard of proof**

20. The Roxadustat Charge Letter gave Ms Halep formal notice that she was charged with the commission of ADRVs under Articles 2.1 and/or 2.2 of the

TADP, on the basis that FG-4592 (Roxadustat) was found to be present in her urine Sample.

21. Roxadustat stimulates erythropoiesis – the production of red blood cells. The consequent increase of haemoglobin and red blood cells results in more available oxygen within the body, which usually improves endurance and recovery. While such benefits are obvious for middle and long distance runners, Ms Halep argues that they are not significant for a tennis player, even at her level. We consider that point later, but the simple fact is that Roxadustat *is* a banned substance under section S2 (1.2) of the WADA Prohibited List incorporated in the TADP. It is a non-Specified Substance under the WADA Code and the TADP, which narrowly limits the scope for reduced penalties for ADRVs involving Roxadustat.

22. Article 2 of the TADP provides, so far as relevant here, that each of the following is an ADRV:

- Article 2.1 (Presence): *The presence of a Prohibited Substance . . . in a Player's Sample*
- Article 2.2 (Use): *Use or Attempted Use of a Prohibited Substance*

in either case “*unless the Player establishes that such presence is consistent with a TUE granted in accordance with Article 4.4*” – though this exception does not arise as it is common ground that Ms Halep never had a TUE for Roxadustat.

23. Under both Articles 2.1 and 2.2, it is expressly stated that it is each Player's personal responsibility to ensure that no Prohibited Substance enters their body and further that:

*“it is not necessary to demonstrate intent, Fault, Negligence, or knowing Use on the Player's part in order to establish an Anti- Doping Rule Violation... nor is the Player's lack of intent, Fault, Negligence or knowledge a defence to a charge that an Anti-Doping Rule Violation ... has been committed...”*

24. The Roxadustat Charge Letter correctly asserted that the presence of Roxadustat in both the Player's A and B samples was sufficient proof of Ms Halep's violation of TADP Article 2.1. That has been accepted by the Player at least since the filing of her Pre-Hearing Brief ("**PHB**") dated 13 January 2023. Noting the other charge under Article 2.2 (Use), we do not need to go further into that at this point.
25. In the light of her acceptance of an ADRV under Article 2.1, the Player's PHB summarised the TADP rules applicable to the Roxadustat Charges in correct terms which are common ground between the parties. The key points can be summarised as:
- (1) The default sanction for the Player's admitted ADRV in breach of TADP Article 2.1 is a 4-year period of Ineligibility (i.e. suspension).
  - (2) That default sanction is reduced to a 2-year period of Ineligibility if the Player can prove that her ADRV was not intentional: TADP Articles 10.2.1 and 10.2.2.
  - (3) "Intentional" means that the Player engaged in conduct that she knew constituted an ADRV or knew that there was a significant risk that her conduct might constitute or result in an ADRV and manifestly disregarded that risk: TADP Article 10.2.3.
  - (4) If the Player can also establish (i.e. as well as non-intention) both No Significant Fault or Negligence for her ADRV and that the Roxadustat came from a Contaminated Product, the period of Ineligibility will be, at a minimum, a reprimand and no period of Ineligibility and at a maximum, two years of Ineligibility, depending on the Player's degree of Fault: TADP Article 10.6.1.2.

- (5) Contaminated Product is defined in the TADP as a “*product that contains a Prohibited Substance that is not disclosed on the product label or in the information available in a reasonable internet search*”.
- (6) The ITIA has the burden of establishing that an ADRV has been committed, which it must do to the comfortable satisfaction of this tribunal. “Comfortable satisfaction” is greater than balance of probability but less than proof beyond a reasonable doubt: TADP Article 3.1.1.
- (7) However, where the TADP places a burden of proof on the Player to rebut a presumption or establish specified facts or circumstances, then (subject to exceptions which do not apply here) the standard of proof will be the balance of probability: TADP Article 3.1.2
26. Ms Halep’s realistic and correct acceptance that she has committed an ADRV under TADP Article 2.1 necessarily means that this Tribunal can be comfortably satisfied that the charge is proven. That still leaves the issues of intention and Fault or Negligence, which could enormously reduce the sanction for Ms Halep’s breach of the TADP.
27. The main issue on the Roxadustat Charges is whether the Player can reduce the default four-year period of Ineligibility to a maximum of two years by satisfying this Tribunal that it is probable (which only requires anything over 50%) that the Roxadustat found in the 29 August Sample came from contamination of a [REDACTED] Keto MCT supplement used by her in August 2022. Although she does have secondary or back-up submissions (discussed later), that is her primary case. If she can establish non-intention, she then has the opportunity of a further reduction on the footing of No Significant Fault or Negligence.
28. The ITIA says that if the Roxadustat Charges and the ABP Charge are both proven against Ms Halep, there are **Aggravating Circumstances** (as defined in the TADP) which should lead the Tribunal to increase the period of Ineligibility beyond the standard suspension of four years, and up to six years, under TADP Article 10.4.



### **ABP Charge: Applicable rules, burden and standard of proof**

29. The ABP Charge Letter gave Ms Halep formal notice that she was charged with the commission of an ADRV under Article 2.2 of the TADP, on the basis that her ABP profile evidenced use of a Prohibited Substance and/or Prohibited Method.
30. TADP Article 2.2 is the same rule already mentioned in paragraph 22 above in relation to the Roxadustat Charge, but two additional points are to be noted:
  - (1) The ABP Charge did not identify a specific Prohibited Substance alleged to have been used by the Player. That was not required, as explained below.
  - (2) “**Prohibited Method**” is defined in the TADP as “*any method so described on the Prohibited List*” issued by WADA. The relevant category on that list is “*M1. Manipulation of blood and blood components*”, which then describes various methods in more detail. In short, that M1 category is what is widely called blood doping.
31. The ABP Charge followed a process required under the TADP and the International Standard for Results Management (the “**ISRM**”), which is expressly incorporated in the TADP by Article 7.1. The process leading to the ABP Charge was triggered by a blood sample taken from the Player on 22 September 2022 (“**Sample 48**”) and led through various prescribed steps to a joint expert opinion on 12 April 2023. That opinion in turn led fairly quickly through remaining steps to the ABP Charge on 19 May 2023.
32. As on the Roxadustat Charge, TADP Article 3.1.1 places the burden of proof on the ABP Charge squarely on the ITIA; and requires the ITIA to establish the ADRV to the same standard of comfortable satisfaction of the

Independent Tribunal (greater than balance of probability but less than proof beyond a reasonable doubt). By contrast with the Roxadustat Charges, there is no burden of proof on the Player on any aspect of the ABP Charges. If the ITIA cannot prove its case to the comfortable satisfaction of this Tribunal, the Player must be acquitted on the ABP Charge.

33. If the ABP Charge is proven against Ms Halep, the sanction is a four-year period of Ineligibility though (as noted in paragraph 28 above) subject to increase if the ITIA can establish Aggravating Circumstances. While it is theoretically possible for the Player to achieve a reduction to a maximum of two years period of Ineligibility under TADP 10.2.1 and 10.2.2 by establishing that her ADRV was non-intentional, no such argument has been raised on Ms Halep's behalf. Nor realistically could it have been. The very nature of the ABP blood doping offence, if proven, means it is practically impossible for it to have been non-intentional.

## **C. PROCEDURAL STEPS: ROXADUSTAT CHARGE, ABP CHARGE AND CONSOLIDATED PROCEEDINGS**

### **Pre-consolidation proceedings**

34. In accordance with TADP Article 7.10.1, on 7 October 2022, the ITIA gave written notice to Ms Halep that she may have committed one or more ADRVs under Article 2, based on the Montreal laboratory's analysis of her A Sample given on 29 August 2022, which showed the presence of Roxadustat. The notice also informed the Player of her immediate mandatory Provisional Suspension under TADP Article 7.12.1.
35. On 10 October 2022, Ms Halep requested analysis of her B sample, which took place on 17 October 2022 at the Montreal laboratory. On 18 October the laboratory reported that the B Sample contained Roxadustat. On 21 October Ms Halep notified the ITIA that she denied the possible ADRV and agreed to attend an interview by the ITIA on 26 October 2022, which she did.

36. Following the Roxadustat Charge Letter dated 31 October 2022, the Player's lawyer, Mr Howard Jacobs, responded on 18 November 2022 on her behalf through the Tennis Anti-Doping Portal, denying the charge.
37. Accordingly, under TADP Article 8 the Roxadustat Charges were to be submitted for determination by an Independent Tribunal appointed by the Chair of the Independent Panel, Mr Charles Flint KC. By letter dated 7 December 2022, Sport Resolutions, Secretariat to the Independent Panel, notified Mr Nicholas Stewart KC that Mr Flint had appointed him to chair this Independent Tribunal; and by letter on 11 January 2023, that Professor Peter Sever and Ms Amani Khalifa had been appointed as the other two members of the Tribunal.
38. As required by rule 2.4 of the Procedural Rules, each of the three members of the Tribunal provided a declaration to the parties (via the Secretariat) disclosing any facts and circumstances known to them that might call into question their impartiality or independence. No objection was made to any member of the Tribunal under rule 2.5 of the Procedural Rules.
39. Article 8.3 of the TADP provides for the Chair of the Independent Tribunal to hold a Preliminary Meeting with the parties, to address procedural issues. That meeting was arranged to be held remotely on 15 December 2022 then postponed to 20 December. Since the parties agreed directions which were approved and issued by the Chair on 19 December 2022, the Preliminary Meeting was not needed.
40. There is no need to record in this decision all the detailed directions and procedural steps between December 2022 and the June 2023 hearing. We confine ourselves to the main points.
41. The 19 December 2022 directions set a timetable for written briefs and a one-day hearing of the case on 27 or 28 February 2023.

42. When the full Tribunal had been appointed in January, the hearing was still scheduled for 28 February 2023 in London, as an in-person hearing (which was Ms Halep's clear preference, shared by the Tribunal and supported by the ITIA). However, on 20 February the Tribunal was notified that the parties had agreed to ask for the hearing to be moved to 24 March 2023 (subject to some confirmations of availability), with other timetable adjustments.
43. The 28 February 2023 date was vacated and agreed adjustments were made to filing deadlines, with a view to holding a one-day, in-person final hearing in London, on 24 March 2023.

#### **ITIA stay application 3 March 2023**

44. On 3 March 2023, the ITIA made a written application for a stay of the Roxadustat proceedings (the "**March Stay Application**") in the light of developments in relation to Ms Halep's ABP, which had been particularly triggered by Blood Sample 48 collected on 22 September 2022. The grounds of that application were justifiably detailed, but the main point can be stated briefly for the purposes of this decision: On 24 February 2023, the ITIA received a notification concerning Ms Halep in the online Anti-Doping Administration & Management System (known as "**ADAMS**") from a representative of the independent Athlete Passport Management Unit (the "**APMU**") at the Montreal laboratory, which runs the ABP Programme on behalf of the ITIA. That notification was that a three-person Expert Panel, acting in accordance with the requisite procedures, had reviewed Ms Halep's ABP and had concluded that it was "*highly unlikely that the longitudinal profile is the result of a normal physiological or pathological condition and [it] may be the result of the use of a Prohibited Substance or Prohibited Method*". The APMU summarised the experts' opinions as all pointing to a probable doping scenario around the 2022 US Open.
45. Where all that fits in with the eventual ABP Charge will be clearer when we come to set out more detail on that part of the case - including the key steps in the ABP process. The main thrust of the March Stay Application was that

time was needed for further necessary investigations and other steps under the ABP Programme; that the results of such further investigations would be potentially relevant to the Roxadustat Charge; that it was quite possible that hearing of the Roxadustat proceedings would be postponed if a stay was granted but committed itself to take all reasonable steps to ensure that the proceedings were progressed, consolidated, and heard as soon as reasonably practicable. they would lead to the ITIA bringing further charges against Ms Halep based on her ABP; and that if such charges were brought, the ITIA would apply for consolidation of the proceedings on the Roxadustat Charges and the new ABP charge or charges. The ITIA said it was not able to predict how long the hearing of the Roxadustat proceedings would be postponed if a stay was granted but committed itself to take all reasonable steps to ensure that the proceedings were progressed, consolidated, and heard as soon as reasonably practicable.

46. On 6 March 2023, the Player submitted a response opposing the March Stay Application. That response also included, as an alternative if the stay was granted, an application for the lifting of Ms Halep's Provisional Suspension.
47. Ms Halep's opposition to the March Stay Application was on three grounds: (1) the ITIA's assertions about Ms Halep's ABP were premature, ignored critical facts and did not justify a delay; (2) the ITIA's assertion that the ABP was clearly relevant to the Roxadustat Charges was speculative in the light of its own supplement testing; and (3) the request for an indefinite stay violated Ms Halep's rights under TADP Article 7.12.7.
48. As of 6 March 2023, the Player had submitted her Pre-Hearing Brief on 13 January 2023 in accordance with the Tribunal's 19 December 2022 directions. Following an agreed extension of the originally directed deadline, the ITIA was to submit its answering brief by 14 March 2023. The March Stay Application also asked for immediate suspension of that deadline pending the Tribunal's determination of the ITIA's application for a stay of the proceedings.

49. The Tribunal issued written directions on 8 March 2023. Those directions maintained the 14 March 2023 deadline for the ITIA answering brief but did not contain any ruling on the March Stay Application or, therefore, the Player's application for lifting of her Provisional Suspension. They also included a direction that by the same 14 March deadline the ITIA should file a separate written submission stating whether, and if so precisely how, it would be prejudiced in the presentation of its case on the Roxadustat Charges if the final hearing took place on 24 March 2023 (including details of what further material relating to the Player's ABP might later become available in support of the ITIA's case but which could not reasonably be available for the hearing on 24 March 2023). However, since (as appears below) those directions were superseded by fresh Tribunal directions on 10 March 2023, there is no need to set out more of the 8 March directions here.
50. On 9 March 2023, the ITIA made a further written application for extension of the deadline for its answering brief to Friday 17 March 2023, setting out fuller details to support its contention that it was not realistically possible for the ITIA to submit its full answering brief by the 14 March deadline.
51. Typically of the assiduous and efficient work by both parties' lawyers throughout this case, the Player's full response to that further ITIA application was submitted from California overnight on 9/10 March 2023. The Player opposed the requested extension of the deadline for the ITIA answering brief, on the ground that it would (as it clearly would) necessitate postponement of the hearing from 24 March 2023, which she wished to go ahead on that date.
52. On our consideration of all the submissions made between 3 and 10 March 2023, it was clear to the Tribunal that 14 March 2023 had become an unfairly tight deadline for the ITIA submissions directed by the Tribunal and, moreover, that it would not be reasonable to go ahead with the hearing of the Roxadustat Charges without first giving the ITIA a fair opportunity of considering the results of remaining steps needed in relation to the Player's ABP and deciding whether or not to bring any charge against Ms Halep based on her ABP. That could not be done in time for a hearing on 24 March

2023. The Tribunal did not accept either of the Player's grounds (1) and (2) for opposing a stay. In our view the results of further investigations in relation to the Player's ABP were clearly potentially relevant for a fair resolution of the Roxadustat proceedings.

53. We also rejected ground (3), as we saw no violation of Ms Halep's rights. Article 7.12.7 of the TADP states: "*A Player who is subject to a Provisional Suspension has the right, if they so wish, to an expedited hearing against them pursuant to Article 8*". However, there is no definition of "expedited hearing" in the TADP or the Procedural Rules. The clear point of Article 7.12.7 is a principle that an Independent Tribunal should apply anyway, which is that where a player is under a Provisional Suspension, the case should be brought to final resolution as soon as can be managed consistently with ensuring a fair hearing for all parties; and that as long as fairness to all parties is not jeopardised, tight timetables may well be needed to achieve that aim. That has been the approach of this Tribunal throughout. Accordingly, an indefinite stay would not violate Ms Halep's right to an expedited hearing, provided that the stay was brought to an end and the case resolved as soon as could be achieved consistently with fairness to both parties.
54. On grounds (1) and (2), the Player's response had gone into considerable detail on the facts of the case. We do not criticise that approach, as we have always understood the importance to the Player of moving the case on as quickly as possible, but it did raise some issues which were not realistically suitable for determination on an interim application in advance of the main hearing. After full consideration of both parties' submissions, we were satisfied that the ITIA had made a sufficient case for the hearing date 24 March 2023 to be vacated. Given the uncertainty over the timing of the remaining ABP investigations, and the realistic possibility of Ms Halep eventually being charged in relation to her ABP, with a consequent application for consolidation of the proceedings, it was not realistic at that point to set even a provisional hearing date.

## **Ruling on the Player's 6 March 2023 application for lifting of Provisional Suspension**

55. The Tribunal therefore needed to consider and rule on the Player's application for lifting of her Provisional Suspension (as in paragraph 46 above). TADP Article 7.12.3.1 limits the circumstances in which a player may apply for lifting of a Provisional Suspension. Ms Halep relied primarily on 7.12.3.1 (c)(iii), which allows (but does not mandate) the lifting of a Provisional Suspension if the Player establishes that the ADRV asserted is likely to have involved a Contaminated Product. However, the problem for Ms Halep was that whether the ADRV involved a Contaminated Product was a key issue for determination in the case, requiring the Tribunal to hear expert evidence (as explicitly recognised by the Player herself in paragraph 2.3 of her 9 March 2023 submission); and a difficult issue too, as shown by this decision. Although the Player's 6 March 2023 submission attempted to establish that *likelihood* for the purposes of Article 7.12.3.1 (c), that was not a conclusion which could be reached by the Tribunal on that interim application in advance of the full hearing.

56. Alternatively, the Player relied on Article 7.12.3.1 (c)(v), which gives an Independent Tribunal a discretion to lift a Provisional Suspension where "*other facts exist that make it clearly unfair, in all of the circumstances, for the Player ... to be subject to a Provisional Suspension prior to the final first instance decision on the merits*". Ms Halep's submission on this point amounted to six lines only and simply noted that she had already been provisionally suspended for five months and contended that a continued Provisional Suspension would be unfair given that the ITIA sought to stay the hearing indefinitely. That paragraph (v) of TADP Article 7.12.3.1 (c) expressly states that it is a ground "*to be construed narrowly and applied only in truly exceptional circumstances*". The Player came nowhere near establishing this ground.

## **Roxadustat proceedings: Directions 10 March and steps to 23 May 2023**

57. On 10 March 2023, the Tribunal issued further directions, which included:



1. *“The final hearing set for 24 March 2023 being vacated to allow the ITIA and the Player to address tests done by the Sports Medicine & Research Testing Laboratory, in South Jordan, Utah (“SMRTL”) and any further evidence to be submitted relating to the Player’s ABP.*
  2. *Dismissal of the Player’s application for lifting of her Provisional Suspension.*
  3. *The ITIA was to file its answering brief and other material, including the full data relating to certain SMRTL laboratory tests, by 17 March 2023.*
  4. *Directions on specific matters to be covered by the ITIA submissions.*
  5. *By the same 17 March 2023 deadline, the ITIA was to file a separate written submission stating:*
    - (1) *ITIA’s expected timetable for steps in the ABP results management procedures mentioned in its 3 March 2023 application.*
    - (2) *The earliest and latest dates on which ITIA expected to make a final decision on whether or not to bring an additional disciplinary charge against the Player based on her ABP results and her Sample 48.”*
58. It will be noted that the Tribunal did not order a full stay of the Roxadustat proceedings, as we directed further procedural steps in those proceedings (which were the only proceedings at that time). But the vacation of the 24 March 2023 hearing date with no direction for a new hearing date was in practical terms a stay on the key point of a hearing leading to determination of the Roxadustat Charges.
59. On the deadline day, 17 March 2023, the ITIA filed the information required by paragraph 5 of the 10 March directions: The final step of a joint Expert Panel’s conclusion on the Player’s ABP was expected by around 5 May and on that footing the ITIA expected to decide by around 10 May 2023 whether or not to bring an ABP charge against Ms Halep. Either side of that 10 May

date, the earliest date on which the ITIA would be able to make that decision was likely to be 28 April and the latest 29 May 2023.

60. Accordingly, the ITIA maintained its request for the Roxadustat proceedings to be stayed until it could be determined whether or not an ABP charge would be brought against Ms Halep and, if so, whether or not the Roxadustat and ABP charges should be heard together.

61. By email on the same day, 17 March 2023, the ITIA asked for an extension to 21 March for filing its answering brief with supporting material. The Tribunal noted that the Player opposed that request but granted an extension to midnight London time on 20 March 2023.

62. The ITIA met that new deadline for filing its answering brief. With mutual non-opposition from the parties, we allowed two further rounds of submissions on the Roxadustat Charges. The result was that the main submissions filed in the Roxadustat proceedings were:

- 13 January 2023 Player's Pre-hearing Brief
- 20 March 2023 ITIA Answer Brief
- 6 April 2023 Player's Reply Brief
- 12 May 2023 ITIA further Reply Brief

As required by the TADP and the Procedural Rules, those submissions were accompanied by extensive supporting material.

63. While the Player's Reply Brief was still pending, and there was continuing uncertainty about timings in relation to the Player's ABP and whether there would be any ABP charge made against her, the Tribunal was nevertheless concerned not to lose the opportunity of as early a hearing of the Roxadustat Charges as could fairly be managed. This was particularly necessary because of the large number of people involved in the hearing – including particularly the parties and their lawyers, factual and expert witnesses, and

Tribunal members – whose diaries would be likely to fill up if we did not book at least a provisional date.

64. Accordingly, on 5 April 2023 the Tribunal proposed four possible hearing dates in late May and early June 2023. After both parties had notified availability, on 13 April 2023 the Tribunal confirmed a hearing date of 31 May 2023 in London. However, that confirmation, emailed to the parties by the Secretariat on behalf of the Tribunal, added that any future application would be considered by the Tribunal as it came. It was obvious to the parties that developments in relation to the ABP process might well affect the position, as so it proved (and on 12 April the ITIA had expressly reserved its right – which it would not have lost anyway – to request postponement of the hearing date depending on the outcome of the ABP process).

#### **Further postponement of the final hearing**

65. On 20 May 2023, the Tribunal received (through the Secretariat):
- an application by the ITIA, dated 19 May 2023, for postponement of the 31 May 2023 hearing in the light of the ABP Charge brought against Ms Halep earlier on 19 May 2023; and
  - the Player's response dated 20 May 2023 to the ABP Charge Letter.
66. That response from the Player mainly consisted of vigorous objections to the ITIA application for postponement. It also again requested an expedited hearing and specifically asked that the hearing of both the Roxadustat and the ABP Charges should be on 31 May 2023.
67. The Tribunal then gave the Player an opportunity to submit a specific response to the ITIA application for postponement, with a deadline of midnight London time on 23 May 2023.

68. That response was submitted by the Player on 22 May. Significantly, the Player explicitly agreed that the Roxadustat and the ABP cases should be heard at the same time, acknowledging that “*it would make no sense*” for Ms Halep to proceed to a hearing on the Roxadustat Charges only, as whatever the Tribunal’s decision on the Roxadustat Charges she would then remain provisionally suspended based on the ABP Charge. Where the Player disagreed with the ITIA was on when the hearing should take place – which the Player submitted should be on the 31 May 2023 date already scheduled for the hearing of the Roxadustat Charges.
69. On the morning of 23 May 2023, the Tribunal granted the ITIA’s request to file a “*short response*” by midnight London time that day, which it did (if on a slightly stretched definition of “*short*”).

### **Consolidation of the Roxadustat and the ABP Proceedings**

70. Earlier that morning, 23 May 2023, the Tribunal had been notified of a not unexpected development which significantly affected the overall procedural picture, including the context of the particular ITIA application for postponement. On application by the ITIA following the bringing of the ABP Charge, the Chair of the Independent Panel had appointed the same members and Chair for the ABP proceedings as for the Roxadustat proceedings and under Procedural Rule 2.7 had ordered consolidation of the Roxadustat and the ABP proceedings before this same Independent Tribunal.
71. That ITIA response, filed on 23 May *after* Mr Flint’s consolidation order, made the point that the Player’s proposed timetable, with a hearing on 31 May 2023, would be contrary to the procedure set out in TADP Article 8. Article 8.3.2.4 states that after the preliminary meeting with the Chair directed by Article 8.3.2, the hearing date must be at least 21 days after the preliminary meeting, unless the parties consent to a shorter period. The ITIA would not consent to a shorter period (which the Tribunal did not and does not criticise).

72. The Tribunal interprets Article 8.3.2.4 as mandatory, so that on its own (given the ITIA's refusal to consent to a shorter period) that 21-day requirement made it impossible to keep to the hearing date of 31 May 2023. However, the Player's 22 May response put forward two arguments why, on a correct interpretation of Article 8.3.2.4, that 21-day requirement could and should be overridden, despite the ITIA's lack of consent:

(1) It was inconsistent with the specific provision of TADP Article 7.12.7 giving the Player, under Provisional Suspension, the right to an expedited hearing.

(2) There had already been a Preliminary Meeting under TADP Article 8.3.2.4 (i.e. back in December 2022: see paragraph 39 of this decision) and after consolidation there was no need or requirement for a second one. The Tribunal understood this submission as meaning that there was no starting point for the specified 21-day period, so the timing of the hearing was at large and subject to the discretion of the Tribunal.

73. The Tribunal rejected both those arguments:

(1) The right to an expedited hearing (already discussed in paragraph 53 above) does not override the specific requirement of consent to any shortening of the 21-day time limit in TADP Article 8.2.3.4. If that had been intended by the TADP or those rules, they would have given the Independent Tribunal a clear power to override that lack of consent. No such power can be inferred from the Article 7.12.7 right to an expedited hearing; and nor can the power in Article 2.11(d) of the Procedural Rules to abbreviate time limits, although wide, be used to override that lack of consent.

(2) We see the technical argument that after consolidation there is only one set of proceedings, and that the wording of the TADP appears to contemplate only one Preliminary Meeting in any single proceeding.

However, the clear rationale of Article 8.3 is that after a Charge Letter and appointment of a Chair of a new Independent Tribunal, there should be a Preliminary Meeting to deal with the procedural matters arising from that charge (unless, as provided by Article 8.3.1, directions are agreed and approved). That remained the position notwithstanding consolidation. The Player's argument was artificial and inconsistent with the clear practical purpose of Article 8.3. (In rejecting this argument, we leave out of consideration the fact that, as noted in paragraph 39 above, the first Preliminary Meeting had not strictly happened in December 2022.)

#### **Directions in consolidated proceedings 24 May 2023**

74. The Tribunal issued directions on 24 May 2023 which included:

1. *"Vacation of the hearing date 31 May 2023.*
2. *Direction of a procedural hearing on 31 May in the consolidated proceedings (to be conducted remotely by the Chair sitting alone, taking advantage of the parties' already confirmed availability for a hearing on that day). That would also be the Preliminary Meeting under TADP Article 8.3 in relation to the ABP Charge.*
3. *The parties were to try to agree directions for approval by the Chair and, in the absence of agreement, present their separate proposals, all such items to be submitted at the latest by midnight London time on 30 May 2023.*
4. *Expressly recognising the Player's right to an expedited hearing, a direction that the hearing should take place as soon as fair and practicable on two consecutive days (starting no earlier than 21 June 2023, to comply with the 21-day requirement in TADP Article 8.3.2.4).*
5. *Notification to the Tribunal as soon as possible and in any event by midnight London time on 30 May 2023 whether the parties agreed to the hearing being fixed for 27/28 or 28/29 June (all being dates when the Tribunal were available)."*

75. It had by then become plain to the Tribunal (as no doubt to others involved) that a one-day hearing could not possibly be enough, but that with tight management it ought to be just possible to complete the hearing in two days. The Tribunal had firmly in mind that any longer than two days would be likely to run into severe obstacles on participants' availability.
76. The parties were unable to agree directions, so submitted their separate proposals on 30 May 2023. The key point of difference was that the Player proposed a two-day hearing on 28 and 29 June but the ITIA proposed 12 and 13 July 2023. That difference was reflected in their different proposed timetables for the further filings needed before the hearing.

#### **The Player's 27 May 2023 application for production of documents**

77. Shortly before the 31 May procedural hearing, the Player had submitted an application by email on 27 May asking for a Tribunal order under TADP Article 8.3.2.7 for production of documents by the ITIA. The request was quite detailed but may be summarised as a request for (so far as not already produced):
- (1) all communications between the ITIA on the one hand and the APMU or any member of an Expert Panel who had reviewed Ms Halep's ABP; and
  - (2) all laboratory documentation for all ABP samples contained within Ms Halep's ABP, including those declared invalid. (On this point, the application added: "*Of particular significance, Ms. Halep requests whatever laboratory documentation is available for [ABP] sample 47.*")
78. In accordance with a direction by the Chair, the ITIA submitted a written response on 30 May and the Player's application was also to be dealt with at the procedural hearing on 31 May 2023. The ITIA's detailed 5-page response submitted that none of the Player's requests were justified, but with that response it did disclose the Certificate of Analysis for blood Sample 47, which had been collected on 26 August 2022 but had been declared invalid.

79. At the procedural hearing, the Chair indicated the Tribunal's inclination towards a full hearing on 28 and 29 June 2023, if manageable fairly to both parties. While that certainly imposed a tight timetable on the parties and their lawyers, by the end of the hearing, that was what the Chair had decided.

80. On 1 June 2023, the Chair issued directions recording decisions given to the parties at the previous day's hearing. The hearing was to be in person in London for two days 28 and 29 June 2023 and the timetable for written submissions on the ABP Charge was:

- 8 June 2023 ITIA Opening Brief
- 15 June 2023 Player's Answering Brief
- 24 June 2023 ITIA Reply Brief

In the usual way, those submissions were to be accompanied by factual and expert witness statements and supporting documents. Happily, those demanding deadlines were met by the parties.

81. Those 1 June 2023 directions also included:

- Denial of the Player's application for production of documents (as the Chair did not consider that the requested items were reasonably and proportionately needed for a fair determination of the Roxadustat or the ABP Charges).
- No order on the ITIA's application for an order that the Player should respect the confidentiality of the proceedings. That application was based on media reports of statements made by Ms Halep. However, the Chair considered that all that was needed was a reminder to both parties of the clear provisions of TADP 8.4.3.2 and the ISRM Articles 4.1 and 4.2 and the need for strict confidentiality. (The Tribunal are not aware of any subsequent problems on this issue.)



- Practical directions about the timetable and documents for the hearing, including a direction for a recording and a transcript.

### **Player's second application to lift her Provisional Suspension**

82. Given the complexities of the case, including the issues involving the Player's ABP and the large number of necessary participants, it would not have been feasible to achieve an earlier hearing of the Roxadustat Charges. Nevertheless, by early April 2023, the Player was understandably frustrated that her Provisional Suspension imposed on 7 October 2022 had already continued for over six months. On 11 April 2023, at which point there was not yet any ABP Charge and the hearing of the Roxadustat Charges was scheduled for 31 May 2023, the Player had filed a motion for lifting of the Provisional Suspension.
83. The ITIA replied by letter on 13 April 2023, opposing the Player's application and raising a preliminary objection that it was not open to her to make a second application following rejection of her 6 March 2023 application (see paragraphs 55 and 56 above). The Tribunal rejected that preliminary objection. TADP Article 7.12.3.1(d)(ii) allows a further application if "*there has been some other significant and material change in circumstances since the original application was decided.*" Up to the point when the Player's original application was dismissed on 10 March 2023, the hearing date had remained fixed as 24 March 2023. Although there was already obvious uncertainty whether that date could be maintained, the fact that it was only subsequently abandoned and had to be replaced by a hearing date more than two months later was itself a significant and material change of circumstances. The condition in TADP Article 7.12.3.1(d)(ii) was therefore clearly satisfied.
84. As far as relevant to the Player's motion, TADP 7.12.3.1(c) states that a Provisional Suspension will not be lifted unless a player establishes either:

*"[...] (iii) the Anti-Doping Rule Violation asserted is likely to have involved a Contaminated Product; or*

*[...] (v) other facts exist that make it clearly unfair, in all the circumstances, for the player ... to be subject to a Provisional Suspension prior to the final first instance decision on the merits."*

85. On the first point under TADP 7.12.3.1(c)(iii), the Player submitted that in that paragraph "*likely*" was a lower test than "balance of probability" and she relied particularly on a decision of the Court of Arbitration for Sport ("**CAS**") *Powell v JADCO*, CAS 2014/A/3571 (7 July 2015). We rejected that submission. It rested on a misreading of that CAS decision, which was concerned with Article 37 of the *CAS Code of Sports-related Arbitration*, relating to provisional measures. In TADP 7.12.3.1(c)(iii), the word "*likely*" simply means "probable" – a straightforward English dictionary definition.
86. Applying that correct interpretation of TADP Article 7.12.3.1(c)(iii), the Tribunal could not be satisfied at that stage that on balance of probability the ADRV involved a Contaminated Product, and that the Player would avoid a suspension going beyond the date of our final decision following the hearing on the merits of the case. That was not to pre-judge those issues in any way. But they lay ahead for the substantive hearing, then due to take place on 31 May 2023, which was less than six weeks away.
87. Given that conclusion, in considering the Player's alternative reliance on TADP Article 7.12.3.1(v), we saw no other facts that made it clearly unfair, in all the circumstances which currently existed, for the Player to remain subject to a provisional suspension prior to the final first instance decision on the merits.
88. On 20 April 2023, the Tribunal issued a full written decision with reasons on the Player's 11 April 2023 motion. In addition to the points summarised above, we recorded that:
- (1) We did not consider that the ITIA had unreasonably delayed the substantive hearing (and nor had the Player).

(2) We reached our decision to dismiss the motion without needing to rely on the ITIA's submissions relating to a potential ABP charge. Accordingly, we expressed no view at all on that question or on anything else which might fall to be considered in circumstances which had not yet arisen.

#### **D. FINAL HEARING: 28 AND 29 JUNE 2023**

89. The main hearing of the consolidated proceedings (the “**June hearing**”) took place in London over two full days, 28 and 29 June 2023. Neither party had made a request under TADP Article 8.4.1 for a public hearing, so the hearing was in private. Apart from witness appearances, the following were present (in person, except where indicated):

##### Tribunal

Mr Nicholas Stewart KC, Chair

Professor Peter Sever

Ms Amani Khalifa

assisted, with consistent efficiency, by Ms Kylie Brackenridge, Senior Case Manager at Sport Resolutions, who acted as the Tribunal Secretariat (and on the second day Ms Astrid Mannheim, Case Manager, Sport Resolutions).

##### ITIA

Mr Richard Liddell KC, Counsel

Mr Chris Lavey, Ms Lauren Pagé, Mr Magnus Wallsten, Mr Khaled Farah and [remotely] Mr Said Sufi, solicitors, Bird & Bird LLP

Ms Katy Stirling, ITIA Legal Counsel

Ms Nicole Sapstead, ITIA Senior Director, Anti-Doping

Mr Ben Rutherford, ITIA Senior Director, Legal

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Ms Karen Moorhouse, ITIA CEO [remote]

Ms Simona Viel, ITIA Anti-Doping [remote]

Mr Josh Coakes, ITIA Anti-Doping [remote]

Mr Adrian Bassett, ITIA Communications [remote]

Ms Jodie Cox, ITIA Legal [remote]

Ms Julia Lowis, ITIA Legal [remote]

The Player

Ms Simona Halep, Respondent

Mr Howard Jacobs and Mr Bogdan Stoica, Counsel, Law Offices of Howard L. Jacobs

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Ms Katy Freeman, Counsel [remote]

Mr Aaron Mojarras, Counsel [remote]

Ms Leah Cameron Bernhard, Counsel [remote]

Mr Patrick Mouratoglou, Ms Halep's Coach

Observers (under TADP, Article 8.4.6)

Dr Stuart Miller, ITF Senior Executive Director

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Ms Courtney McBride, WTA Senior Vice-President [remote]

Mr Stefan Ronean, President, Romanian National Anti-Doping Organisation [remote]

French-English interpreter

Mr Michael Wells

90. The Tribunal was provided with a hearing bundle containing the parties' written submissions in the Roxadustat and the ABP proceedings, expert reports, witness statements, Ms Halep's detailed competition schedule since 2014, her doping test history since 2013 and the relevant rules and guidelines. We were also supplied with a bundle of 130 case authorities from the ITIA and (with some overlap with the ITIA's authorities) about 20 from the Player. As required by the Tribunal, all these items were in searchable electronic form. Our task was greatly helped by the parties' cooperative and efficient preparation of all this material.

91. We have fully considered all the parties' submissions and all the relevant material. Although this decision contains our reasons for our overall conclusions and addresses the issues which have needed resolving to reach those conclusions, we have not attempted to set out every point of contention between the parties. That particularly applies to the expert evidence, which quite properly went into much greater detail than we need to cover in this decision.
92. Moreover, from the 150 or so case authorities cited by the parties, we have generally not felt it necessary to cite cases to support clearly established principles or where those previous decisions essentially turned on their own facts.
93. Consolidation of the Roxadustat and the ABP proceedings has the effect that evidence on any of the charges may be used as evidence on any other charge. However, taking account of all the evidence in the consolidated proceedings, we have nevertheless reached our decisions on liability on the Roxadustat Charges on the one hand and the ABP Charge on the other hand independently of each other.
94. There were witnesses of fact and expert witnesses on both sides. The expert evidence was extensive and is at the heart of several key issues in the case. We first deal with the factual evidence, before turning to the expert evidence.

### **Factual evidence**

95. Witness statements had been filed from Ms Halep and from four witnesses of fact on her behalf: Ms Candice Gohier, Mr Patrick Mouratoglou, Mr Frédéric Lefebvre and Mr Darren Cahill.
96. Ms Halep gave brief supplementary evidence-in-chief/direct evidence at the June hearing and was cross-examined by Mr Liddell. The ITIA waived cross-examination of all the Player's other four witnesses, while reserving its right to make submissions on the effect and weight of their evidence, so none of

them, except for Mr Patrick Mouratoglou (the Player's Coach), attended either in person or remotely.

97. The ITIA's only witness of fact was [REDACTED]. [REDACTED] had made a witness statement and attended the hearing by videolink.

#### Ms Halep's own evidence

98. We had signed witness statements of Ms Halep dated 1 December 2022 and 15 June 2023 as well as a transcript of her interview with the ITIA on 26 October 2022. Ms Halep gave supplementary evidence-in-chief/direct evidence on the first day of the June hearing, starting with her confirmation that everything in her two witness statements and everything she had said in that 2022 interview was true. Her witness statements, that interview and her oral evidence were all in English, which she speaks and understands with no noticeable difficulty.

99. Recognising the importance of this case for Ms Halep, we gave her a full opportunity of telling us how she first got into tennis and progressed to her indisputably impressive tennis career. Summarising the main points in her evidence for the purposes of our decision:

- (1) Ms Halep was adamant that she had always been a strong supporter of clean drug-free sport, had never taken any banned substance, had not even heard of Roxadustat until it was found in her 29 August Sample and had never given or received blood even on the two occasions when she had undergone surgery.
- (2) She had begun working with her new coach Mr Patrick Mouratoglou in March 2021 and moved to his Mouratoglou Academy in France later that year.
- (3) Ms Halep described her 2022 season. She had struggled with heat, humidity and nasal problems at the Citi Open in Washington DC from 1 to 7 August and was unable to finish her last-16 match. But she was

then given a TUE for medicine to help her nasal breathing problems and she won the singles title at the National Bank Open in Toronto which took place from 8 to 14 August 2022. On 17 August she withdrew from the Western & Southern Open in Cincinnati with a right thigh injury before her second-round match, but still had high hopes for the US Open.

- (4) At that point, Ms Halep's physiotherapist Ms Candice Gohier recommended adding a collagen supplement to her nutrition, as she was not taking one.
- (5) She described how she came to use three supplements from the supplier [REDACTED]. On a recommendation to Ms Gohier from Frédéric Lefebvre (who was the Director of Physical Preparation at the Mouratoglou Academy), Ms Gohier recommended three products from a supplier, [REDACTED] (to replace her electrolyte drink), [REDACTED] (to replace her recovery drink), and [REDACTED] ("Keto MCT").
- (6) Ms Halep had never previously heard of those [REDACTED] supplements. She asked Ms Gohier if she had checked them and she said yes. Also, Ms Halep and Ms Gohier together checked the container and there was no banned substance listed. Ms Halep also checked with her coach Mr Mouratoglou, who said that all three products were safe to use as no banned substances were shown on the label and they did not appear to be risky. Ms Halep was aware of the possibility of supplement contamination, so had always taken care to ensure that products were checked and recommended by specialists in the field.
- (7) All three supplements were ordered by Ms Gohier on 16 August 2022 and sent directly by the supplier to Ms Gohier in New York. The Player then started using the three [REDACTED] supplements in the middle of August 2022. (The Tribunal notes that it is only the Keto MCT supplement which needs further consideration, as the other two products were apparently harmless).

- (8) Ms Halep took the Keto MCT on five days between Tuesday 23 August and Sunday 28 August 2022, missing just Wednesday 24 August 2022 because it was a day off from practice and she normally did not take supplements on a non-practice day. Sunday 28 August 2022 was the last day she took the Keto MCT. That was the day before her US Open first-round match, which she lost unexpectedly.
- (9) She had been unconcerned when selected for In-Competition sample collection on 29 August, as her dozens of previous tests (including on 26 August 2022) had all been negative.
- (10) Ms Halep then stopped playing and training as she decided to have the [REDACTED] surgery which she had been contemplating for some time. [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] She knew that was going to require three months off tennis.
- (11) [REDACTED]  
[REDACTED]  
[REDACTED]
- (12) Ms Halep had not exercised at all since 28 September and did not exercise, except walking, until she started to run slowly at the beginning of November 2022. She had decided that after the [REDACTED] surgery she would not compete again in 2022.
- (13) She was shocked to be told on 7 October 2022 that the 29 August Sample had tested positive for Roxadustat.
- (14) On 21 October 2022, Ms Halep received confirmation that her B Sample had also tested positive for Roxadustat. By that time, she had already arranged for Ms Gohier to provide samples of her supplements, including



Keto MCT, to Professor Jean-Claude Alvarez for testing; and on 19 October 2022 she had gone to Professor Alvarez's laboratory and provided a hair sample to be tested for Roxadustat.

100. Ms Halep was adamant throughout her evidence that she had never taken and never would take any banned substance. She added two other reasons why she would not have used Roxadustat: [REDACTED]  
[REDACTED]  
[REDACTED] and she understood that Roxadustat would interfere with the effectiveness of that treatment; and secondly, she had [REDACTED] surgery scheduled [REDACTED]  
[REDACTED] she understood that using Roxadustat in close proximity to that surgery would have been a serious health risk. (The Tribunal notes that on her own evidence Ms Halep would have known nothing of either of those two points before she first heard of Roxadustat on 7 October 2022, but also that her main point was that she did not and would not ever use any prohibited substance anyway.)
101. Ms Halep's second witness statement exhibited her competition schedule from March to September 2022. During her oral evidence her counsel Mr Jacobs led Ms Halep through her tennis programme around dates in 2014 and 2017 relating to her ABP blood Samples 2 and 19 (mentioned later in this decision), and then her 2022 programme, including dates relating to her ABP Samples 44 and 46. However, we do not need to go into detail at this point.
102. We do note that Ms Halep did not disclose the Keto MCT supplement on her Doping Control Form ("DCF") for her urine test on 29 August 2022. She also did not mention it in her 26 October 2022 interview with the ITIA. In cross-examination at the June hearing, she said that for the DCF, she had forgotten and that at the interview she had also probably just forgotten. That was distinctly careless of her, especially at the interview when the need for complete openness would have been even more apparent.

103. Otherwise, apart from one or two tiny discrepancies of no significance, everything in her witness statements and oral evidence was consistent with what she said in her 26 October 2022 interview with the ITIA. She confirmed in that interview that she had never suffered from anaemia.

#### Evidence of Ms Halep's other witnesses

104. We summarise the main points in the signed witness statements of Ms Halep's other four witnesses:

##### Ms Candice Gohier

105. Ms Gohier's witness statement basically confirmed her part in these events as described by Ms Halep. She had worked as a physiotherapist with high-level tennis players for several years at the Mouratoglou Academy and with Ms Halep since spring 2022. Ms Gohier said she was well aware of players' anti-doping responsibilities and the importance of sourcing supplements from reputable companies.

106. In or around August 2022, Ms Halep, Mr Mouratoglou and Ms Gohier had reviewed Ms Halep's nutritional supplements and she and Mr Mouratoglou recommended replacements for some of her supplements which they believed contained too much sugar. Ms Gohier asked Mr Lefebvre for his opinion of [REDACTED] supplements that one of his regularly drug-tested professional tennis players had been using. Mr Lefebvre recommended the three supplements already mentioned above, including Keto MCT, and gave Ms Gohier the contact information for [REDACTED].

107. Ms Gohier texted [REDACTED] and ordered the products, which arrived in New York on 23 August 2022. She and Mr Mouratoglou checked and agreed that the products contained no banned substances and were safe for Ms Halep to use. Ms Halep then used the Keto MCT for six days from 23 to 28 August 2022.

Mr Patrick Mouratoglou

108. Mr Mouratoglou's two witness statements confirmed his involvement in recommending replacing supplements taken by Ms Halep, as already described above. Since opening his Academy in 1996, he had worked with many elite tennis players (and the names he gave certainly included players at the top of the sport). He had never had any reason to believe that Ms Halep used any Prohibited Substances or doping methods, including blood doping. He had no hesitation in saying she was an honest player who would never take any substance that would jeopardise her career and reputation.

109. He was well aware of the anti-doping responsibilities of athletes and coaches and did his best to ensure that his athletes complied with the WADA Code. He had confirmed with Ms Gohier that she had checked those three supplements from [REDACTED]. He discussed them with Ms Halep and told her they were safe to use. He was also aware that [REDACTED] sponsored a number of athletes, some of whom were tennis coaches and retired athletes.

Mr Frédéric Lefebvre

110. Mr Lefebvre's witness statement confirmed his involvement as already described above. He had given Ms Gohier the contact details of [REDACTED]. There is no need to add anything more here.

Mr Darren Cahill

111. Mr Cahill had been Ms Halep's main tennis coach from March 2015 to September 2021. Apart from Ms Halep, he has coached some tip-top players.

112. He had no involvement at all in the events of 2022, with which this case is concerned. His statement is essentially a character reference for Ms Halep. That is not a criticism. Mr Cahill tells how he became Ms Halep's coach and gives a glowing account of Ms Halep as a clean, dedicated professional tennis player of integrity and impeccable character. However, he is not able to cast any further light on the issues we have to resolve.



than SMRTL's negative results, but equally that we cannot say that SMRTL's negative results were more probably correct. It follows that Ms Halep has failed to establish that the Keto MCT was a source of non-intentional use of Roxadustat. We reach that conclusion without any need to assess the degree of practical likelihood or unlikelihood of Roxadustat having found its way into the Keto MCT at some point in the manufacturing and production. What we do find is that it cannot be ruled out.

117. Accordingly, although we have considered everything [REDACTED] told us, we need only a brief summary of the main points of [REDACTED] evidence:

- (1) [REDACTED] company [REDACTED] worked with a private label company, [REDACTED], which was the trading name of [REDACTED], located in [REDACTED].
- (2) [REDACTED] supplied the Keto MCT to [REDACTED] as a finished product, including packaging and labelling. Although [REDACTED] sometimes assisted in the sourcing, it was [REDACTED] who actually received the raw ingredients from sources and prepared and combined them into the product at a designated facility.
- (3) Keto MCT contained four ingredients:
  - (a) Medium-chain triglycerides ("MCTs") from coconut oil, in powder form;
  - (b) Collagen from fish;
  - (c) Inulin – a soluble prebiotic fibre from plants which assists healthy gut bacteria;
  - (d) Vitamin C (ascorbic acid).
- (4) [REDACTED] asked [REDACTED] to source all those ingredients from [REDACTED], a supplier of nutritional raw materials based in [REDACTED], with whom [REDACTED] worked previously.

(5) ■ had sourced those ingredients from Canada, Chile and China. ■ had confirmed to ■ (clearly since Ms Halep's case had come up) that they did not open the packaged ingredients received from its suppliers before sending them on to ■; that they had never previously heard of Roxadustat; and that while the supplier of the Keto MCT coconut oil powder (ingredient (a)) was based in Qingdao, China, ■ had no further information on their manufacturing process.

(6) Ingredient (d), ascorbic acid, had also come from China but he could not be sure whether it was natural or synthetic.

118. ■ had only ever produced one batch of Keto MCT. ■ would be shocked and surprised if ■ Keto MCT contained Roxadustat. Although we have no way of telling from the evidence how likely or unlikely it is that any of the raw ingredients supplied to GI contained Roxadustat, we cannot rule that out. We have no information about the particular raw ingredient sources in China but as a sports tribunal we take notice (what in national courts would be judicial notice) of the simple fact that China is a notoriously risky source of potentially contaminated supplements and ingredients of supplements used by athletes and players in many countries. Although we are appreciative of ■ cooperation, in the end, his evidence does not help us in deciding whether or not there was Roxadustat in the Keto MCT tested by Professor Alvarez and SMRTL. Our conclusions on that issue have to be drawn from all the other evidence, particularly from the expert witnesses.

119. ■ did helpfully confirm Ms Gohier's contact and the ordering and supply of ■ products in August 2022, as well as the steps taken by ■ to supply their products for testing by Professor Alvarez and SMRTL. All of that evidence was consistent with what we are told by the expert and other factual witnesses on those points, which we have no reason to doubt.

## **Expert evidence**

120. Expert witnesses, who all attended (either in person or remotely) to give evidence at the June hearing, were:

### Player's expert witnesses

- Professor Jean-Claude Alvarez – Professor of Pharmacology-Toxicology, University of Versailles Saint-Quentin-en-Yvelines
- Professor Pascal Kintz – Professor of Legal Medicine, University of Strasbourg.
- Professor Antoine Coquerel – Professor of Pharmacology, University of Caen
- Mr Paul Scott – President of KorvaLabs Inc., Sin Dimas, California; President and Chief Scientific Officer, Scott Analytics Inc., South Pasadena, California.

### ITIA's expert witnesses

- Dr Daniel Eichner – President of the WADA-accredited SMRTL, located in Salt Lake City, Utah
- Professor Guiseppe d'Onofrio – Professor in Clinical and Laboratory Hematology and in Clinical Pathology; member of WADA ABP Expert Panel.
- Dr Jakob Mørkeberg – Senior Science Manager, Anti-Doping Denmark; member of WADA ABP Expert Panel.
- Dr Laura Garvican-Lewis – Director of Science, US Anti-Doping Agency; member of WADA ABP Expert Panel.

121. Those brief descriptions of all these experts' positions come nowhere near indicating their overall expertise and standing. We have been supplied with their CVs and take due note of their academic and professional qualifications. Professor d'Onofrio, Dr Mørkeberg and Dr Garvican-Lewis are together the Expert Panel who reviewed Ms Halep's ABP under the ABP Programme.

122. An interpreter of French to English was present throughout the June hearing, particularly to assist Professor Alvarez as needed, though that was only occasionally necessary. The Tribunal was alert to the fact that English was the first language of only some of the expert witnesses.
123. There were 15 expert reports in evidence, some of them quite long: for example, Professor Alvarez’s reports were accompanied by 355 pages of scientific papers and documents referenced, and Mr Scott’s by 431 pages of such papers and documents. Dr Eichner’s report Eichner (1) was 33 pages plus 333 pages of appendices. We also had in evidence an APMU document Initial expert and APMU evaluation ABP noting the ABP Programme’s experts’ evaluations of Ms Halep’s ABP passport from 24 July 2014 through to 3 April 2023. In this decision we use shorthand labels for those 15 expert reports as in this table:

<b>Report/author(s)</b>	<b>Date 2023</b>	<b>Topic</b>
Alvarez (1)	23 Jan	Roxadustat
Alvarez (2)	9 March	Roxadustat
Alvarez (3)	17 March	Roxadustat
Eichner (1)	20 March	Roxadustat/ABP
Kintz Report	23 March	Roxadustat
Alvarez (4)	26 March	Roxadustat/ABP
Joint Experts (“ <b>JE1</b> ”)	12 April	ABP
Coquerel/Alvarez	26 April	ABP
Scott (1)	27 April	ABP
Eichner (2)	12 May	Roxadustat/ABP
Joint Experts (“ <b>JE2</b> ”)	19 May	ABP
Eichner (3)	7 June	Roxadustat/ABP
Alvarez (5)	15 June	Roxadustat/ABP
Scott (2)	15 June	ABP
Eichner (4)	22 June	ABP
Joint Experts (“ <b>JE3</b> ”)	23 June	ABP



## Hot-tubbing of expert witnesses

124. As agreed between the parties and approved by the Tribunal, the expert evidence was given in two separate “hot-tub” sessions, the first directed to the Roxadustat Charges and the second to the ABP Charge (though the experts appreciated that there was some overlap between the two sets of charges).
125. The hot-tub sessions meant that for each session all the relevant expert witnesses from both sides were present either in person or by videolink at the same time. Their reports stood as their evidence-in-chief. After a brief opportunity for counsel to question them on their qualifications and expertise, instead of the conventional process of their examination one after another by the two opposing counsel, questioning was led first by the Tribunal, with a list of issues which had been agreed between the parties and approved by the Tribunal. Counsel were also able to ask questions, usually towards the end of each issue. The advantage of the hot-tubbing over the conventional procedure was that questions could be put flexibly whenever and to whichever expert as seemed useful. There was also the opportunity for any of the experts to indicate at any time if they wanted to raise a point or put a question to one of the other experts. Given that nearly all the issues on the hot-tub list were of a scientific nature, the Tribunal’s questioning was largely led by Professor Sever.
126. The hot-tub session on the Roxadustat Charges took place on the first day and the early part of the second. The participating experts were Professors Alvarez, Kintz and Coquerel, and Dr Eichner. Professor Alvarez and Dr Eichner were present in person, and Professors Kintz and Coquerel by videolink.
127. The hot-tub session on the ABP Charge was on the second day. The participating experts were Professor Alvarez, Mr Scott, Professor d’Onofrio, Dr Garvican-Lewis, Dr Mørkeberg and Dr Eichner. Professors Alvarez and

d'Onofrio, Dr Mørkeberg and Dr Eichner were present in person, and Mr Scott, Dr Garvican-Lewis by videolink.

128. The agreed list plainly covered all the issues which the parties considered relevant for the experts. We need not set out that three-page detailed list of issues. All the issues have been considered and are covered in one way or another by the Tribunal in this decision. Key points are included as we now examine the merits of the case, first, on the Roxadustat Charges and then on the ABP Charges.

## **E. THE ROXADUSTAT CHARGES**

### **Testing of Keto MCT for Roxadustat contamination**

129. The central issue on the Roxadustat Charges is whether or not the source of the Roxadustat in Ms Halep's 29 August Sample was a Keto MCT supplement used by her in August 2022. In other words, given that there was no indication of Roxadustat in the listed ingredients of the Keto MCT, was that supplement contaminated with Roxadustat?

130. A startling feature of this case is that on this central point there is a head-on clash of the testing results of several of the same containers of Keto MCT, either claimed to have been used by the Player or from the same (and the only existing) batch. Professor Alvarez and Professor Kintz have both reported the presence of Roxadustat in several of their tests of the Keto MCT. By contrast, SMRTL have conducted a series of tests which have consistently shown no presence of Roxadustat in the Keto MCT.

131. Professors Alvarez and Kintz both have the highest professional standing and the same can be said of Dr Eichner, SMRTL and those who work there. The professional integrity of every expert in this case is beyond question (and unsurprisingly no doubt was ever raised by either party on that point). Professor Alvarez, supported by Professor Kintz, is adamant that the SMRTL

failure to detect Roxadustat in the Keto MCT, despite all the explanations given by Dr Eichner as to the reliability and thoroughness of their testing, is a false negative. In Professor Alvarez's unshaken view, the Roxadustat was definitely there in the Keto MCT and SMRTL have simply failed to find it.

132. Dr Eichner was equally confident that if Roxadustat had been present in the Keto MCT, in at least anything like the quantities reported by Professor Alvarez, SMRTL would certainly have detected it. Although he admitted that he could not identify where Professors Alvarez and Kintz had gone wrong in their testing procedures, something had gone wrong for them to have produced a false positive. Essentially, he was saying that it was just not possible that SMRTL's testing could have failed to pick up the presence of Roxadustat.

133. By way of introductory explanation of both Professor Alvarez's and the SMRTL's testing methods, all such tests involve use of an "internal standard" and the term "matrix", which we summarise:

- An internal standard is a chemical that is structurally very similar to the compound under investigation: here, Roxadustat. A known quantity is added to biological samples such as urine and in this case to the Keto MCT, as a marker substance that would behave in a very similar way to Roxadustat as it progresses through the various stages of the analytical procedure. It appears as a separate peak on chromatograms and can be used to determine the amount of the drug in the original sample. Dr Eichner claims that the methandrostenolone used by SMRTL is a better internal standard than testosterone.
- The matrix is the material (in this case, the Keto MCT powder) which is allegedly contaminated with Roxadustat. Chemical substances may stick or bind to constituents of the matrix which make it difficult to extract and subsequently measure. Professor Alvarez carried out control experiments using a mock up matrix to mimic the Keto MCT powder, to confirm that his procedures extracted the drug from the matrix. The

methodology, however, differed between the two labs. Dr Eichner believes the SMRTL lab experiments were preferable since they used the actual Keto MCT powder as the matrix for their control studies.

### **Professor Alvarez's tests for Roxadustat**

134. At the request of Ms Halep, Professor Alvarez's laboratory investigated possible origins of Roxadustat in various food supplements, which amongst other supplements included cans of Keto MCT powder. Analyses were carried out on the original supplement used by Ms Halep (Sample 2) and four unopened boxes of the same supplement from the same batch,
135. The analytical method involved an aliquot of each of the powders (approximately 10g) dissolved in pure water and the solution stirred and filtered. These solutions were then extracted with difluoromethane, in the presence of testosterone-d<sup>3</sup>, used as the internal standard. Extractions were then evaporated and taken up in a formate buffer and acetonitrile and injected on to a liquid chromatograph coupled with tandem mass spectrometry, in order to detect Roxadustat.
136. The following tables shows the results of the analyses identifying Roxadustat in the original sample consumed by Ms Halep and in three of the boxes, in amounts varying between 0.3-1.2ng/g<sup>1</sup>.

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<sup>1</sup> Nanograms per gram. A nanogram is one billionth of a gram. The experts sometimes presented results as pg/g, which is picograms per gram. A picogram is a trillionth of a gram and therefore a thousandth of a nanogram.

**Summary table:**

Sample No.	Type	Weight analyzed	Appearance	Color	Contents
Sample No. 1 (NEW ZEALAND PROTEIN SWISS CHOCOLATE)	Powder	10.012 g	fine powder	brown	Roxadustat absent
Sample No. 2 (KETO MCT MARINE COLLAGEN)	Powder	5.4 g	fine powder	white	<b><u>Roxadustat present</u></b>
Sample No. 3 (KETO BOOST ELECTROLYTES)	Powder	10.126 g	fine powder	unbleached	Roxadustat absent
Navy blue box No. 1 (KETO MCT MARINE COLLAGEN)	Powder	10.2139 g	fine powder	white	<b><u>Roxadustat present</u></b>
Navy blue box No. 2 (KETO MCT MARINE COLLAGEN)	Powder	10.8062 g	fine powder	white	<b><u>Roxadustat present</u></b>
Navy blue box No. 3 (KETO MCT MARINE COLLAGEN)	Powder	10.1458 g	fine powder	white	<b><u>Roxadustat present</u></b>
Navy blue box No. 4 (KETO MCT MARINE COLLAGEN)	<i>Not analyzed, stored closed in the laboratory</i>				
Pill from box No. 1 (EUTHYRON)	Pill	96 mg		White	Roxadustat absent
Pill from box No. 2 (KARISSA)	Pill	74.5 mg		Unbleached	Roxadustat absent
Pill from pill box	Pill	289.3 mg x 5		Blue	Roxadustat absent

137. In a further study, a volunteer subject consumed the Keto MCT powder in quantities similar to those reported by Ms Halep, and her urine was collected over the subsequent six days. Seven samples out of 34 samples, collected post ingestion, were positive for Roxadustat (concentration range <2.5 – 4 pg/ml). These values were substantially lower than the concentrations recorded in Ms Halep’s urine.
138. In the Alvarez (2), Professor Alvarez comments that the concentration range for Roxadustat in the original powder (0.2 - 1.2 ng/g) is a very low concentration and required analyses derived from 10g samples of the original powder. In addition, Professor Alvarez comments that the nature of the powder is gelatinous, making extraction impossible if the dissolved powder is not filtered. He also refers to a matrix effect of the extract which reduces the possibility of detecting Roxadustat.

**SMRTL’s tests for Roxadustat**

139. In the introductory comments from Eichner (1), Dr Eichner states that he does not consider the product to be the source of the Adverse Analytical Finding. SMRTL tested various canisters of the powder, including the

canister that had been used by the player, together with other canisters from the same batch provided by the supplier.

140. The SMRTL method, in summary, includes the extraction of 1g of powder with 10ml of methanol. The aliquot is taken up after centrifugation and spiked with methandrostenolone-d<sup>3</sup>, as the internal standard. The extract is concentrated on nitrogen, water and sodium acetate added and extracted on a reverse phase column. The column is washed, adsorbed material eluted, dried under nitrogen and analysed by liquid chromatography and tandem mass spectrometry.
141. SMRTL subsequently carried out three different methods: first, the conventional method for the Keto MCT powder product (as described above); second, a modified Alvarez method replacing filtration with centrifugation; and third, replicating Alvarez as closely as possible after receiving further details of the Alvarez methodology.
142. Finally, SMRTL conducted further studies using both 1 and 10 grams of powder for the initial extraction using the Alvarez replica method. In none of these studies was SMRTL able to detect Roxadustat in any of the samples tested. Moreover, using a series of positive and negative controls, they demonstrated that they could easily identify Roxadustat at levels of concentration below those reported by Alvarez.
143. SMRTL has considerable expertise in measuring Roxadustat. It developed specific methods for testing the drug in biological fluids but not in food supplements. However, it does have experience in the development of the best extraction methods for various products including powders. It also has experience in identifying the best internal standards for individual assays, the best solvents for extraction and the best matrix designs for controlled analyses.

Box/Canister Name <sup>a</sup>	Alvarez Box/Canister Source	Alvarez Test Method	Alvarez Report Date	Alvarez Result	Kintz Box/Canister Source	Kintz Test Method	Kintz Report Date	Kintz Result	SMRTL Box/Canister Source	SMRTL Test Method	SMRTL Report Date	SMRTL Result
Player sample No 2 (from box/canister 5)	Player	Alvarez Method <sup>b</sup>	19/12/2022	Present (0.4 ng/g; 1.1 ng/g)	-	-	-	-	-	-	-	-
Player-Manufacturer Box/Canister 1	Manufacturer	Alvarez Method	19/12/2022	Present (0.4ng/g)	-	-	-	-	Prof Alvarez (received only sample vial of Product)	SMRTL-Replica Alvarez Method	07/03/2023	Absent (SMRTL Report ID: ALV-B1-9751567)
Player-Manufacturer Box/Canister 2	Manufacturer	Alvarez Method	19/12/2022	Present (1.2 ng/g)	Alvarez (received box/canister and two vials)	Replica Alvarez Method <sup>c</sup>	04/03/2023	Present	Prof Alvarez (received only sample vial of Product)	SMRTL-Replica Alvarez Method	07/03/2023	Absent (SMRTL Report ID: ALV-B2-9751575)
Player-Manufacturer Box/Canister 3	Manufacturer	Alvarez Method	19/12/2022	Present (0.3 ng/g)	Alvarez (received only a vial)	Replica Alvarez Method	04/03/2023	Present	Prof Alvarez (received only sample vial of Product)	SMRTL-Replica Alvarez Method	07/03/2023	Absent (SMRTL Report ID: ALV-B3-9751586)
Player-Manufacturer Box/Canister 4	Manufacturer	-	-	-	-	-	-	-	Prof Alvarez	SMRTL Conventional Method; <sup>11</sup> SMRTL-Modified Alvarez Method; and SMRTL-Replica Alvarez Method	08/02/2023	Absent (SMRTL Report ID: SUPP-20230117-03-9709479)
Player Box/Canister 5	Player	Alvarez Method	20/02/2023	Present (0.64ng/g)	Alvarez (received only a vial)	Replica Alvarez Method	04/03/2023	Present	Prof Alvarez	SMRTL Conventional Method	08/02/2023	Absent (SMRTL Report ID: SUPP-20230117-04-9709492)
Player-Manufacturer Box/Canister 6	Manufacturer	Alvarez Method	20/02/2023	Present (0.2 ng/g)	Alvarez (received both box/canister and vial)	Replica Alvarez Method	04/03/2023	Present	-	-	-	-
SMRTL-Manufacturer Box/Canister 1	-	-	-	-	-	-	-	-	Manufacturer	SMRTL Conventional Method; SMRTL-Modified Alvarez Method; and SMRTL-Replica Alvarez Method	08/02/2023	Absent (SMRTL Report ID: SUPP-20230117-01-9709465)
SMRTL-Manufacturer Box/Canister 2	-	-	-	-	-	-	-	-	Manufacturer	SMRTL Conventional Method; SMRTL-Modified Alvarez Method; and SMRTL-Replica Alvarez Method	08/02/2023	Absent (SMRTL Report ID: SUPP-20230117-02-9709467)

The test results of Alvarez and Kintz are set out in the table alongside the results from the SMRTL laboratory.

144. Dr Eichner was unable to point out why he believed both Professor Alvarez and Professor Kintz provided positive results. He expressed a number of concerns regarding the Alvarez methodology. The key differences in the methodologies are shown in the following table.

SMRTL Conventional Method	Alvarez Method
1g of the Product tested	10g of the Product tested
Methanol extraction	Aqueous solvent (i.e. water) extraction.
Internal standard (methandrostenolone-d3)	Internal standard (testosterone-D3)
Centrifugation	Filtration

145. Dr Eichner defends the use of a smaller amount of the powder (1g vs 10g) on account of the fact that the latter is likely to introduce too much “junk” into the assay system. Nevertheless, using SMRTL’s methodology, it has shown

that it can reliably detect Roxadustat using either methanol or water extractions. Dr Eichner argued that SMRTL's internal standard – methandrostenolone-d<sup>3</sup> – was a much better internal standard for Roxadustat than testosterone and provided further details to support his argument (below). SMRTL uses centrifugation rather than filtration to avoid contamination, but in subsequent analyses, SMRTL claims to be able to identify Roxadustat from positive control samples using both procedures.

146. Despite these differences between the SMRTL methods and the Alvarez methods, SMRTL has demonstrated their successful identification of low concentrations of Roxadustat in control samples using the replica Alvarez method.
147. Dr Eichner expressed concerns about the matrix used by Professor Alvarez for control analyses. SMRTL used a sample of the actual product powder for positive control analyses. Professor Alvarez used a matrix considered by Dr Eichner to be inferior, although how this would lead to a false-positive result is not clear. Dr Eichner reaffirmed that the differences in the use of internal standards could lead to overestimation of Roxadustat in samples, but again it is difficult to see how this can generate a false-positive finding for Roxadustat.
148. Dr Eichner concluded his report with an example of a chromatogram from Professor Alvarez's study, showing a signal to noise level (background interference) which would be unacceptable by WADA standards and could raise the risk that the peak identified as Roxadustat could simply be a chemical noise.
149. In Alvarez (3), Professor Alvarez reported the outcome from further experiments. He reported that the concentration of Roxadustat in the Keto MCT was considerably lower than he had previously reported. The new values for Roxadustat in the collagen powder were 60-100pg/g or 0.06-0.1ng/g.



150. Professor Alvarez claimed that the failure of SMRTL to detect Roxadustat was due to its lower limit of detection being 160pg/g of original Keto MCT powder - a point vigorously denied by Dr Eichner.
151. Professor Alvarez concluded that there was no discrepancy between the three laboratories other than the difference being due to the analytical sensitivity of the different instruments used by the three laboratories - again disputed by Dr Eichner.
152. In Alvarez (4), Professor Alvarez responded to Dr Eichner claiming that although SMRTL was experienced in Roxadustat analysis, this experience applied specifically to biological samples, including urine and blood, but that it had no experience analysing food supplements for Roxadustat.
153. Professor Alvarez also questions how it would be possible for contamination in the assay to explain the positive findings for Roxadustat in fourteen separate successive tests. He concludes that a false-positive explanation for his observed chromatographic findings would be very unlikely.
154. Professor Alvarez also points out that when he used the SMRTL method, using 1g of powder rather than 10g of powder and extraction with methanol, he was unable to find Roxadustat. He points out in addition, but does not explain, that when the analytical process excludes filtration (as opposed to centrifugation carried out by SMRTL), he could not find Roxadustat.
155. Professor Kintz, in his evidence, using the Alvarez methods of analysis, essentially confirms the Alvarez findings in studies on five extracted vials provided by Professor Alvarez and on two boxes of the Keto MCT.
156. In Eichner (2), Dr Eichner comments further on additional reports from Professor Alvarez which claim that the concentrations reported for the amounts of Roxadustat in the original powder were considerably lower and ranged from 70-100pg/g. Professor Alvarez had stated that the reason for this downward revision in concentrations of Roxadustat was due to a strong

matrix effect of the Keto MCT [REDACTED] powder. Again, Dr Eichner challenged the Alvarez methodology, commenting that these had been recently developed methods which had not been published or subject to peer review. He considered that the continuing changes in the actual amounts of Roxadustat reported by Professor Alvarez raised questions as to the reliability of the methodology. Dr Eichner also raised further concerns about the quality of the chromatograms provided by Professor Alvarez, which he believed did not meet WADA acceptance criteria and would have led to an overestimate of the amount of Roxadustat present in the sample and, as stated above, in certain cases leaves questions about the identity of particular peaks where there is high background noise in the chromatograms.

#### **Tribunal's conclusion on the testing for Roxadustat**

157. We have two diametrically opposed opinions on whether or not the [REDACTED] Keto MCT [REDACTED] powder was contaminated with Roxadustat. One of these views is correct, the other is not. One view is that Professor Alvarez's laboratory, as confirmed by Professor Kintz, has identified Roxadustat as a contaminant of the marine powder and the failure of the SMRTL lab to confirm this finding is a false negative. The other view is that SMRTL has correctly failed to identify Roxadustat in any of the Keto MCT samples (because there never was any Roxadustat contaminant) and the identification of Roxadustat in the samples analysed by Professor Alvarez was a false positive finding.

158. In general, it is easier to explain a false negative finding than a false positive finding. However, the issues in this case are complex and an attempt to resolve the opposing findings and opinions is challenging.

159. Professor Alvarez presents a considerable number of chromatograms purporting to demonstrate Roxadustat peaks. These are confirmed by Professor Kintz. There are clearly concerns about the actual level of Roxadustat reported from the assays and Professor Alvarez has altered his

conclusions a number of times in this respect. Professor Alvarez points to steps in his methods which he believes are essential for the identification of Roxadustat, including aqueous extraction, the use of filtration and a sample size of 10g powder.

160. Whilst the original SMRTL method differed in several of these steps, revised methods incorporating a number of the Alvarez steps still failed to identify any Roxadustat. What is frustrating is that SMRTL continued to justify various stages of their methodology and, even when they claimed to have adopted an Alvarez-like methodology, there were still significant differences in the two methods. We will never know whether, if SMRTL had precisely copied the Alvarez method, they would have identified Roxadustat.
161. Professor Alvarez consistently claimed that the SMRTL method was simply not sufficiently sensitive to detect the small amounts of Roxadustat his method had found. Dr Eichner denies this by demonstrating that the SMRTL method could identify, in spiked control samples, amounts of Roxadustat in much lower concentrations than those found by Professor Alvarez. Whilst Dr Eichner's points about centrifugation, optimal solvent extraction and using the appropriate matrix for control samples are all fair points, they still do not explain the positive findings of Professor Alvarez. Dr Eichner raises a number of concerns about the lack of validation, publication and peer review of the Alvarez method. All fair points but again, providing no explanation for the Alvarez findings. Dr Eichner also raises concerns about the quality of the Alvarez chromatograms, the level of background noise in the chromatographic analyses and the potential that this could lead to misinterpretation of the nature and identity of the apparent Roxadustat peaks.
162. In attempting to resolve this complex situation we should recall, first, that Dr Eichner stated that he could not provide a definitive explanation as to why Professor Alvarez had identified Roxadustat whereas SMRTL had not and, secondly, that Professor Alvarez's criticism of the SMRTL method on grounds of lack of sensitivity is unlikely to be correct, based on several studies using

the SMRTL method and the modified Alvarez method in which no Roxadustat was found in the marine powder, whereas in control samples using very low amounts of Roxadustat, the drug could be easily identified.

163. There are sufficient uncertainties arising from the evidence provided, on the one hand by Professor Alvarez supported by Professor Kintz and on the other hand by Dr Eichner, that from the Alvarez/Kintz and SMRTL direct testing of the Keto MCT, we should not be able to form a reliable judgement on whether or not the Keto MCT consumed by Ms Halep was contaminated with Roxadustat. On this footing, the Player would not have established on the balance of probability that first vital element of her primary case.

164. However, that is not the only evidence before the Tribunal. We next consider a further control study done by Professor Alvarez.

#### **Alvarez Control Study**

165. In December 2022, Professor Alvarez conducted a control study (the “**Alvarez Control Study**”) involving a volunteer from his laboratory.

166. The Alvarez Control Study is described in Alvarez (1). A 58-year-old woman, height 1.69m and weight 63kg, consumed the same Keto MCT powder as had Ms Halep, in the same 10g quantities and at the same times of day on five days, D1 and D3-D6, so as to exactly match Ms Halep’s consumption set out in the table at paragraph 190 below.

167. One urine sample was taken from the volunteer before the first ingestion and 34 samples afterwards, over the period D1 to D7. All 35 samples were tested for Roxadustat. In the pre-ingestion sample and in 27 of the post-ingestion samples, no Roxadustat was detected. The levels of Roxadustat detected in the other seven samples were less than 2.5pg/ml in five cases and, in the two other cases, were 4.0pg/ml (on D5) and 2.7pg/ml (on D6). Expressed in ng/ml, that is less than 0.0025ng/ml in five cases and 0.004ng/ml and 0.0027ng/ml in the other two cases.

168. Eichner (2) notes that after adjustment for specific gravity, the values in the Player's urine of 0.186ng/ml and 0.341ng/ml are respectively 46 and 85 times higher than the highest value of 4.0pg/ml (0.004ng/ml) found on testing of the volunteer's urine. (The expert reports continually switch from nanograms to picograms, but as far as possible we have used and translated into nanograms throughout this decision. However, using picograms here, that figure of 46 is obtained by dividing 186 by 4; and the figure of 85 is obtained by dividing 341 by 4.)
169. We shall need to return to the question whether in the end the Alvarez Control Study supports the Player's overall case (see paragraphs 228 and 234 below). However, on the specific question of contamination of Keto MCT used as described by the Player, the results of that study do support the Player's position. False positives, though not impossible, are less likely on testing of urine than on testing of a supplement such as Keto MCT. Although the amounts of Roxadustat detected in seven of the volunteer's urine samples were all tiny, the fact is that Roxadustat was found. Accordingly, to conclude that the Keto MCT was not probably contaminated with Roxadustat, we should be going against both the Alvarez/Kintz results of their direct testing of that supplement and the results of the separate testing by Professor Alvarez of his volunteer's urine sample. While we cannot say that it is a conclusion we reach with any higher degree of confidence, we do find that the Keto MCT, if (as we shall assume) used as described by the Player, was contaminated with Roxadustat.

### **Hair Testing**

170. On 19 October 2022, Ms Halep travelled to Professor Alvarez's laboratory to provide a hair sample for follicle testing for Roxadustat. Ms Halep's sample was compared with that of a patient treated medically with Roxadustat. She argues that the level of Roxadustat found in her hair is consistent with limited use of a contaminated supplement, and that it therefore supports her explanation on the source of the Roxadustat found in her urine.

171. When he analysed Ms Halep's hair, Professor Alvarez found less than 0.5pg/mg (the lower limit of quantification) of Roxadustat in each of the six one-centimetre segments closest to the root. The six hair segments containing Roxadustat grew between April 2022 and October 2022, when the hair test was undertaken. Although Professor Alvarez concedes that he cannot quantify the precise level of Roxadustat in each segment because it fell below the lower limit of quantification, he testified that the concentration of Roxadustat was higher in segment B, the segment corresponding to the period from mid-August 2022 until mid-September 2022. However, it is clear that he cannot conclude that Ms Halep's consumption of Roxadustat in August was greater, because as an accredited laboratory, he cannot properly quantify a concentration that falls below the lower limit of quantification. By contrast with the low concentrations of Roxadustat found in Ms Halep's hair, Professor Alvarez found that the levels of Roxadustat in the hair of a known user who had been prescribed it for medical reasons was approximately 100 times greater (between 41-57 pg/mg).

172. Ms Halep maintains that the hair testing conducted by Professor Alvarez is further evidence that her violation was due to unintentional contamination because the low concentration of Roxadustat in her hair is inconsistent with a therapeutic or performance enhancing dose. As far as the presence of Roxadustat throughout the hair sample that grew over six months is concerned, she asserts that colouring and thermal hair straightening caused the Roxadustat in her hair to diffuse or migrate throughout the tested hair segment. Professor Kintz explains the possible impact of colouring and thermal straightening on Ms Halep's hair test results as follows:

*"I was informed that the athlete performed a hair coloration in September and uses thermal smoothing every day. These 2 cosmetic treatments can be responsible for*

*- axial diffusion of Roxadustat along the hair fiber, as it has been observed for other drugs (Kintz, Ther Drug Monit, 2013, 35, 408-410)*

*- loss of some amounts of drug as coloring will open the hair cuticle (the outside protein matrix). This damage to the ultrafine structure of the hair*

*cuticle (surface, endocuticle, and cell membrane complex) and cortex (cell membrane complex) is a situation prone to drug evasion (Zhang et al, J Cosmet Sci, 2016).*

*In some case of thermal straightening, it was observed an increase of drug concentration that may be explained by denaturation of the hair matrix by thermal treatment possibly causing a better extraction of the drugs (Ettliger et al, Drug Test Anal, 2014; Ettliger et al, Forensic Sci Int, 2016).*

*Of course, the fact that the athlete performed cosmetic treatment will modify the early simple interpretation. Cosmetic treatment, such as coloring, will increase hair porosity. In this situation, hair swelling and water absorption capacity increase, producing a displacement of the spot of exposure by radial migration of the drug. Although this has not been published for Roxadustat, it has been observed for other drugs, including pharmaceuticals, drugs of abuse and alcohol markers.”*

173. The existence of axial diffusion or migration caused by cosmetic hair treatments is supported by other scientific studies referred to by Professor Kintz in his report. On this basis, Professor Kintz concludes:

- a. *“it is scientifically plausible that the cosmetic treatments performed by Ms. Halep explain the presence of Roxadustat throughout the hair sample that was tested;*
- b. *Professor Alvarez’s test results do not contradict Ms Halep’s explanation on contamination and the source of the Roxadustat in her urine; and*
- c. *the concentrations in her hair demonstrate that she was not using Roxadustat in sufficient quantities to enhance her performance.”*

174. Notably, Professor Kintz does not go so far as to state that the Player’s explanation is the only, or even the most likely, explanation for Professor Alvarez’s results.

175. The ITIA contests the reliability of the hair testing conducted by Professor Alvarez and maintains that, in any event, the results are inconsistent with exposure to low levels of Roxadustat starting from 23 August 2022.

176. On reliability, Dr Eichner observed that Professor Alvarez's hair testing for Roxadustat broke new ground scientifically and he criticises Professor Alvarez' conclusions on the grounds that the testing method was not subject to peer review or other scientific scrutiny. However, shortly thereafter Professor Alvarez published an article on detecting Roxadustat in hair in *Clinica Chimica Acta*, a peer-reviewed scientific journal. The article sets out the method that he used to test Ms Halep's hair. Separately, Dr Eichner maintains that there are inherent limitations on the probative value of hair testing, especially at low concentrations, because of factors including diffusion that make it difficult to reliably detect concentration. He notes in his report that Professor Kintz did not independently conduct any hair testing himself, but relies on the methodology and results of Professor Alvarez.
177. On the results themselves, Dr Eichner maintains they do not support Ms Halep's explanation because, whilst diffusion is possible, it has not been studied specifically in relation to Roxadustat and he therefore does not consider that straightening accounts for the diffusion along the full length of the hair segment that was growing between April and October 2022. He argues that Professor Alvarez's results could be consistent with repeated small exposures over time to Roxadustat.
178. There are therefore two contested issues between the parties in relation to hair testing: first, whether the hair testing itself is reliable and secondly, whether, in any event, the hair testing conducted supports Ms Halep's explanation on contamination.

### **Is Hair Testing Reliable?**

179. Professor Alvarez testified that his laboratory frequently analyses hair and that it has processed anywhere between 1,000 and 1,500 hair samples. Professor Kintz is a widely published expert in hair testing who is frequently instructed to conduct hair testing in athlete doping cases. Clearly, both Professors Alvarez and Kintz have the requisite expertise when it comes to hair testing in doping cases and specifically in contamination cases. Dr



Eichner was clear in his evidence that Professor Kintz is a renowned expert in hair testing, and he was careful to point out that he disagreed with Professors Kintz and Alvarez mainly because of their interpretation of Ms Halep's hair test results and not because of the quality of the tests performed by Professor Alvarez.

180. During these proceedings, Professor Alvarez published a paper on detecting Roxadustat in hair using liquid chromatography with tandem mass spectrometry. He testified that this article was the first on this subject. Although there is a dearth of scientific literature that specifically addresses the reliability of hair testing in relation to Roxadustat, the Tribunal is not persuaded by the ITIA's submission or Dr Eichner's evidence that the hair testing conducted by Professor Alvarez is therefore inherently unreliable or that the results should be disregarded.
181. The Tribunal accepts Professor Alvarez' evidence that "*there is always the first time for each compound*" and that where a previously relied-upon and well-recognised method is used to detect a new compound, it would be unreasonable to disregard the results produced by that method entirely. Indeed, the panel in the CAS appeals *ITF v Gasquet* and *WADA v ITF & Gasquet*, CAS 2009/A/1926 & 1930, relied on the results of hair testing (conducted, incidentally, by Professor Kintz) to conclude that the Player had not consumed cocaine at an amount above 10mg. In the June hearing, Professor Kintz testified that hair testing is scientifically sound and that it is used frequently for workplace drug testing and by criminal courts around the world. He maintains that hair testing can reliably be used to distinguish between contamination cases in which a person has ingested or been exposed to very small amounts of a particular substance and cases in which an athlete has cheated by using high concentrations of a Prohibited Substance to enhance performance. Dr Eichner also conceded that, in his experience, hair testing is widely used for example in abstinence programmes because it has a long detection window.

182. Given the expertise of Professors Kintz and Alvarez in this field as well as Dr Eichner's own evidence, the Tribunal accepts that the hair tests conducted by Professor Alvarez are scientifically sound and not inherently unreliable.
183. The Tribunal therefore considers that whilst hair testing for Roxadustat is still in its infancy, it is reliable, and the testing conducted by Professor Alvarez should not be disregarded.

### **Does the Hair Testing support Ms Halep's explanation?**

184. Even if the Tribunal were to accept Professor Kintz's evidence that colouring and thermal straightening could have caused the Roxadustat to migrate down to the hair growing in April 2022 and up to the hair growing in October 2022, it does not follow that Professor Alvarez's hair testing results support Ms Halep's explanation regarding the source of Roxadustat in her urine. In fact, Professor Kintz's evidence is that cosmetic treatments *could* explain why Roxadustat is present throughout the hair sample. Another explanation is, as the ITIA argues, that Ms Halep ingested Roxadustat before she claimed to have done so on 23 August 2022.
185. Although the concentrations of Roxadustat found in Ms Halep's hair may show that she did not ingest a therapeutic dose, this is not relevant to her explanation. It is not for the Tribunal to speculate regarding the impact of Roxadustat on Ms Halep's performance. Therefore, the fact that she may have ingested a much lower quantity than that given to a medical patient who was treated with a therapeutic dose is not strictly relevant. An alternative explanation of the results could be that Ms Halep was microdosing with Roxadustat throughout the period between April to October 2022. In fact, Professor Alvarez testified that the test results were consistent with "*microdoses*" of Roxadustat and that he could not exclude that another explanation for his results was contamination during the entire six-month period covered by Ms Halep's hair sample.

186. Because the results of the tests conducted by Professor Alvarez could equally be explained by Ms Halep ingesting small doses of Roxadustat throughout the period between April and October 2022, the Tribunal is not persuaded that the hair testing adds support for the contamination of the Keto MCT with Roxadustat, although it is consistent with our conclusion that it was so contaminated. Moreover, in the light of our conclusion on the question of concentration of Roxadustat in the 29 August Sample (below), the hair testing has no effect on our overall decision on the Roxadustat Charges anyway.

**Concentration of Roxadustat in Ms Halep’s 29 August 2022 urine sample (the “Concentration Question”)**

187. While we have decided that the Keto MCT supplement probably was contaminated with Roxadustat, there is then a further crucial question to resolve: If the Keto MCT supplement was contaminated with Roxadustat as shown by the Alvarez/Kintz test results, is it possible (and if it is possible, how likely or unlikely) that the concentration of Roxadustat in the 29 August Sample was entirely caused by the Player’s use of MCT as described by the Player in her evidence?

188. If the concentration of Roxadustat in the 29 August Sample was not entirely caused by contamination of the Keto MCT, Ms Halep would then face the obvious difficulty that she must have ingested Roxadustat from some other source altogether. She would then have the burden of proving that her ingestion from that other source was non-intentional.

189. The Player’s counsel Mr Jacobs argued that the TADP does not say that the Player has to prove that the amount of the Prohibited Substance in the contaminated supplement is consistent with the amount in the urine sample. At that point in his oral submissions, Mr Jacobs was specifically addressing TADP Article 10.6.1.2 (see paragraph 25(4) above) but his submission appeared to go more widely and require the Tribunal to decide the contamination issue without taking into account the concentration of

Roxadustat in the Player’s 29 August Sample. He cited an Interim Arbitral Award of a North American Court of Arbitration for Sport Panel in *USADA v Hardy*, (AAA No 77 190 00288 08), 4 May 2009, which considered DC 10.5.2 of the Doping Control Rules of the Federation Internationale de Natation (“**FINA**”) – a provision which, like TADP Article 10.6.1.2, allowed a reduction of the period of Ineligibility if the athlete proved non-intention as well as No Significant Fault or Negligence and could also establish the source of the Prohibited Substance. The factual findings in *Hardy* are irrelevant. The point is that the *Hardy* panel accepted an argument from the Respondent swimmer that FINA’s DC 10.5.2 only required her to prove how the Prohibited Substance entered her system, which she had done; and that it did not require her to prove that it entered her system in certain quantities to yield the level of the Prohibited Substance which caused the positive result. That was a plainly wrong interpretation, so leaving aside that the *Hardy* decision is not binding on us anyway, we disregard it entirely. In Ms Halep’s case, it is clear on principle and in common sense that the concentration of Roxadustat in the 29 August Sample is a potentially relevant piece of evidence in deciding if her ingestion of Roxadustat was non-intentional. If contamination of the Keto MCT with Roxadustat cannot explain the concentration found in her 29 August Sample, she ingested some quantity of Roxadustat from another, unidentified source.

### **The Player’s use of Keto MCT**

190. The starting point on the Concentration Question is Ms Halep’s own account of her use of MCT. Whether or not that account is truthful, the Player obviously cannot complain if we assume its correctness for the purposes of answering this question (and generally in this case). Her evidence of dates, times and quantities is:

<b>Days</b>	<b>2022 Date of Keto MCT powder intake</b>	<b>Time (local, EDST)</b>	<b>Quantity</b>
D1	Tuesday 23 August	16:30	10 g
D3	Thursday 25 August	16:30	10 g

D4	Friday 26 August	15:30	10 g
D5	Saturday 27 August	13:00	10 g
D6	Sunday 28 August	14:30	10 g

The times and quantities could never have been quite so exact in real life, but any differences would have been trivial, and we can safely use those details as given in Ms Halep's own evidence.

191. The next step is to take the amounts of Roxadustat reported by Professor Alvarez as found by him in the Keto MCT. That is evidence on which the Player relies. Those amounts are:

Alvarez original test results

192. On his initial testing, Professor Alvarez reported four positive findings of Roxadustat in the following quantities:

- 0.4 ng/g (nanograms/gram)
- 0.4 ng/g
- 1.2 ng/g
- 0.3 ng/g

Alvarez's revised test results

193. Alvarez (4) reported further testing by him, from which he estimated the concentration of Roxadustat in the Keto MCT to be around 0.07 to 0.1 ng/g and "*maybe slightly higher*".

194. The estimated concentrations of Roxadustat found by the Montreal laboratory in the Player's sample were:

- Sample A: 0.289 ng/ml
- Sample B: 0.529 ng/ml

195. Eichner (1) stated a conclusion from which Dr Eichner has never resiled. Always remembering that Dr Eichner does not agree that the Keto MCT was contaminated with Roxadustat at all, his opinion was that even if it had been contaminated at the levels reported by Professor Alvarez, those levels could not have caused the concentrations of Roxadustat in the Player's A and B samples as estimated by the Montreal laboratory.
196. Professor Alvarez does not agree. In his view, the evidence does not show any inconsistency between the amounts of Roxadustat found by him in the Keto MCT and the results of the Montreal laboratory analysis of the Player's urine samples. Professor Alvarez's view forms part of the Player's case.
197. We approach this by considering: first, Dr Eichner's explanation of his opinion; secondly, Professor Alvarez's reasons for rejecting Dr Eichner's opinion and maintaining his own. Many of the points are in their written expert reports, but these issues were also explored in their evidence on hearing day 2, when we completed the first hot-tub..
198. Professor Alvarez and Dr Eichner disagreed throughout on the reliability of the Montreal laboratory's estimated levels of concentration of Roxadustat in the 29 August Sample. We examine this below. It is a key issue, because if those estimates are not reliable, that destroys the value of Dr Eichner's conclusion (paragraph 191 above) for our decision on this question.

#### **Dr Eichner's opinion based on the original Alvarez test results**

199. In Eichner (1), Dr Eichner set out reasons for his conclusion. At this point he was working with the figures from Alvarez's original testing.
200. Dr Eichner explained his conclusion based on the timing of ingestion by the Player of Keto MCT, the timing of her urine sample collection and the pharmacokinetics of Roxadustat. He provided two different scenarios for the results of the drug test based on the Player's explanation and what was known about the metabolism of Roxadustat.

201. Scenario 1 he described as heavily prejudiced in favour of the Player. Scenario 2 he described as more realistic, using the Player's own explanation and average values for pharmacokinetic parameters. Each of those scenarios calculated how much of the Keto MCT the Player would have had to consume in order to account for the original urinary findings of Roxadustat by the Montreal laboratory.

202. We do not need to set out here all the full details of each scenario, although we have taken every point into account for our decision. In summary:

Scenario 1 took the 1.2 ng/g highest concentration of Roxadustat reported by Professor Alvarez and the lower of the two Montreal laboratory estimates of Roxadustat in the Player's urine, i.e. the 0.289ng/ml in her Sample A. Dr Eichner listed further assumptions, including assumptions about the Player's urinary output, excretion and elimination of Roxadustat, her food intake and the timing of her ingestion of MCT during the relevant period 23 to 29 August 2022.

Scenario 2 took the concentration of Roxadustat in the Keto MCT as 0.7ng/g, being near the middle of the range reported by Professor Alvarez, and took the concentration of Roxadustat in the Player's urine as 0.4ng/ml being the average of the A and B Sample estimates of Roxadustat by the Montreal laboratory. Dr Eichner used the times of ingestion provided by the Player and listed what he described as more realistic assumptions including assumptions on the specific points we have mentioned under Scenario 1.

There is no doubt that the assumptions under Scenario 1 were overall more favourable to the Player than any realistic picture, including under Scenario 2.

203. Dr Eichner concluded that under Scenario 1, the Player would have needed to ingest nearly seven times the recommended 10g serving size of MCT in order to produce the estimated concentrations of Roxadustat detected in her

29 August Sample. He did not consider that plausible or in line with what the Player says she ingested.

204. Under Scenario 2, Dr Eichner's conclusion was stronger: the Player would have needed to ingest 900 times the recommended 10g serving size of MCT in order to produce the estimated concentrations of Roxadustat in the 29 August Sample.

### **Dr Eichner's opinion based on Professor Alvarez's revised test results**

205. In section E of Eichner (2), Dr Eichner set out revised versions of Scenarios 1 and 2. Those revised versions were not corrections. They were adjustments to take account of the new concentrations of 0.06 - 0.1ng/g Roxadustat (60 - 100pg/g) that Professor Alvarez reported finding on further testing of the Keto MCT. Dr Eichner set out his revised versions under the headings *Scenario 1 (unrealistically biased in favour of the Player)* and *Scenario 2 (using average parameters suggested by the literature)*.

206. As with the two scenarios presented in Eichner (1), if we put aside for the moment the question of the reliability of the Montreal laboratory estimates of the Roxadustat concentration in the Player's urine samples, we accept that overall the assumptions under Scenario 1 were strongly biased in favour of the Player.

207. Under that revised Scenario 1, Dr Eichner's conclusion was that the Player would have needed to ingest over 50 times the recommended 10g serving size of MCT in order to produce the estimated concentrations of Roxadustat detected in her 29 August 2022 Sample. He did not consider that plausible or in line with what the Player says she ingested.

208. Under revised Scenario 2, Dr Eichner's conclusion was again stronger: the Player would have needed to ingest 5,000 times the recommended 10g serving size of MCT in order to produce the estimated concentrations of Roxadustat in her 29 August Sample.



### **Professor Alvarez's response**

209. The Player's expert witness, Professor Alvarez, rejected Dr Eichner's conclusions. He identified what he considered to be flaws in Dr Eichner's approach and analysis, which meant that in his opinion there was no inconsistency between Professor Alvarez's Keto MCT test results and the Montreal laboratory's results of analysis of the Player's 29 August Sample.
210. Professor Alvarez's main objection to Dr Eichner's analysis was that the Montreal laboratory's estimated levels of 0.289ng/ml and 0.529ng/ml were not reliable. He correctly noted that the Montreal laboratory's analyses of Samples A and B were qualitative and not quantitative analyses. That is clear common ground. Roxadustat is not a Threshold Substance in the TADP, where a minimum level has to be detected for there to be an AAF in the first place. Accordingly, the Montreal laboratory's finding of any quantity of Roxadustat in Sample A was enough for an AAF; and its testing of Sample B was only to confirm (or not) the presence of Roxadustat in any amount. As freely acknowledged by Dr Eichner, those levels reported by the Montreal laboratory were estimates and not precise measurements. However, unlike Professor Alvarez, he considered them sufficiently reliable to support his conclusions on this question.
211. Professor Alvarez explained that a quantitative analysis would involve seven reference points, or control samples, giving an accuracy which could not be achieved by a single reference point, or control sample, as normally used for a qualitative analysis (though, he added that a WADA-accredited laboratory would use two control samples on a qualitative analysis). There was no dispute on this and we do not need to go into more detail. It is clear that a quantitative analysis will produce a more reliable measurement than a qualitative analysis, as those labels imply. But that is not the issue. We have to consider the reliability of the Montreal laboratory's 0.289ng/ml and 0.529ng/ml for answering this question.

212. Professor Alvarez pointed to the 83% difference between the Sample A and Sample B levels (i.e. 0.529 is 1.83 x 0.289). He said that according to international guidelines (which he did not specifically identify), an accurate measure of concentration required a maximum 15% variation; and that 83% was not acceptable and meant that these results were unreliable.
213. It is important to be clear about some of the terms referred to in the evidence of Professor Alvarez and Dr Eichner. In his oral evidence in the first hot-tub, Professor Alvarez said that a WADA laboratory had one standard for Roxadustat, which was 2.0ng/ml (i.e. nearly four times the estimate in Sample B). That figure of 2.0ng/ml, in relation to Roxadustat, is the Minimum Required Performance Limit (“MRPL”) required by WADA for accreditation of a laboratory. Professor Alvarez said that the level of Roxadustat in the urine could be evaluated above that limit but below that limit was totally inaccurate. In his view, all that could be said was that the concentration was somewhere between the MRPL and the (lower) limit of detection (i.e. the level below which a laboratory is not able to detect the substance at all). He did not know the limit of detection for the Montreal laboratory. He thought the MRPL varied between laboratories (which it clearly does).
214. Dr Eichner explained why the MRPL did not have the significance given to it by Professor Alvarez. Although the Montreal laboratory’s testing of Sample B was a “*qualitative assay*”, that did not mean it was “*open season*”, by which we understood him to be saying that there would still be care taken to produce a useful estimate of the quantity. He expressly added “*so when you're reporting out a qualitative assay, you give a good estimate*”. The MRPL was not a reporting level and not a threshold. It was the minimum required level of detection set by WADA for the more than 30 WADA-accredited laboratories around the world. In practice, the level of detection was usually well below that.
215. The Tribunal’s view is that the MRPL is not relevant and does not help us at all in answering this question. We do not accept Professor Alvarez’s view that the MRPL amounts to any sort of line below which a laboratory estimate – in

this case by the Montreal laboratory - becomes unreliable, even less (to use Professor Alvarez's words) "*totally inaccurate*". Although the concentrations of urine estimated by the Montreal laboratory in the A and B samples were only about one-eighth and one-quarter of the MRPL, we believe these to be reliable estimates.

216. We find specifically that there is a clear explanation of the 83% increase in concentration from 0.289ng/ml for sample A to 0.529ng/g for Sample B which means that it does not cast any significant doubt on those figures being sufficiently reliable estimates to be used fairly as values in Dr Eichner's two original and two revised scenarios.

217. That explanation involves photoisomerization, a well-recognized chemical process by which molecules of some chemical compounds change shape when a substance is exposed to light. Although we spent three-quarters of an hour on this single topic at the June hearing, we can summarise the process here without any need for scientific detail.

218. There is no dispute that Roxadustat is affected by photoisomerization. The way Dr Eichner described it was that on exposure to light, some of the Roxadustat converts into a mirror image of itself (those are photoisomers). However, although all the drug is still there, the mirror/photoisomer form is not quantified by normal testing methods. Accordingly, the company FibroGen, which has developed Roxadustat as a drug for therapeutic use, has produced a standard or method for detecting that mirror form as well as the non-photoisomerized form. That is important to them because of the need to ensure that patients are receiving the correct dosages.

219. FibroGen has provided that standard to SMRTL, who have used it and seen that when Roxadustat is exposed to light there is a decrease in the amount detectable by normal testing. On the normal SMRTL testing, the converted Roxadustat is still there but has not been detected. By contrast, use of the FibroGen standard detects both the mirror/isomerized and the non-photoisomerized Roxadustat. The Montreal laboratory's testing of Sample B

similarly would not have detected any mirror/photoisomer form of Roxadustat (and to make it clear, the Player's experts never made any criticism of the Montreal laboratory testing).

220. The relevance of this to the Montreal laboratory estimates is that in practice, as described by Dr Eichner, A and B samples are handled differently in WADA-accredited laboratories. There is a clear practical explanation for that. The A sample is being tested to see whether or not it contains *any* Prohibited Substance on the very large WADA list incorporated in the TADP. The B sample is only tested to confirm (or not) the presence of a Prohibited Substance or substances detected in the A sample. The result, as described by Dr Eichner, is that the A sample is much more likely to be exposed to light during the processing of that A sample to test for the many potential Prohibited Substances, whereas the B sample following removal from the freezer for testing is less likely to be exposed to light. The precise handling will vary from time to time and from one laboratory to another; and how long a sample is out of the refrigerator and exposed to light will sometimes depend simply on how much else is going on in the laboratory at the time.
221. Dr Eichner does not work in the Montreal laboratory but that laboratory and SMRTL do closely similar work and we can be confident that his account of the handling of A and B samples would be broadly applicable there too.
222. Dr Eichner did indicate that quite apart from photoisomerization, there may be slight differences between results on A and B samples because the testing laboratory might not use exactly the same instrument on the B sample as on the A sample. But he regarded photoisomerization as the only logical explanation of the 83% difference in this case. Under cross-examination by Mr Jacobs, he stated clearly that he was not *speculating* that Sample A had been more exposed to light than Sample B. He was firm that it had been.
223. Dr Eichner's opinion, after reviewing all the laboratory data, was that the Montreal laboratory analysis of the urine samples had given an accurate estimation; and that he did not mean, for example, that the actual

concentrations could vary between, say 500 or 5000. He meant that they could vary by smaller margins, such as 500 or 510 or 520. That indicated his level of confidence in the concentration amounts reported.

224. We were not convinced by Professor Alvarez's attacks on the reliability of the Montreal laboratory results. We have already rejected his point based on the MRPL. He also did not accept that the mirror/isomerized Roxadustat would have been undetectable on the Montreal laboratory's standard analysis of the B Sample, but we found his reasons unconvincing.

### **Specific gravity of the Player's 29 August Sample**

225. A separate point raised by Professor Alvarez was that the concentration of Roxadustat in the Player's A and B samples would have been raised by the high specific gravity of her urine, which was [REDACTED] g/ml as compared with a normal range of 1.010 – 1.030g/ml. The morning urine of a normal person has a specific gravity of 1.020g/ml. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

226. Professor Alvarez's opinion was that in accordance with WADA's correction method, the Montreal laboratory estimates ought to have been corrected by Dr Eichner to reflect a specific gravity of 1.020 g/ml, which would result in lower (and even less reliable) estimates of the concentration of Roxadustat in the A and B Samples.

227. Apart from Professor Alvarez's conclusion of the unreliability of the results, Dr Eichner did not dispute any of those points. Eichner (2) gave the figures for the Montreal laboratory estimates if adjusted for specific gravity. The revised estimates would be [REDACTED] ng/ml for Sample A (instead of 0.289ng/ml) and [REDACTED] ng/ml (instead of 0.529ng/ml). There was no subsequent contention from the Player's side that these adjustments had not been done

correctly. Professor Alvarez's point about the specific gravity is completely answered.

### **Effect of Alvarez Control Study on the Concentration Question**

228. While the Alvarez Control Study supports the Player's case on the question whether the Keto MCT was contaminated at all with Roxadustat, it has the opposite effect on her position on the Concentration Question.

229. The tiny level of Roxadustat found in the volunteer's urine samples reinforces Dr Eichner's essential point that on the Player's own evidence of her use of Keto MCT and her own experts' reported test results of Roxadustat in the Keto MCT, the amounts of Roxadustat estimated by the Montreal laboratory in the A and B samples cannot have been caused by her use of Keto MCT. It would follow that there must have been some other source of the Roxadustat in her 29 August Sample.

230. In principle, that last conclusion depends on the reliability of two values: the Roxadustat ingested by the Player and the Roxadustat in her urine. While, on this question, the main focus has been on the second of those values (as fully discussed above), Professor Alvarez has also questioned the reliability of the first.

231. Professor Alvarez observes (correctly) that where there is contamination of a powder such as Keto MCT, the contaminant is unlikely to be evenly distributed within the container. Accordingly, 10g quantities of Keto MCT taken by the Player may have contained higher amounts of Roxadustat than reported as detected in the samples analysed by Professor Alvarez.

232. That is a weak point, which we confidently reject. It is obvious that a contaminant such as Roxadustat will at least to some degree be unevenly distributed in the powder. However, the number of positive tests for Roxadustat reported by Professors Alvarez and Kintz and the extremely low levels of Roxadustat shown in the urine tests of the volunteer make it

extremely unlikely that any significantly higher amounts of Roxadustat were ingested by the Player than those used in Dr Eichner's calculations and scenarios. That is so speculative as to be disregarded altogether.

233. Moreover, Dr Eichner's scenarios and calculations show that, compared with the amounts used in Dr Eichner's calculations and scenarios, it would have taken a very large increase for the Roxadustat reported by the Montreal laboratory to be explicable only by the Player's consumption of contaminated MCT.

### **Conclusion on the Concentration Question**

234. Our firm conclusion is that it is not realistically possible that contamination of the Keto MCT as reported from the Alvarez tests of the Keto MCT and the Alvarez Control Study could have produced the amount of Roxadustat actually present in the Player's A and B Samples collected on 29 August 2022.

235. If Ms Halep did use contaminated Keto MCT as she describes, it could not have been the sole source of the Roxadustat detected by the Montreal laboratory. If we apply the test of comfortable satisfaction to our conclusion on this specific question, we are at least comfortably satisfied.

### **Tribunal's conclusions on contamination of the Keto MCT supplement**

236. Our conclusion is that Ms Halep has proved that on the balance of probability the Keto MCT supplement was contaminated with Roxadustat.

237. However, it follows from our conclusion on the Concentration Question that there was another source of either all or most of the Roxadustat in the Player's 29 August Sample. Accordingly, in order to avoid the default sanction of a 4-year period of Ineligibility Ms Halep must also establish that on the balance of probability her use of Roxadustat from that other source was not intentional (see paragraph 25 above).

**Has the Player established non-intentional use of the Roxadustat from another source (the “Other Roxadustat”)?**

238. It is clear from the TADP and relevant case law, including decisions of the Court of Arbitration for Sport, that in principle a player *could* meet this burden without being able to identify any specific source of the Other Roxadustat found to have been present in her body, but only “*through the narrowest of corridors*”: see *Fiol Villanueva v FINA*, CAS 2016/A/4534. However, this is extremely difficult for the Player to prove if she cannot produce any evidence of what that source might be. This is a matter of common sense and we do not see value in going into fact-specific earlier decisions of the CAS or any other tribunals on this point. The principles are clear, and our task is to apply them to the evidence presented to us in this consolidated case.

239. Ms Halep strongly denies ever having intentionally used Roxadustat. However, although the Tribunal accepts the theoretical possibility that a player could persuade a tribunal that a violation was unintentional without proving source, it is not persuaded that Ms Halep has done so in relation to the Other Roxadustat. Establishing a possible origin of the substance is “*an important, even critical*” first step and a finding of lack of intent should be reached by reference to all the circumstances of the case: see *Fiol Villanueva v FINA*, CAS 2016/A/4534, at paragraph 37. The Tribunal has concluded that although the Keto MCT powder was a source of Roxadustat found in her 29 August 2022 Sample, the amounts she ingested do not explain the concentration of Roxadustat in her urine. Ms Halep has not been able to identify the source of the Other Roxadustat and the Tribunal considers her bare denial of having knowingly consumed Roxadustat insufficient to discharge her burden of proof.

**Tribunal’s conclusion on the Roxadustat Charges**

240. Accordingly, as Ms Halep has failed to establish that her admitted Anti-Doping Rule Violations charged by the ITIA on 31 October 2022 and based on her 29 August Sample were non-intentional, she will be sanctioned for



those intentional ADRVs. We deal with the question of sanctions after setting out our decision and reasons on the ABP Charges.

241. We recognise that our conclusions involve a finding of something which in itself appears highly improbable: that around the same time in 2022, Ms Halep ingested Roxadustat from two entirely separate sources, the Keto MCT and another source never identified. It is common sense and logic that as our earlier decisions have led to such a questionable conclusion, we should ask ourselves whether it is one or other of those earlier conclusions which is flawed. But we have done that. Acting, as we must, on the evidence before us, including particularly the extensive scientific evidence, we are satisfied that it leads us to conclude that (1) on balance of probability the Keto MCT was contaminated with Roxadustat, but also (2) that Ms Halep clearly must have ingested Roxadustat from some other source. We should not, and do not, speculate on how the apparently highly unlikely coincidence of the two separate sources of Roxadustat came about. The evidence just does not tell us. All we can add here is that if we were to discard one or other of conclusions (1) and (2) in order to eliminate that coincidence, it would be conclusion (1). The evidence in support of conclusion (2) is too compellingly strong for that to be the one to give.

## **F. THE ABP CHARGE**

### **Blood doping: The ABP process**

242. The Athlete Biological Passport Programme is complex in the underlying science, mathematics and statistics; and the prescribed procedures are detailed. It is not necessary in this decision to set out the fine details of the ABP process, and no one would thank us if we did. As stated in TADP Article 5.5, the ITIA has established its ABP Programme in accordance with the relevant International Standards, has set up its Athlete Passport Management Unit to manage the ABP Programme on its behalf and has appointed suitably qualified independent experts as the Expert Panel for the ABP Programme. The ITIA also decides which tennis players will be selected

for ABP Testing. Ms Halep, as an elite level player, has been selected and subject to testing since 2013.

243. Further provisions setting out rules and procedures for the ABP Programme are in TADP Article 7, particularly Article 7.6 (Review of Adverse Passport Findings) and in ISRM Annex C.

244. We now summarise the essential elements of the ABP Programme, which we largely draw and adapt (with grateful acknowledgment) from the award in a CAS appeal decision *Wanjiru v World Athletics*, CAS 2020/A/7510, by a CAS panel chaired by Professor Jan Paulsson (and including the Chair of this Tribunal as one of the two other arbitrators). But the actual decision in that CAS case turned on its own facts and has no relevance to Ms Halep's case.

245. Three substances or methods are well-known to be used for blood doping:

- (i) injecting recombinant human erythropoietin ("**rEPO**") to trigger erythropoiesis, the stimulation of red blood cells;
- (ii) infusion of a synthetic oxygen carrier e.g. a blood substitute such as a haemoglobin-based oxygen carrier or a perfluorocarbon to increase haemoglobin ('**HGB**') well above normal levels; and
- (iii) blood transfusion (i.e. infusing a matching donor's or the athlete's own previously extracted red blood cells to increase the oxygen available in the athlete's blood).

246. WADA developed and refined the concept of the ABP, and formally introduced its blood testing programme in 2009, which was subsequently adopted by the ITF and since 1 January 2022, the ABP Programme has been run by the ITIA on behalf of the ITF. The ABP consists of an electronic record that compiles and collates players' blood test results and other data over time. Each player has their own unique ABP.

247. Under the ABP Programme, by a series of tests over a period, the ABP records values in a player's blood samples of parameters known to be sensitive to changes in red blood cell production. The values collected and recorded include HGB concentration and a percentage of immature red blood cells called reticulocytes ("**RET%**").
248. The ratio of the HGB and RET% values is used to calculate a further value, known as the "**OFF-score**", which is sensitive to changes in erythropoiesis. High HGB with low RET% produces a high OFF-score. Low HGB with high RET% produces a low OFF-score. This can be seen in the values for samples 48 and 50 in the table under paragraph 251 below.
249. The marker values from the blood samples collected under the ABP Programme are fed into a statistical model, known as the "**Adaptive Model**". The Adaptive Model uses an algorithm that takes into account both (i) variability of such values within the population generally (i.e. blood values reported in a large population of non-doped players) and (ii) factors affecting the variability of each particular player's individual values (including sex, ethnic origin, age, altitude, type of sport and instrument related-technology).
250. The selected biological markers are monitored over a period of time and a longitudinal profile is created that establishes upper and lower limits within which that player's values would be expected to be found, assuming normal physiology (i.e. that of a healthy and non-doping individual).
251. The Adaptive Model calculates the probability of abnormality of the sequence of values in the ABP profile. At the outset, when the first samples are collected from a particular player, the upper and lower limits are based on population norms at the level of specificity of 99%. But over time, as more blood samples are collected from the same player, the limits become more individualised based on the player's own values. A player therefore becomes their own point of reference.

252. Each time a blood sample is collected and analysed, the Adaptive Model calculates where the reported HGB, RET% and OFF-score values fall within the player's expected distribution and sets a new range of expected results for that player.

253. Where the Adaptive Model flags a sample as abnormal, a process is triggered whereby the ABP is assessed in conformity with the International Standard for Testing and Investigations, the WADA ABP Guidelines, and the ISRM.

**Ms Halep's ABP and blood samples**

254. The ABP Charge has been largely triggered by Ms Halep's blood sample taken on 22 September 2022 (Sample 48 in the table below), although any single blood sample is just one ingredient of a player's ABP and all the player's blood tests are taken into account as her ABP is continuously reviewed.

255. Between August 2013 and 3 March 2023, Ms Halep gave 56 blood samples under the ABP Programme. As noted in the table below, the five shown in red are invalid: Samples 13, 45 and 47 had been declared invalid before the joint Expert Panel's review and Samples 23 and 43 were stated as invalid in JE1 on 12 April 2023. Of the 51 valid samples, particular focus has been placed on samples 44, 46, 48, 50, 51 and 52.

No.	Sample Code	Sample Date	HGB (g/dL)	RET %	OFF-score
1	██████	27 Aug 2013	████	████	████
2	██████	16 Apr 2014	████	████	████
3	██████	23 Jun 2014	████	████	████
4	██████	7 Jul 2014	████	████	████
5	██████	14 Oct 2014	████	████	████
6	██████	19 Jan 2015	████	████	████
7	██████	29 Apr 2015	████	████	████

8	██████	19 May 2015	██	██	██
9	██████	25 May 2015	██	██	██
10	██████	17 Jan 2016	██	██	██
11	██████	11 Apr 2016	██	██	██
12	██████	17 May 2016	██	██	██
13	██████	21 Jun 2016	██	██	██
14	██████	23 Aug 2016	██	██	██
15	██████	28 Aug 2016	██	██	██
16	██████	12 Jan 2017	██	██	██
17	██████	1 Mar 2017	██	██	██
18	██████	26 May 2017	██	██	██
19	██████	24 Jul 2017	██	██	██
20	██████	6 Sep 2017	██	██	██
21	██████	14 Sep 2017	██	██	██
22	██████	26 Feb 2018	██	██	██
23	██████	23 May 2018	██	██	██
24	██████	19 Jun 2018	██	██	██
25	██████	19 Jul 2018	██	██	██
26	██████	26 Aug 2018	██	██	██
27	██████	4 Sep 2018	██	██	██
28	██████	29 Jan 2019	██	██	██
29	██████	25 Feb 2019	██	██	██
30	██████	11 Apr 2019	██	██	██
31	██████	22 May 2019	██	██	██
32	██████	30 Jun 2019	██	██	██
33	██████	29 Jul 2019	██	██	██
34	██████	11 Sep 2019	██	██	██
35	██████	18 Jan 2020	██	██	██
36	██████	11 Feb 2020	██	██	██
37	██████	17 Dec 2020	██	██	██
38	██████	6 Jun 2021	██	██	██
39	██████	21 Jul 2021	██	██	██
40	██████	26 Aug 2021	██	██	██
41	██████	27 Sep 2021	██	██	██
42	██████	13 Dec 2021	██	██	██

43	██████	13 Jan 2022	███	███	███
44	██████	8 Mar 2022	███	███	███
45	██████	21 Mar 2022	███	███	███
46	██████	27 Apr 2022	███	███	███
47	██████	26 Aug 2022	███	███	███
48	██████	22 Sep 2022	███	███	███
49	██████	7 Oct 2022	███	███	███
50	██████	13 Dec 2022	███	███	███
51	██████	23 Dec 2022	███	███	███
52	██████	6 Jan 2023	███	███	███
53	██████	27 Jan 2023	███	███	███
54	██████	14 Feb 2023	███	███	███
55	██████	22 Feb 2023	███	███	███
56	██████	3 Mar 2023	███	███	███

256. The Player does not challenge the accuracy and efficacy of the Adaptive Model or the accuracy of the results of the testing of the 51 valid samples as set out in the table above. Nor does she contend that there were any failures to comply with the requirements of the TADP or the ISRM which invalidate the ABP Charge so that we should dismiss the charge without even examining its merits. Ms Halep's defence is that when all her blood test results are considered together with all the other factual and expert evidence, the Tribunal cannot be comfortably satisfied that Ms Halep has used any Prohibited Substance or Prohibited Method.

### **The ABP process between 22 September 2022 and 19 May 2023**

257. The TADP and ISRM prescribe a process which has to be followed before the testing of a blood sample under the ABP Programme can lead to a charge of an ADRV based on a player's ABP profile.

258. Before we go through some detailed steps in the process, we note a useful explanation by Mr Charles Flint KC when chairing a UK National Anti-Doping Panel Tribunal in *UKAD v Tiernan-Locke*, 15 July 2014:

*“Charges based on abnormalities detected under an ABP programme are fundamentally different from cases based on direct evidence from an adverse analytical finding. An adverse analytical finding is, in general, an objective fact, whereas the conclusions to be drawn from deviations from a longitudinal profile require scientific judgement as to the significance of observed abnormalities. That is why the WADA Operating Guidelines require that each stage following the detection by the model of an atypical value should be the subject of expert review. A single expert reviews the atypical value against the passport to decide whether the abnormality is unlikely to be the result of a normal physiological condition or a pathological condition. A panel of three experts is then required to consider whether it can reach a unanimous opinion that it is highly likely that a prohibited substance or method has been used. The athlete is then asked for his explanation, following which the panel of three experts is required to consider whether it remains of the unanimous opinion, taking into account the explanation from the athlete, that it is highly likely that the athlete used a prohibited substance or method. So proof of an anti-doping contravention in ABP cases depends critically on expert evidence.”*

259. Although the Player’s entire ABP is relevant, we can start this account of the process with her Sample 48 taken on 22 September 2022. The expert, Dr Jakob Mørkeberg, then reviewed Ms Halep’s ABP on 30 September 2022, assessed it as “*suspicious*” and recorded his comments in ADAMS:

*“Profile now consisting of 48 samples of which Sample 13<sup>2</sup>, 45 and 47 have been deemed invalid and hence excluded from the evaluation. Sample 46 has an elevated %ret and a Hb in the lower range for the athlete. The sample is collected in the morning, raising further suspicion to this sample, since usually the Hb tends to be high in the morning. The last sample (no. 48) indicates an elevated Hbmass and erythropoietic suppression reflected in the elevated Hb, low %ret and low IRF [Immature Reticulocytes Fraction]. I*

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<sup>2</sup> The document *Initial expert and APMU evaluation ABP* in evidence at B.5.30 of the hearing bundle, setting out texts of expert evaluations from 2014 to 2023 including this text of Dr Mørkeberg’s 13 December 2022 comments, refers here to sample 33 but that has always been a valid sample. So this is likely to be a misprint for sample 13 (whether originating from Dr Mørkeberg or in that document).

*would recommend targeting this athlete with two more tests ? one asap and the next ten days after.”*

260. On 7 October 2022, Sample 49 was collected from the Player. It was analysed and the results logged in ADAMS. The Adaptive Model did not automatically flag the sample as abnormal.

261. On 13 December 2022, Sample 50 was collected from the Player. It was analysed and the results logged in ADAMS. Based on an atypical OFF-score sequence, on 14 December 2022 the Adaptive Model automatically flagged an Atypical Passport Finding (i.e. as having a less than one in a hundred chance that it was the result of normal physiological variation). That triggered a single expert review and on 16 December 2022, the single expert, Dr Mørkeberg, reviewed the Player’s passport, assessed it as *“Likely doping”*, and recorded his comments in ADAMS:

*“Profile consisting of 50 samples of which Sample [13<sup>3</sup>], 45 and 47 have been deemed invalid and hence excluded from the evaluation. The last four valid samples show great variability in Hb and %ret. Samples 46, 49 and 50 all have Hb values in the lower range with %ret in the higher range for the athlete. In contrast, Sample 48 has a high OFF-score both driven by an elevated Hb and a low %ret indicating a supra-physiological Hbmass. Also the IRF is low. Sample 48 and 49 are divided by only 15 days and show completely different blood pictures.”*

262. On 16 December 2022, the APMU recorded Dr Mørkeberg’s comments in ADAMS and added: *‘Based on the Likely doping recommendation from the first expert, the passport will now be sent for review to two additional experts’*.

263. On 18 December 2022, a second expert Professor Giuseppe d’Onofrio reviewed the ABP and assessed it as *“Suspicious”*, and recorded his comments in ADAMS:

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<sup>3</sup> As footnote 1.



*“The passport comprises 47/50 valid samples collected from 2013 until 13-12-2022. The ABP status is atypical due to a low OFF score in the last sample and a statistically abnormal OFF sequence. The HB and reticulocyte profiles recently displayed a moderate variability increase, with a low outlier at ██████g/dL on 12/12/2021 for HB and two results above ████% (unseen before) for reticulocytes, with some high IRF. This change can depend on the absence of INC tests in the second part of the profile. The low OFF score outlier in sample 50 (similar to sample 46) reflects the combination of relatively low HB and increased reticulocytes. There is no evident blood doping scenario, and the use of AAS [Anabolic-Androgenic Steroids] could hypothetically contribute to the blood changes.”*

264. On 20 December 2022, a third expert Dr Laura Garvican-Lewis reviewed the passport, assessed it as “Suspicious” and recorded her comments in ADAMS:

*“Profile of female tennis player, 50 samples with two invalid, since 2013. ABP status is atypical for low offscore, arising from increased rets up to the upper limit and low Hb. In the last three samples there has been a large drop in Hb and concomitant increase in rets. Red cell indices are normal and do not indicate anaemia. A similar picture of the last two samples is seen in sample 46 in April, thus the increased Hb in sample 48 is the anomaly. No confounding factors declared and all samples collected in the morning. Recommend **[ESA analysis (for Erythropoietic Stimulating Agents)]** if possible on sample 46 and 50. In addition, I recommend another sample within one month, plus ESA analysis. Finally, the competition schedule would be useful to put context around sample 48.”*

265. On 23 December 2022, sample 51 and on 6 January 2023 sample 52 were taken. Following each, the Adaptive Model automatically flagged an Atypical Passport Finding.

266. On 12 January 2023, the three joint experts Professor d’Onofrio, Dr Garvican-Lewis and Dr Mørkeberg held a telephone conference to discuss the Player’s ABP. In accordance with the prescribed procedure, they had not

previously been informed of the Player's identity but on 22 December 2022, they had been provided with Ms Halep's competition schedule since 9 March 2022:

<b>Event</b>	<b>Dates</b>	<b>Location</b>	<b>Finish</b>
BNP Paribas Open	9 March – 20 March	Indian Wells, CA, USA	Adv to Semi-Finals
Mutua Madrid Open	28 Apr – 7 May	Madrid, Spain	Adv to Quarterfinals
Internazionali BNL D'Italia	9 May – 15 May	Rome, Italy	Adv to Round of 32
Roland Garros	22 May – 5 June	Paris, France	Adv to Round of 64
Rothesay Classic Birmingham	13 June – 19 June	Birmingham, GB	Adv to Semi-Finals
BAD Homburg Open	19 June – 25 June	Bad Homburg, Germany	Adv to Semi-Finals
Wimbledon	27 June – 10 July	Wimbledon, GB	Adv to Semi-Finals
CITI Open	1 Aug – 7 Aug	Washington DC, USA	Adv to Round of 16
National Bank Open	8 Aug – 14 Aug	Toronto, Canada	Won in Finals
Western & Southern Open	15 Aug – 21 Aug	Cincinnati, USA	Withdrew before second-round
US Open	29 Aug – 11 Sept	New York, USA	Lost in first-round

267. On 12 January 2023, the Expert Panel were also informed for the first time of the AAF on the Player's 29 August Sample. That is expressly allowed by Article 8.3.2 of the WADAABP Operating Guidelines, although not obligatory. They were also told the type of the Player's dosages of Roxadustat. They also easily knew it was Ms Halep, because her positive test for Roxadustat had been highly publicised, although Prof d'Onofrio was adamant (and we accept) that the Joint Experts were not influenced by that at all. Each of the three Joint Experts was expressly asked at the June hearing if their opinion had placed any weight on the AAF and each told us it did not. We accept that their professionalism enabled them to disregard that point, and that they did.

268. On 13 January 2023, Dr Mørkeberg reviewed the ABP, assessed it as "*Likely doping*" and recorded his comments in ADAMS:

*"Profile consisting of 52 samples of which Sample [13<sup>4</sup>], 45 and 47 have been deemed invalid and hence excluded from the evaluation. The competition schedule from 2021 and 2022 was provided. In all valid samples (2, 19, 23 and 48) with high Hb for the athlete, there is indication of erythropoietic suppression either through lowered %ret or IRF values indicating an increased Hbmass. Sample 48 is collected 25 days after the beginning of the US Open and shows a completely different blood picture than previous and subsequent samples that year. Sample 48 has an elevated Hb value in tandem with a low %ret and IRF. Sample 48 and 49 are divided by only 15 days and Sample 49 show completely different blood picture than in Sample 48. In Sample 49 the the [sic] Hb is much lower and %ret and IRF higher. Samples from 2022 collected before Sample 48 e.g. Sample 43, 44 and 46 indicate an erythropoietic stimulation either evidenced by an elevated %ret, IRF or both and with a shift towards larger red cells (increased MCV), which indicate a shift towards a population of younger red blood cells."*

269. On 14 January 2023, Dr Garvican-Lewis reviewed the ABP, assessed it as "*Likely doping*" and recorded her comments in ADAMS:

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<sup>4</sup> As footnote 1.

*“Two new samples have been added and the competition schedule has been provided. Profile of female tennis player, 52 samples with two invalid, since 2013. ABP status is atypical for offscore sequence. In the last five samples there has been a large drop in Hb and concomitant increase in rets. Red cell indices are normal and do not indicate anaemia. A similar picture of the last two samples is seen in sample 46 in April, thus the increased Hb in sample 48, with a clear down regulation of rets is the anomaly. No confounding factors declared and all samples collected in the morning. When compared to the competition schedule, sample 48 was collected shortly after a major competition (US Open). Thus, the doping scenario is apparent of blood manipulation around competition.”*

270. On 29 January 2023 Professor d’Onofrio reviewed the ABP, assessed it as “Likely doping” and recorded his comments in ADAMS:

*“The passport now comprises 48/51 valid samples. The ABP status is atypical. The last sample collected on 6-1-2023 confirms the values of HB, reticulocytes and OFF score observed in the preceding three samples taken out of competition. On such basis, the results observed in sample 48, collected on 23-9-2022, are abnormal and indicate an anomalous condition, for the athlete, of erythropoietic suppression with increased HB and OFFs, with relatively low reticulocytes and IRF, highly likely related to a previous exogenous stimulation.”*

271. In the meantime, Sample 53 had been taken on 27 January 2023. It was analysed and the results logged in ADAMS, but the Adaptive Model did not flag an Atypical Passport Finding.

272. During February 2023, each of the three experts, d’Onofrio, Garvican-Lewis and Mørkeberg reviewed the ABP, taking sample 53 into account, and recorded their comments in ADAMS:

- (i) On 2 February 2023, Dr Mørkeberg assessed the ABP as “Likely doping” and recorded:

*“Profile consisting of 53 samples of which Sample [13<sup>5</sup>], 45 and 47 have been deemed invalid and hence excluded from the evaluation. The competition schedule from 2021 and 2022 was provided as well as the Lab Doc Pack for Sample 48. In all valid samples (2, 19, 23 and 48) with high Hb for the athlete, there is indication of erythropoietic suppression either through lowered %ret or IRF values indicating an increased Hbmass. Sample 48 is collected 25 days after the beginning of the US Open and shows a completely different blood picture than previous and subsequent samples that year. Sample 48 has an elevated Hb value in tandem with a low %ret and IRF. Sample 48 and 49 are divided by only 15 days and Sample 49 show completely different blood picture than in Sample 48. In Sample 49 the the [sic] Hb is much lower and %ret and IRF higher. The same is true for the following 4 samples (no. 50-53). Samples from 2022 collected before Sample 48 e.g. Sample 43, 44 and 46 indicate an erythropoietic stimulation either evidenced by an elevated %ret, IRF or both and with a shift towards larger red cells (increased MCV), which indicate a shift towards a population of younger red blood cells.”*

- ii) On 4 February 2023 Professor d’Onofrio also assessed the ABP as “Likely doping” and recorded:

*“Sample 53 was collected on 27-1-2023. The ABP status is atypical (abnormal OFFs sequence). The blood markers do not display any substantial variation. I confirm my previous opinion.”* (His previous opinion had been on 29 January 2023, as above.)

- (iii) On 23 February 2023 Dr Garvican-Lewis assessed the ABP as “Likely doping” and recorded:

*“Two new samples have been added and the competition schedule has been provided. Profile of female tennis player, 52 samples with two invalid, since*

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<sup>5</sup> As footnote 1.

2013. ABP status is atypical for offscore sequence. In the last five samples there has been a large drop in Hb and concomitant increase in rets. Red cell indices are normal and do not indicate anaemia. A similar picture of the last two samples is seen in sample 46 in April, thus the increased Hb in sample 48, with a clear down regulation of rets is the anomaly. No confounding factors declared and all samples collected in the morning. When compared to the competition schedule, sample 48 was collected shortly after a major competition (US Open). Thus, the doping scenario is apparent of blood manipulation around competition. Update: Profile now contains 54 samples. Hb has recovered and rets are stable. The new values do not explain the abnormalities around sample 48, therefore my opinion remains the same.” (Her previous opinion had been on 14 January 2023 as above.)

273. As required by ISRM article C.4.1., because the three experts had each given an opinion of likely doping, on 24 February 2023 the APMU declared a “*Unanimous likely doping*” evaluation on ADAMS and proceeded to compile the ABP Documentation Package, which was then sent to the three experts for them to review and provide a joint expert report signed by all three of them.

274. On 12 April 2023 the Expert Panel issued its first joint expert opinion (“**JE1**”), which concluded:

*“It is our unanimous opinion that in the absence of an appropriate physiological explanation, the likelihood of observing the described abnormalities assuming blood manipulation, namely the artificial increase of red cell mass using, for example, erythropoiesis stimulating agents, is high. On the contrary, the likelihood of environmental factors or a medical condition causing the described pattern is low. We therefore conclude that it is highly likely that a prohibited substance has been used and that it is unlikely that the passport is the result of any other cause.”*

275. On 12 April 2023 the APMU declared an Adverse Passport Finding (“**APF**”) in ADAMS, as required by ISRM article C 5.1 in the light of the three experts having confirmed their unanimous opinion of “*likely doping*”.

276. On 13 April 2023, in accordance with ISRM article C 5.2, the ITIA notified the Player of the APF, provided her with the ABP Documentation Package and JE1, inviting her to provide her own explanation of the data provided.
277. Although there is no restriction on the content of any explanation by a player under ISRM C 5.2, in practical terms (linked to the wording of JE1) this step was Ms Halep's first opportunity to provide "*an appropriate physiological explanation*" or to bring up "*environmental factors or a medical condition*" causing the described pattern of her ABP. Such matters, and any other matters which would support an innocent explanation of the ABP, would all fall under "*confounding factors*"- a label used in the joint experts' written reports and during the June hearing. Although this Tribunal rigorously holds in mind that the burden of proof on the ABP Charge always remains on the ITIA to the standard of comfortable satisfaction, a player who does not offer any cogent explanation is at serious risk of being held guilty as charged.
278. On 27 April 2023, the Player responded to the Notice and provided her explanation for the ABP data (in which she also denied blood manipulation of any kind). It was accompanied by an expert report of Mr Paul Scott, dated 27 April 2023 (Scott (1)) and a joint expert report of Professor Alvarez and Professor Antoine Coquerel, dated 26 April 2023 (Alvarez (5))
279. The ITIA forwarded the Player's explanation (with its supporting material) to the APMU, who sent it to the Expert Panel for consideration as required by TADP Article 7.13.1.1 and ISRM article C.6.1.
280. We do not summarise the contents of that initial explanation at this point. The Player's contentions will all be considered when we come to examine the merits of the ABP Charge in detail.
281. On 19 May 2023, the ITIA received from the APMU, the Expert Panel's opinion of that date (JE2), which maintained their unanimous opinion, expressed in their conclusion:

*“Based on our evaluation of the explanations presented by the athlete, we confirm it is highly likely that a prohibited substance has been used and that it is unlikely that the passport is the result of any other cause.”*

282. We note that this conclusion referred only to a Prohibited Substance and not to a Prohibited Method (but see paragraph 333 below).
283. In accordance with ISRM Annex C, Article C.6.2, once the Expert Panel had confirmed their opinion of *“likely doping”*, then the APMU was required promptly to update their recommendation in ADAMS as *“APF confirmed”* and inform the ITIA (as the *“Passport Custodian”*). The ITIA was then bound by TADP Article 7.13.1.3 and ISRM Article to charge the Player in accordance with TADP Article 7.13.2, which it did by the ABP Charge Letter on the same day, 19 May 2023.
284. By way of the ABP Charge Letter, the ITIA also impose a mandatory Provisional Suspension on the Player, in accordance with TADP Article 7.12.1, effective immediately. That Provisional Suspension ran alongside the continuing Provisional Suspension already in force since 7 October 2022.
285. The parties’ written submissions then followed according to the timetable in paragraph 80 above: ITIA Opening Brief (8 June 2023), Player’s Answering Brief (15 June) and ITIA Reply Brief (24 June).
286. On 23 June 2023, after considering the Player’s 15 June Answering Brief, the Expert Panel gave a third joint opinion (JE3), again expressing a unanimous conclusion:

*“We maintain our previous conclusion that it is highly likely that the hematological abnormalities in the passport are the result of use of a prohibited substance. However, having considered the further expert evidence provided and the further explanations of the Player, we consider that use of a prohibited method (such as a blood transfusion) is also a*



*plausible scenario. Therefore, we confirm that it is highly likely that the hematological abnormalities in the passport are the result of illicit blood manipulation (use of a prohibited substance or prohibited method) and that the passport is unlikely to be the result of any other cause.”*

287. The Tribunal notes their addition of a Prohibited Method as a plausible scenario. We also note that whereas the conclusion in the last sentence states as “*highly likely*” that the passport abnormalities were the result of illicit blood manipulation, it says only that it is “*unlikely*” that the passport is the result of any other cause. However, we attach no significance to that change of expression omitting the word “*highly*”, as it is clearly implicit in the first limb of that conclusion that they considered any other cause as “*highly unlikely*”.

### **The ABP Charge and Ms Halep’s defence**

288. The Player’s explanation in her 27 April 2023 response was developed in her ABP Answer Brief dated 15 June 2023.

289. The Player’s counsel, Mr Jacobs, has made clear throughout that the Player accepts that the ABP Programme, with its Adaptive Model, is a valid and effective tool for identifying blood doping. The main thrust of her defence is that:

- a) Her ABP profile was always within a normal range and should never have been flagged by the Adaptive Model as an Atypical Passport Finding, which then led to the ABP Charge against her.
- b) There were three particular sets of circumstances (“**Three Confounding Factors**”) which explained the values in her blood samples and showed that her ABP had not been caused by any form of blood doping: (a) blood loss during ██████ surgery; (b) ██████ ██████; and (c) periods of detraining (all considered below).

290. We consider those arguments before examining a number of further points raised by the Player.

The Player's ABP profile was always within a normal range

291. The Player's contention is that although she accepts the accuracy of the measurements, the results of all her blood tests under the ABP Programme are within a normal range and do not justify any allegation or even suspicion of blood doping. The main basis for this contention comes from Professor Alvarez, also supported by Professor Coquerel (as the joint author of their 26 April 2023 report).

292. Professor Alvarez's position was first indicated in Alvarez (4), where he commented on the Player's ABP data. He first made the point, by specific reference to the HGB value of ██████g/dL for Sample 48, that there was never a single value taken as normal for a biological parameter; there would always be a range. However, although he is right on that point, we do not understand anyone else involved in this case to disagree. The Adaptive Model calculates whether the combination of values from a player's blood tests is outside an acceptable range in the sense of a range which raises no suspicion of doping requiring further investigation.

293. That leads on to a further point made by Alvarez in the same report, that according to the findings of a study by the *Haute Autorité de Santé* (Ministry of Health) in France, the value of ██████g/dL for HGB was within a normal range of 11.9 to 15.6g/dL for women aged 25 to 35 (Ms Halep was born on 27 September 1991). That finding can obviously be taken as accurate but it misses an essential point of the ABP, which is that the Player's blood values are not measured against the general run of women of her age, but against a range of values established by her own blood tests. It is when a blood sample is abnormal by reference to a player's own ABP profile that it may be flagged as abnormal and then may be judged by the designated experts as suspicious or as likely doping.

294. A third point made by Professor Alvarez in that report was that even by reference to Ms Halep's own ABP, stemming from her first ABP test in 2013, Ms Halep has always remained within her own upper and lower limits for

HGB and RET%. We can deal with this point quite briefly, although it was thoroughly explored in evidence. The simple fact, which was absolutely clear from the evidence before us, is that the Adaptive Model may legitimately flag a player's blood sample as abnormal even though all the values are within the player's own limits . The Expert Panel illustrated this by reference to anonymised examples of other athlete's ABP profiles. It is the overall combination of values derived from a blood test and all the information about that particular player recorded on ADAMS (such as age, sex, altitude of normal location and all her previous ABP blood test results) which go into the Adaptive Model calculation. While it is far more often values outside the player's own upper and lower limits which will trigger an Atypical Passport Finding by the Adaptive Model, the calculation is not so limited.

295. That is explicitly reflected in the ISRM, Annex C, Article C.2.1.2:

*“An Atypical Passport Finding is a result generated by the Adaptive Model in ADAMS which identifies either:*

- a) a primary Marker(s) value(s) as being outside the Athlete's intra-individual range, or,*
- b) a longitudinal profile consisting of (up to) the last five (5) valid primary Marker values as deviating from expected ranges (sequence Atypical Passport Findings), assuming a normal physiological condition.”*

Where there is a sequence Atypical Passport Finding in accordance with paragraph (b), that is in circumstances where the player's recent blood samples have not shown values outside their individual parameters. In such a case – where Alvarez would regard all those values as normal – Article C.2.1.2 expressly requires “*further attention and review*” of the APF in exactly the same way as in the case of a paragraph (a) APF based on values outside the athlete/player's intra-individual range. This was exactly what happened when the Adaptive Model flagged Ms Halep's ABP as atypical and each of the three experts then reviewed her ABP and assessed it as “*likely doping*”.

296. The ITIA gains support from the decision on an appeal to CAS: *Ivanov v RUSADA*, CAS 2019/A/6254, where the sole arbitrator rejected the argument that there were no abnormalities because there had been no breach of the upper or lower limits of the athlete's individual parameters. Although not binding on this Tribunal, that decision has persuasive authority and accords with our own analysis.
297. It is clear that the Adaptive Model may produce an Atypical Passport Finding without any breach of those upper or lower limits.
298. Alvarez (4) also referred to the results of a blood sample given by Ms Halep privately in Romania on 9 September 2022, which showed values of HGB [REDACTED] g/dL and RET% [REDACTED]. The Expert Panel and Dr Eichner expressed a firm view that results of such private tests should be disregarded, for the reasons given in JE2: *"There are no quality control data related to the private test data nor any information about pre-analytical factors provided for us to examine the quality of the provided test results. Furthermore, private tests have to be considered unreliable simply due to the uncertainty of the analytical and pre-analytical conditions, the possibility of the athlete selecting specific test results in favor or [sic] his case, the lack of evidence of identification of the athlete and the possibility for the athlete to manipulate and adjust the test outcome due to the fact that the test is not collected unannounced as is the case in the ABP."* Whatever the position might be under the ABP Programme rules and procedures, this Tribunal cannot dismiss those test results on any technical ground, as they are there in evidence. But for just the reasons set out in JE2, they are too unreliable to be given any significant weight.
299. Alvarez (4) was written before the ABP Charge and before the Expert Panel had even produced JE1, so was specifically directed to the Roxadustat Charges. Nevertheless, although his points, which we have considered above, were carried through into his later reports, in reaching our decisions on those points, we have taken full account of those later reports and all the evidence at the June hearing.

300. The Coquerel/Alvarez report expressed the same conclusion that all the parameters shown by the Player's ABP Samples 1 to 53 were normal. Again, we find that conclusion unconvincing. Their reliance on that same *Haute Autorité de Santé* study has the essential flaw we have already identified. They also relied on the results of the 9 September 2022 private test, which is a clear weakness in their analysis for the reasons we have given in paragraph 298 above. They commented that Ms Halep's Sample 23 (on 23 May 2018) had already reached HGB ██████g/dL and Sample 19 (on 24 July 2017) showed HGB ██████g/dL without raising any suspicion. But leaving aside that Sample 23 had been declared invalid by JE1 on 12 April 2023 (and Coquerel/Alvarez also referred to Sample 43, which had been declared invalid by JE1), that approach disregards a basic element of the ABP Programme: it is a moving picture where each successive test result refines the information and whether or not a player's upper and lower limits are breached is clearly relevant but not determinative of whether the up-to-date ABP is abnormal. Moreover, as they recognise themselves by referring to Ms Halep's ██████ surgery, ██████ and detraining, the bare numbers need to be evaluated taking into account confounding factors affecting the particular player (which must happen before bringing any charge of an ADRV).

301. The Coquerel/Alvarez report includes this comment:

*"We choose to analyze these results without the sophisticated equations of ABPS (what are the true coefficient and the different selected primary parameters?) or Off-score (which equation is perhaps statistically efficient but not physiologically validated **especially for high level athletes during training or competitions**)"*

That comment reinforces what we see as the overall weakness of their report, that physiological validation is an essential part of the process leading to an ADRV charge based on the ABP.

302. Professor Alvarez's 15 June 2023 report responded to Eichner (3) on the ABP issue. We do not see any value in our giving an elaborate account of the propositions and counter-propositions from all the numerous expert reports. Again, we see significant weaknesses in Alvarez (6). Alvarez says that because Ms Halep's upper and lower limits are not exceeded, there is no anomaly. That is a point we have already rejected (see paragraph 297 above). He then writes:

*"I find it astonishing that samples are designated as abnormal after months when they were initially considered normal. This shows just how unreliable this biological passport is, because people want to make it more sensitive than the biological analysis allows. The important thing is to stay within the upper and lower limits that have been refined over time for an athlete, and not to try to interpret the results of variations that are simply physiological variations."*

That very last comment once again misses the point of the ABP. The whole purpose of the ABP expert examination of the results is to assess whether or not the abnormalities are simply due to physiological variations. Because it is a decision for this Tribunal whether or not there has been an ADRV, we shall come to consider the reliability of the joint Expert Panel's assessment in Ms Halep's case. But we reject those views in Alvarez (6).

303. Professor Alvarez's argument that all Ms Halep's ABP values were normal was clearly intended by the Player as a knock-out blow to the ITIA case on the ABP Charge. Our firm rejection of that argument still requires us to examine all the relevant evidence, including the joint Expert Panel's opinion, to see whether or not we are comfortably satisfied that the ABP Charge is proven. But it does mean that we find no flaw in the process under which the ABP Charge has been brought. The APF was a legitimate result of the application of the Adaptive Model. The single expert's and then, in the light of his conclusions, the joint Expert Panel's review followed as a required step; and in the light of the joint Expert Panel's unanimous opinion, the ITIA had no choice but to bring the ABP Charge.

### Three Confounding Factors

304. We now examine the three Confounding Factors which the Player relies on as sufficiently affecting her ABP blood samples as to remove any serious possibility that her ABP values have been caused by blood doping; or at the very least (and this would be enough for a successful defence to the ABP Charge) to prevent this Tribunal being comfortably satisfied that Ms Halep is guilty of blood doping.

#### (a) Blood loss during [REDACTED] surgery

305. Ms Halep had planned [REDACTED] surgery in [REDACTED] on [REDACTED]. It was not major surgery but was done under general anaesthetic. [REDACTED] [REDACTED], which is consistent with her signed 22 September 2022 DCF where she answered “No” to the question whether she had lost blood during the previous 3 months.

306. All the experts agree that blood loss would cause a decrease in HGB, which is not what was shown by Sample 48 taken 11 days after the surgery. There is no need to go into any more detail on this first confounding factor, as the factual and expert evidence together come nowhere near showing that bleeding during Ms Halep’s [REDACTED] surgery could have had any significant impact on the values in Sample 48 or otherwise on her ABP.

#### (b) [REDACTED] [REDACTED]

307. [REDACTED]  
[REDACTED]

(1) [REDACTED]  
[REDACTED]

(2) [REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED]

(3) [Redacted]  
[Redacted]

308. [Redacted]  
[Redacted]

309. [Redacted]  
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313. The Tribunal conclude that [REDACTED] had no significant effect on Ms Halep's ABP and can be disregarded for our decision.

**(c) Detraining**

314. Ms Halep's evidence was that after losing at the US Open on 29 August 2022, she decided to go ahead with her [REDACTED] surgery and suspended training and other physical exercise up to 7 November 2022. We accept that particular evidence.

315. Her 27 April 2023 response referred to a conclusion of Mr Scott in Scott (1) that this period of detraining was inconsistent with her Sample 48 hematological parameters relative to what were described as still highly variable normal parameters during her normally rigorous training.

316. Scott (1) did not include supporting documentation for that conclusion, but he returned to the question in Scott (2). In Scott (2) he stated that detraining had a significant effect on plasma volume and thus on haemoglobin concentration. That was in response to the discussion of detraining in JE2, which included, at pg.3:

*“Biological variation, as well as seasonal variation, of basic hematological parameters, such as Hb and reticulocytes, is usually very small (Coskun et al. 2018, Borel et al. 1991) - less than 3% for Hb, less than 15% for reticulocytes). Such small intraindividual variability is one of the main reasons, together with analytical precision and accuracy, that Hb and %ret have been selected as key markers for the hematological module of the Athlete Blood Passport. Therefore, it is unlikely that a period of decreased physical activity will result in such a pronounced increase in Hb and decrease in %ret (Astolfi et al. 2021) resulting in such an elevated OFFscore. Of particular note, is that %ret is independent of the plasma volume shifts that might occur during periods of increased or decreased training activities. Hence, detraining will not acutely affect the %ret value. Furthermore, the Hb, %ret and OFFscore values in Sample 48 are markedly different from the*

*values observed in Sample 49 collected only 16 days later under the same 'detraining' conditions.*

*On the other hand, the use of an ESA has been shown to result in an elevated OFFscore several weeks after cessation of administration (Haile et al. 2019)."*

That reference to a "pronounced increase" was specifically to Sample 48.

317. In Scott (2), Mr Scott stated that the typical professional athlete's haematological parameters were far more variable than suggested in JE2. He observed that the subjects of the two papers they cited (Coskun 2018 and Borel 1991) were not elite athletes. He then cited a paper (Astolfi 2021, also cited in JE2) which had examined seasonal variation and training load variation of haematological parameters of elite cyclists. In the Astolfi study, not a single athlete had a variation of HGB or RET% within the limited ranges suggested in JE2.

318. Mr Scott relied on Ms Halep's ABP as itself supporting his contention of much greater variability. It is certainly correct that the variations of Ms Halep's HGB concentration and her RET% are frequently much greater than the 3% and 15% from the Coskun and Borel studies. He also cited papers, including a 2020 paper of Dr Garvican-Lewis, recognising the effects of training, athletic performance and detraining on plasma volume and therefore on HGB concentration.

319. Mr Scott stated that about four weeks after training stopped, there would be on average a 12% loss of plasma volume, which would roughly translate to a 6-7% increase in HGB concentration. That would account for more than half the difference between the [REDACTED] HGB g/DL for sample 46 on 27 April 2022 and the [REDACTED] HGB g/DL for sample 48 on 22 September 2022 (which was an increase of [REDACTED]%). The balance he put down to normal biological variation.

320. Scott (2) then commented on JE2's reference to suppression of RET% in Sample 48 and made the further point that there was only a █% change between the RET% in sample 48 and the RET% in Sample 49, which was well within the range seen in elite athletes (as in the Astolfi 2021 study). We note that, as pressed by Mr Liddell when cross-examining Mr Scott, that █% is the percentage decrease from Sample 49 back to Sample 48, and the same comparison may equally be expressed as a █% increase from Sample 48 to Sample 49. Both figures are obviously correct, but whether the change is expressed as █% or █%, JE3 correctly observes that the RET% in Sample 48 is low and unexplained.
321. The Expert Panel agreed that HGB concentration might be affected by shifts in plasma volume but noted that the studies cited by Mr Scott particularly related to sudden and drastic changes in training load following strenuous exercise. The Expert Panel referred to recent studies, one by Dr Garvican-Lewis and others [2020] following a multi-day cycle race and another where Dr Eichner was a co-author with Dr Miller and others [2019] following an ironman triathlon. Each addressed consequent plasma volume fluctuations and showed that changes in plasma volume were apparent in the days following the change in training status, not several weeks later. This was relevant because Ms Halep's Sample 48 had been collected over three weeks after she had ceased exercise.
322. In rejecting Mr Scott's view that detraining would have accounted for █ in █ in HGB concentration between Samples 46 and 48, the Expert Panel placed significance on the comparison between the HGB concentrations in Samples 48 and 49. Sample 49 had been taken 15 days after Sample 48 but showed █ HGB g/dL as compared with █ HGB g/dL in Sample 49.
323. The joint Expert Panel's opinion was that if plasma volume shifts due to detraining had been responsible for the increased HGB concentration in Sample 48, one would have expected a similar picture in Sample 49 and not the very different picture seen. That is a telling point and does strongly

support the Expert Panel's view that Ms Halep's detraining after 29 September 2022 was not a significant confounding factor in explaining the haemoglobin value in Sample 48.

324. Also telling is that detraining does not affect the RET% value, so provides no explanation for the low RET% value of [REDACTED] in Sample 48. That was a point on which Mr Scott did not offer any explanation.

325. The Tribunal concludes that detraining is not a confounding factor which significantly affected the values in the Player's ABP blood samples.

### **Comfortable satisfaction for the ABP decision of this Independent Tribunal**

326. However firm the opinion of the Expert Panel, their view is not to be rubber-stamped by this Independent Tribunal. The question is whether on all the evidence, including the joint Expert Panel's opinions, we are comfortably satisfied that Ms Halep is guilty of the blood doping ADRV alleged by the ABP Charge Letter.

327. The test of comfortable satisfaction has been applied for many years by CAS and other sports disciplinary tribunals. All three members of this Tribunal are experienced in applying that standard of proof and well understand where it lies above mere balance of probability but below proof beyond reasonable doubt.

328. On the test of comfortable satisfaction, there is a slight disagreement between the parties in this case. The Player's counsel cited *USADA v Montgomery*, CAS 2004/O/645, paragraph 36, where it was said that the standard of comfortable satisfaction required that the prosecuting body "bears the burden of proving, by strong evidence commensurate with the serious claims it makes, that the [Respondent] committed the doping offences in question". The ITIA submit that this comment was emphatically rejected by the CAS panel in *WADA v Bellchambers*, CAS 2015/A/4059, at paragraph 105, although from our reading of what the *Bellchambers* panel

were saying, it is only the word “*strong*” that they disapproved if intended as a general statement beyond the specific facts of the *Montgomery* case. What the *Bellchambers* panel did expressly say was that inherent in the immutable standard of comfortable satisfaction was “*a requirement that the more serious the allegation, the more cogent the supporting evidence must be in order for the allegation to be found proven.*”

329. We apply the direction in TADP Article 3.1.1 that the standard of proof is “*the comfortable satisfaction of the hearing panel, bearing in mind the seriousness of the allegation that is made.*” If the word “*strong*” is taken out of the citation from *Montgomery*, the statements mentioned in our previous paragraph are entirely consistent with TADP Article 3.1.1 anyway. In deciding whether the case is proven to our comfortable satisfaction, we simply weigh all the relevant evidence, applying common sense and drawing whatever inferences we judge right. Embellishment of that clear approach can quickly become an exercise involving angels dancing on the head of a pin.

330. In *Ivanov v RUSADA*, CAS 2019/A/6254, the joint Expert Panel’s opinion was that from the athlete’s ABP it was “*highly likely*” that he had used a Prohibited Substance or a Prohibited Method and that any alternative explanation was “*highly unlikely*”. On the evidence before her, the sole arbitrator (at paragraph 145) accepted that conclusion, which she then said established the ADRV to the requisite standard of comfortable satisfaction. In other words, she equated the experts’ expressed level of “*highly likely*” with the standard of “*comfortable satisfaction*”. Although this Tribunal is not bound by her views, we agree with her on that point.

331. In the present case, the joint Expert Panel’s unanimous conclusion in JE3 was that illicit blood manipulation was “*highly likely*”. The question for us to decide is whether or not that conclusion is justified on all the evidence, by which we mean all the evidence before this Tribunal whether or not it was in the hands of the Expert Panel when they gave their written opinions.

332. Always remembering that the overall burden of proof is on the ITIA, the Player needs to persuade us that the Expert Panel's conclusion is wrong or, which would be enough for us to dismiss the ABP Charge, that there is sufficient doubt about their conclusions that we cannot be comfortably satisfied that they are right.
333. We have already explained our rejection of the Player's contention (a contention supported particularly by Professor Alvarez) that the joint Expert Panel's opinion is invalidated because all the values in her ABP were normal. Further, we have set out above our reasons for rejecting her [REDACTED] surgery, [REDACTED] and detraining as explanations of the values in her ABP blood samples.
334. The Player's 15 June 2023 written ABP Answer Brief (headed "Pre-hearing brief" so here called the "**ABP PHB**") included a section dealing with what she described as the changing and inconsistent ITIA case:

*"The ITIA claims in its 8 June 2023 Pre-Hearing Brief that "This is a clear case of deliberate blood doping in tennis". See ITIA Opening Brief, par. 1.1 If that that were true, then the ITIA would be able to clearly and consistently explain both what samples it claims are evidence of blood doping and would be able to clearly and consistently provide a plausible "blood doping scenario"."*

We accept that the ITIA clearly does have to give that explanation and also has to provide a plausible blood doping scenario; and we fully consider both those issues, taking all relevant points into account. But we put aside the Player's complaint that the ITIA has changed its stance and has abandoned earlier assertions so that it can better "*sell its story*" (as her ABP PHB puts it) to the Tribunal. It is punchy advocacy but does not offer anything of substance. The question will be whether the current evidence taken as a whole, supports the up-to-date case put by the ITIA. Changes or abandonment of previous positions are only relevant where they have a bearing on the reliability of current evidence. It is an integral aspect of the

ABP Programme that the Expert Panel jointly develops and may change or modify their views as they review additional material. Moreover, parties to contested proceedings frequently change their positions, knowing that they will always need to support their latest position – which is no more and no less than the ITIA must do here if it is to succeed in proving the ABP Charge.

### **Tribunal's evaluation of the joint Expert Panel's opinion**

335. The three joint Expert Panel's opinions reach a consistent unanimous conclusion that it was "*highly likely*" that the Player's ABP was caused by blood doping. The only change in their conclusion after JE2 was that after consideration of further expert evidence (which came particularly from Dr Eichner) and the Player's further explanations (in her ABP PHB), they considered that use of a Prohibited Method (such as blood transfusion) was also a plausible scenario, i.e. a plausible explanation of how the Player could have actually done the illicit manipulation of her blood which had produced the abnormal ABP values.

336. In evaluating the joint Expert Panel's conclusions, it is useful to note how different forms of blood doping affect the relevant blood parameters. We accept as correct Dr Eichner's summary:

(1) If an athlete dopes with a blood doping agent, initially the immature reticulocytes go into overdrive and so the RET% will increase. Some time afterwards, there will be an increase in HGB. If the athlete continues to use the blood doping agent, their RET% and HGB levels will remain high. If the athlete stops using the blood doping agent, the RET% will go down quickly, whereas the HGB will remain high for some time afterwards and then drop down. It is therefore not possible to say that every time an athlete has a low RET% that they will have a high HGB.

(2) If an athlete dopes by infusing blood, then after the infusion there will be an increase in HGB and continued suppression of RET% for 3-4 weeks, which means that "*the body has more oxygen carrying capacity and a*



*lower percentage of reticulocytes – young red blood cells – because the blood contains more mature red blood cells”.*

337. The three joint Expert Panel opinions were all based on the Player’s ABP consisting of the 51 valid samples shown in the table above. Of those 51, the samples specifically mentioned in those opinions were 44, 46, 48 and 49 (all taken in 2022), as well as 50 to 56, and the much earlier Samples 2 and 19.

338. Sample 48 was taken 24 days after Ms Halep’s 29 August 2022 elimination from the US Open and her positive urine sample taken later that same day. Their “*strong opinion*”, expressed in JE3, was that the Player’s explanations could not (individually or collectively) account for the abnormalities in her ABP profile, particularly those surrounding Sample 48.

339. A crucial element of the ABP Programme is that all valid blood samples are taken into account and any one sample is evaluated in the light of the Player’s complete ABP record. Key points of the three Expert Panel’s evaluations leading up to JE3 are:

(i) Professor d’Onofrio

- Sample 50 (on 13 December 2022) triggered an automatic expert review of Ms Halep’s ABP profile. It breached her OFF-score lower limit, owing to a combination of decreased HGB g/dL and increased RET% [REDACTED] compared to previous samples. Professor d’Onofrio considered the profile “*suspicious*”, based on a moderate increase in variability of both HGB and RET%. In particular, he noted that Samples 46 (on 27 April 2022) and 50 (on 13 December 2022) had shown RET% [REDACTED] higher than ever seen before in the Player’s ABP (and the previous highest among 41 valid samples had been [REDACTED]). Sample 46 also showed a high Immature Reticulocytes Fraction (“**IRF**”) value of [REDACTED]. Professor d’Onofrio’s conclusion on 18 December 2022 was of a possible use of anabolic steroids in April 2022, as they are known to

produce moderate erythropoietic stimulation. He also noted: “*There is no evident blood doping scenario.*”

- The Player’s competition schedule had been made available to the Expert Panel on 22 December 2022 and on 12 January 2023, Professor d’Onofrio (like Dr Mørkeberg and Dr Garvican-Lewis) learned of the Player’s AAF on her 29 August Sample. However, on 12 January 2023, he felt more information was needed and requested further sample collection.
- After the Expert Panel’s conference call on 12 January 2023, Professor d’Onofrio again reviewed the Player’s ABP profile, now with the addition of Samples 51 (on 23 December 2022) and 52 (on 6 January 2023). He considered Sample 52 as clearly indicating the abnormality of Sample 48, with its increased HGB g/dL and RET% suppression. His opinion therefore changed to “*likely doping*”. He confirmed that opinion on 4 February 2023, when Sample 53 (on 27 January 2023) became available.
- We note particularly that Professor d’Onofrio did not come to a specific connection between the US Open and the Player’s blood results until 23 February 2023. That connection, when made, accords with Dr Eichner’s summary in paragraph 332 above. The clear abnormality of Sample 48, as seen by Professor d’Onofrio, was reinforced by the return to a normal picture in Sample 49 taken on 7 October 2022, only 15 days after Sample 48.

(ii) Dr Mørkeberg

- Dr Mørkeberg reviewed the Player’s ABP profile on 5 May 2022. He noted a few low OFF-scores and recommended a follow-up but deemed the profile “*normal*”.

- On further evaluation on 1 October 2022, Dr Mørkeberg deemed Ms Halep's ABP profile "*suspicious*". He identified abnormalities in Samples 46 and 48 (on the same lines as those seen on Professor d'Onofrio's later reviews) and recommended two follow-up tests and monitoring of the profile.
- His next evaluation on 16 December 2022 contrasted Samples 46, 49 and 50 with the blood picture in Sample 48, and also drew attention to the short interval of 15 days between Sample 48 and the very different Sample 49. Dr Mørkeberg evaluated Ms Halep's profile then as "*likely doping*". We note that this conclusion was reached without Dr Mørkeberg knowing the identity of the Player, her competition schedule or that there had been an AAF on that anonymous Player.
- Dr Mørkeberg's 13 January 2023 evaluation noted that the Player's 2021 and 2022 competition schedule had been provided (and by then he and the other two experts knew it was Ms Halep and that there had been an AAF on her 29 August Sample). Dr Mørkeberg specifically mentioned the elevated HGB value and low RET% and IRF on sample 48. He described Sample 48 as showing a "*completely different blood picture*" from previous and subsequent samples that year and again Sample 49 as showing a "*completely different blood*" from Sample 48. In all valid samples (2, 19, 23 and 48) with a high HGB, there was an indication of erythropoietic suppression.
- When Dr Mørkeberg made his last separate evaluation of the Player's ABP profile, the Expert Panel had been provided at their request with the full Laboratory Documentation Package for Sample 48.

(iii) Dr Garvican-Lewis

- Dr Garvican-Lewis first reviewed Ms Halep's ABP profile on 20 December 2022 and deemed it "*suspicious*". She noted the atypical OFF-score for Sample 50, arising from RET% [REDACTED] increased up to the

upper limit and low HGB. The three Samples 46, 49 and 50 all showed a large drop in HGB and concomitant increase in RET%, when compared with Sample 48. The increased HGB in Sample 48 was the anomaly. No confounding factors had been declared. Red cell indices were normal and there was no indication of anaemia. Dr Garvican-Lewis specifically added that the competition schedule would be useful to put context around Sample 48. She also recommended Erythropoietic Stimulating Agents analysis, if possible, on Samples 46 and 50 and that another sample should be taken within a month, with ESA analysis.

- On her further review on 14 January 2023, Dr Garvican-Lewis had confirmed her opinion of “*likely doping*”. She had the Player’s competition schedule, noted that Sample 48 had been collected shortly after the US Open. She concluded that “*the doping scenario is apparent of blood manipulation around competition*”.
- Dr Garvican-Lewis’s third evaluation on 23 February 2023 confirmed her opinion of “*likely doping*”. Additional Samples 53 (on 27 January 2023) and 54 (on 14 February 2023) had been collected and in Dr Garvican-Lewis’s view did not explain the anomalies around Sample 48.

### **JE3 conclusions and response to Player’s explanations**

340. As well as explaining the evolution of their separate opinions and confirming the unanimous opinion of the Expert Panel that Ms Halep’s ABP showed “*likely doping*”, JE3 responded to the Player’s explanations for the abnormalities they had observed in her ABP. They focused specifically on Scott (2) and an amended version of Alvarez (6) provided to them on 21 June 2023; and had reviewed the sections of Eichner (1) and Eichner (2) dealing with ABP as well as Eichner (3).

341. The “*strong opinion*” of the Expert Panel was that the explanations provided by the Player could neither individually nor collectively account for the

abnormalities in her ABP profile. Moreover, it could not be explained by the ingestion of a product contaminated with low levels of Roxadustat.

342. The Tribunal have already dealt with the Player's experts' contention that all the values in her ABP were within a normal range and that haematological parameters not going outside the Player's own upper and lower limits provided no basis for an APF, let alone charges of an ADRV based on the Player's ABP. We simply note that Sample 48, described by the Expert Panel in JE3 as the most abnormal sample of the Player's ABP, did not itself breach the upper or lower limits of the Player's intra-individual range.

343. The three specific Confounding Factors of [REDACTED] surgery, [REDACTED] and detraining have also been covered already.

The Joint Experts' knowledge of Ms Halep's AAF and her competition schedule

344. The ABP PHB observes that Ms Halep's ABP was not flagged as "*likely doping*" until 16 December 2022, which was well after her Roxadustat positive test had been well publicised. That is correct, in the sense that the first expert opinion of "*likely doping*" was by Dr Mørkeberg on 16 December 2022, although it does not appear that any of the three experts knew before 12 January 2023 that the ABP was Ms Halep's.

345. At the June hearing, the Tribunal did express discomfort about the fact that by the time Professor d'Onofrio and Dr Garvican-Lewis (though not Dr Mørkeberg) first expressed their opinions of "*likely doping*", they knew it was Ms Halep and of the AAF.

346. The technical position on disclosure of a player's identity is in Article 8.3.2 of the WADA ABP Operating Guidelines, and ISRM Annex C (*RESULTS MANAGEMENT REQUIREMENTS AND PROCEDURES FOR THE ATHLETE BIOLOGICAL PASSPORT*), Article C.4.3:

- ABP Operating Guidelines Article 8.3.2 provides that the APMU Report, which goes to the Expert Panel, shall not contain any reference to an AAF. But it also says: *“If the APMU assessment leads to an Expert review, the APMU may, however, separately inform the Expert(s) of the existence of the AAF.”* There is a comment to Article 8.3.2: *“The information regarding an AAF shall therefore not be recorded in the APMU Report and shall not be disclosed unnecessarily.”*
- ISRM Annex C, Article C.4.3 states that at the stage where the APMU passes the matter to the Expert Panel for their joint review in accordance with Article C.4.2, *“the identity of the Athlete is not mentioned but it is accepted that specific information provided may allow to identify the Athlete. This shall not affect the validity of the process.”*

347. Noting the comment to Article 8.3.2 of the ABP Operating Guidelines, we can see why it could have been regarded as necessary to disclose the AAF to the Expert Panel on 12 January 2023. It might well have been thought potentially relevant to their identification of at least one plausible doping scenario (which we discuss at paragraphs 353 to 359 below). But it is not necessary for us to explore that point. The fact is that it was disclosed and that Ms Halep’s case was sufficiently well-known by then that, as Professor d’Onofrio acknowledged, it was easy to see or find out the name of the player involved. Article C.4.3 of ISRM Annex C makes clear that none of this invalidates the process. The question is whether the Expert Panel’s knowledge of the AAF undermines the authority and independence of the joint Expert Panel’s opinion.

348. We are sure that it does not. The Expert Panel were adamant that their knowledge of the AAF did not affect their opinions at all. We accept that. They are all experts of the highest reputation, who would understand the need to take an objective and independent view and would have been fully capable of putting the AAF aside in reaching an unbiased opinion. It is important to

appreciate their function in the ABP Programme. While they have an active and significant role in the whole anti-doping programme, they have no interest in penalising clean athletes. This is not to rubber-stamp their opinions, which we have made clear is not our approach. It is to give proper recognition to their professional integrity and their function in the ABP Programme.

349. The provision of the Player's competition schedule is unobjectionable and also casts no doubt on the integrity and independence of the Expert Panel's opinions. Dr Garvican-Lewis explained why it is necessary for the experts to know the context of an athlete's or player's programme, particularly as they need to consider how the profile of an athlete's or player's ABP might or might not be the result of a plausible doping scenario. In many cases the fuller context, including a player's competition and training schedule, may serve to clear the player and avoid an unjustified charge of an ADRV.

Negative analysis for Erythropoietic Stimulating Agents ("ESAs")

350. JE3 specifically considered the Player's point that ESA analysis had been done 33 times on Ms Halep's blood samples between April 2016 and March 2023 (the period between Samples 11 and 56), with all results negative.

351. There is nothing solid to contradict the joint Expert Panel's answer, which is that negative tests for ESA do not rule out blood manipulation and the detection window for ESAs can be very short when micro-dosing. The Expert Panel observes that one of the reasons for the introduction of ABP was to overcome that very point. We accept their view.

352. ABP blood sample collections are more expensive and practically complicated than urine samples. In Ms Halep's case, no ABP blood samples were taken between April and August 2022. The Expert Panel rejected Mr Scott's contention in Scott (1) that because the Player's entire red blood cell population would have been replaced in the intervening four months, Samples 46 and 48 could not be related to each other. We accept that the

life span of red blood cells has no bearing on the matter. The Expert Panel was still able to relate Samples 44 and 46 (in March and April 2022), showing a period of stimulation of red blood cells, to Sample 48 (in September 2022) showing a period of suppression. They maintained their view that Samples 2 and 19 indicated erythropoietic suppression but added that owing to a lack of data, those samples were not the focus of the doping scenario.

### Doping scenario

353. It is well-established, particularly by consistent CAS case law, that proof of an ADRV based on an athlete's ABP requires it to be shown that there is at least one plausible doping scenario which could have produced the blood test values in the athlete's ABP profile.
354. The Player's ABP PHB helpfully cited the CAS appeal decision *Farnosova v IAAF & ARAF*, CAS 2017/A/5045, paragraphs 103 and 105-109. The CAS Panel expressly stated that the party that had the burden of proof therefore in principle also had the burden of presenting the relevant facts to the tribunal. That starting position is clear and is common ground between the ITIA and the Player. However, it is subject to the exception discussed at paragraphs 106-109, summarised in paragraph 109:

*"The Panel finds that, in the present matter, the IAAF is confronted with a "Beweisnotstand", because, in order to discharge its burden of proof, it must show—in principle—that not only the doping scenario is plausible, but that all potential explanations other than doping—have to be excluded to the applicable standard of proof. Such proof of "negative facts", however, is impossible. It is for this very reason that the Athlete cannot limit herself to (simply) contesting the doping scenario, but is under an obligation to cooperate in the fact finding, i.e., must submit in detail alternative (natural) scenarios to explain the blood values. It is, thus, up to the Athlete to submit and substantiate any alternative explanations for blood values that the Panel must balance with the doping scenario."*



355. All CAS appeal cases are arbitrations with their seat in Switzerland. The “Beweisnotstand” principle of Swiss law (also found in German law) is sufficiently explained in that cited passage above. Although we are not applying Swiss law, there is no difference of approach by this Tribunal from how it is described in that passage. Once the Expert Panel gave a convincing opinion of illicit blood doping, supported by one or more plausible doping scenarios, the Player has to provide an alternative explanation which prevents this Tribunal from being comfortably satisfied that the Player has committed the ADRV(s) alleged in the ABP Charge Letter. We did not understand there to be any dispute between the parties on these principles, as opposed to their application to the facts.
356. Five different doping scenarios were set out in the list of issues for the second day of the June Hearing:
- (1) Use of microdoses of Roxadustat or another ESA (e.g. rEPO).
  - (2) Use of an autologous (player’s own blood) or homologous (matching donor’s blood) blood transfusion in addition to the use of Roxadustat that led to the Player’s AAF.
  - (3) Use of an autologous or homologous blood transfusion that contained low levels of Roxadustat.
  - (4) Use of therapeutic doses of Roxadustat.
  - (5) Use of therapeutic doses of another ESA (e.g. rEPO).
357. As set out in their conclusion to JE3, since their previous report the Expert Panel had considered the further expert evidence and had added blood transfusion to the plausible doping scenarios.
358. At the hearing, Mr Scott made clear that he did not believe that microdoses of Roxadustat would have worked – a view shared by the Expert Panel and by Dr Eichner. However, Mr Scott also agreed with the Expert Panel and Dr

Eichner that all the other scenarios were plausible. With that agreement, and with nothing in the evidence to cast serious doubt on that conclusion, in deciding whether the ABP Charge is proven we do not need to explore the relative likelihoods of the various scenarios – whether taken individually or possibly by a combination of a Prohibited Substance and a Prohibited Method. The Expert Panel, and the ITIA as prosecutor of these charges, are not required to establish which doping scenario or combination of scenarios has produced the Player's ABP, or even to specify which they say is or are the most likely explanation. We find there is a sufficiently sound basis for those plausible scenarios to support the joint Expert Panel's overall opinion that it is "*highly likely*" that the Player's ABP was caused by illicit blood manipulation.

359. We are not persuaded by Mr Jacobs's suggestions of practical difficulties in relation to either autologous or homologous blood transfusion, whether or not that blood contained Roxadustat. If the Player wished to use any type of blood transfusion, we have no doubt that any difficulties on storage or transport of blood or the obtaining of Roxadustat would have been overcome.

### **Tribunal's conclusion on the ABP Charge**

360. Professor Alvarez was dismissive of the idea that a tennis player would gain any help from increasing haemoglobin because, he said, "*in tennis you don't need to have oxygen*". Dr Garvican-Lewis, who is a sport physiologist, was equally dismissive of Professor Alvarez's view and explained why she said that "*improving aerobic capacity is absolutely important in tennis*". While there may be other sports, such as long-distance running, where the advantages are more obvious, Dr Garvican-Lewis's view is clearly right.

361. Each of the three experts had a high degree of confidence that there was no innocent explanation for Ms Halep's ABP profile. Professor d'Onofrio expressed it as 90% probability, even without knowledge of the player and the competition schedule. Dr Garvican-Lewis told us she would not say "*likely doping*" until she was sure. Dr Mørkeberg, who looks at about 500 ABP

passports a year from around 12 different sports, had concluded “*likely doping*” on his first review on 16 December 2022, when all he had in addition to the ABP profile and the relevant DCFs was Ms Halep’s age, sex and sport.

362. We find no reason to doubt their unanimous conclusion. On our detailed review of all the written and oral evidence, we are comfortably satisfied that the Player has committed the Anti-Doping Rule Violation under TADP Article 2.2 alleged in the ABP Charge Letter, on the basis that her Athlete Biological Passport evidences use of a Prohibited Substance and/or Prohibited Method. She will be sanctioned accordingly.

## **G. SANCTIONS ON THE ROXADUSTAT AND ABP CHARGES**

### **Aggravating circumstances**

363. Our conclusion of intentional doping on both the Roxadustat charges and the ABP charges leaves no room at all for a finding of No Significant Fault or Negligence, so TADP Article 10.6 has no application. The minimum sanction is therefore a four-year period of Ineligibility, giving credit for the Provisional Suspension served since 7 October 2022 in accordance with TADP Article 10.2.

364. The ITIA acknowledges that there is no room for increasing the period of Ineligibility under TADP Article 10.9 (**Multiple Violations**), under which a heavily increased period of Ineligibility may be imposed for a second ADRV. That applies where a second ADRV was committed after a player has received notice of a first ADRV. In this case, the Player’s ADRV based on her ABP was committed at the latest some time before 22 September 2022, which was *before* she had been notified, on 7 October 2022, of the ADRV based on her 29 August Sample.

365. In those circumstances, the effect on Ms Halep, as a result of her having committed ADRVs as charged separately by the Roxadustat Charge Letter

and the ABP Charge Letter, is clear from TADP Article 10.9.4.1, which includes:

*“[...] the first and second Anti-Doping Rule Violations ... will be considered together as one single first Anti-Doping Rule Violation, and the sanction imposed will be based on the Anti-Doping Rule Violation that carries the more severe sanction, including the application of Aggravating Circumstances.”*

Apart from Aggravating Circumstances, the sanction for the first ADRV (on the Roxadustat Charges) and the second ADRV (on the ABP Charge) would each be the same four-year period of Ineligibility anyway.

366. However, we have the ITIA's further submission that there are Aggravating Circumstances which should lead to an increase of that four-year period of Ineligibility, up to a total of six years as we think fit in all the circumstances. The ITIA submits that there are Aggravating Circumstances that justify a period of Ineligibility of more than four years for the ABP violation, which is therefore the ADRV carrying the more severe sanction, so that by TADP Article 10.9.4.1 it is that increased period of Ineligibility which should be imposed on Ms Halep.

367. TADP Article 10.4 states:

*“If the ITIA establishes, in an individual case involving an Anti-Doping Rule Violation under Article 2.1, 2.2, 2.3, 2.4, 2.5, 2.6 or 2.10, that Aggravating Circumstances are present that justify the imposition of a period of Ineligibility greater than the standard sanction otherwise applicable in accordance with Article 10.2 or 10.3, the period of Ineligibility otherwise applicable will be increased by an additional period of Ineligibility of up to two years depending on the seriousness of the violation and the nature of the Aggravating Circumstances, unless the Player or other Person can establish that they did not knowingly commit the Anti-Doping Rule Violation.”*

The Player's ADRVs in this case are all under Articles 2.1 and 2.2.

368. Aggravating Circumstances are defined in the TADP as:

*“Circumstances involving, or actions by a Player or other Person that may justify the imposition of a period of Ineligibility greater than the standard sanction. Such circumstances and actions include, but are not limited to: the Player or other Person Used or Possessed a Prohibited Substance or Prohibited Method on multiple occasions, or committed multiple other Anti-Doping Rule Violations; a normal individual would be likely to enjoy the performance-enhancing effects of the Anti-Doping Rules Violation(s) beyond the otherwise applicable period of Ineligibility; the Player or other Person engaged in deceptive or obstructive conduct to avoid the detection or adjudication of an Anti-Doping Rule Violation; or the Player or other Person engaged in Tampering during Results Management. For the avoidance of doubt, these examples are not exhaustive, and other similar circumstances or conduct may also justify the imposition of a longer period of Ineligibility.”*

Ms Halep being the Player, the references to “other Person” have no application here.

369. The Aggravating Circumstances alleged by the ITIA may be summarised as:

- (1) Ms Halep’s blood doping was repetitive and sophisticated.
- (2) The Expert Panel was clear that the stimulation was effective from at least March 2022 to September 2022. She must therefore have been using more than one Prohibited Substance and/or method on multiple occasions.
- (3) The Player engaged in deceptive and/or obstructive conduct to avoid the detection or adjudication of a violation.
- (4) The timing of the erythropoietic suppression suggests that the blood doping was timed to provide the Player with highly oxygenated blood during Wimbledon (July 2022) and then the US Open (August 2022).

The ITIA says the CAS jurisprudence is clear that “*the intent to illegally enhance sporting performance in the most important and prestigious international competitions may be taken into account as an aggravating factor*”: *IAAF v RUSAF & Shkolina*, CAS 2018/O/5667; *IAAF v RUSAF & Ukhov*, CAS 2018/O/5668. The ITIA’s ABP Reply Brief described this as a finding by “*multiple CAS panels*”, although it was the same arbitrator expressing an identical view in just those two closely connected cases heard together.

370. We make these preliminary observations:

- (1) All facts proposed to support a finding of Aggravating Circumstances must be established to the comfortable satisfaction of the Tribunal.
- (2) A degree of sophistication is practically always going to be found in an ADRV based on a player’s ABP. Something more is needed for it to become an Aggravating Circumstance.
- (3) Deception is inherent in practically all intentional doping and, as we have already remarked, a non-intentional ADRV based on a player’s ABP is hard to contemplate. To establish Aggravating Circumstances, something more is needed than the original deceptive doping followed by the Player’s continuing denial of the ADRV throughout the proceedings.
- (4) The minimum four-year period of Ineligibility for intentional doping applies without variation to cases over a potentially wide range of seriousness. A tribunal should not increase that period unless it is comfortably satisfied that there are truly Aggravating Circumstances, and not just that the case is at the top end of that range.

371. A key allegation by the ITIA on Aggravating Circumstances is that the Player must have been using at least one Prohibited Substance or Prohibited Method from March 2022 at the latest. However, although there are strong

grounds for suspicion, we are not comfortably satisfied that this is so. The Expert Panel, in JE3, rejected Mr Scott's contention that Samples 44 (8 March 2022) and 46 (27 April 2022) could not be related to Sample 48 (22 September 2022). But they added: "*All that can be determined is that a period of stimulation is indicated in samples 44 and 46 followed by a period of suppression in sample 48.*" That ties in with a passage in Eichner (4): "*all that can be said based on the scientific data is that samples 2, 19 and 48 are abnormal (indicating suppression) and that there is an indication of erythropoietic stimulation around sample 44 and 46*". We note that in JE3 the Expert Panel made it clear that although there was an indication of erythropoietic suppression in those much earlier Samples 2 (2014) and 19 (2017), those samples were not the focus of the doping scenario due to lack of available data.

372. By contrast with their opinion relating to August 2022 and the US Open towards the end of that month, there is no unequivocal assertion by the Expert Panel that blood doping by the Player in March 2022 was "*highly likely*". The same applies to the allegation of blood doping in connection with the Wimbledon Championships in June/July 2022. No ABP samples were collected from Ms Halep between April and August 2022 and the invalidation of Sample 47 (26 August 2022) means that there is a period from 27 April 2022 to 22 September 2022 for which the Player's blood values are unknown.

373. Accordingly, while we are comfortably satisfied that the Player's ABP proves a blood doping ADRV, we are not comfortably satisfied that she was blood doping in March 2022 or around the time of the Wimbledon Championships in June/July 2022.

374. We recognise that the plausible doping scenarios which support the finding of an ADRV on the ABP Charge include possible combinations of Prohibited Substances and/or Methods. Nevertheless, we do not consider that what has been proven to our comfortable satisfaction reaches a level of repetitive or

sophisticated doping, or uses of a Prohibited Substance and/or Prohibited Method on “*multiple occasions*”, so as to amount to Aggravating Circumstances justifying the imposition of an increased period of Ineligibility. On this point, the ITIA cites IAAF v RUSAF & Vasilyeva, CAS 2017/O/4980. That was a far more serious case on its facts and the sole arbitrator found that the athlete had been involved in a doping plan or scheme over a five-year period during which his career appeared “*to have been built on blood doping*”. Our different result in Ms Halep’s case is based on our different facts.

375. The ITIA cited a decision of a disciplinary tribunal on *World Athletics v Taye Girma Arit*, 15 August 2022, SR/367/2021, where two EPO injections within just over two months were held to be ADRVs on “*multiple occasions*” under the same definition of Aggravating Circumstances and were regarded as serious, leading to an increase of 16 months’ period of Ineligibility. But we are not comfortably satisfied that Ms Halep’s conduct is comparable.

376. Applying our observation (3) in paragraph 370 above, we also do not consider that there has been deceptive and/or obstructive conduct by Ms Halep amounting to Aggravating Circumstances justifying the imposition of an increased period of Ineligibility.

377. The Tribunal therefore rejects points (1) to (3) of the Aggravating Circumstances alleged as summarised in paragraph 369 above.

378. Given our conclusion about blood doping at the 2022 Wimbledon Championships, that leaves the ITIA’s point (4) in paragraph 369 above, so far as it related to the 2022 US Open. The ITIA says that the CAS jurisprudence is clear, as cited from those two CAS cases *Shkolina* and *Ukhov*. The cited passages from those cases are clear, but we intend no disparagement of the CAS arbitrator by saying that his clear and consistent view cannot be taken as firmly established CAS jurisprudence (jurisprudence



which always merits respect but is not binding on this Tribunal and not even binding on other CAS panels).

379. The tribunal in *World Athletics v Taye Girma Arit*, 15 August 2022, SR/367/2021, took a different view:

*“[...] we did not regard the fact that the doping was targeted at qualification of the Olympic Games (as opposed to some “lesser” regulated competition) could of itself be regarded as constituting Aggravating Circumstances. If it did so then all doping targeted at qualification (or presumably competition in) the Olympics would be regarded as Aggravating Circumstances. The [Athletics Integrity Unit] accepted that, by itself, that could not be the case.”*

We prefer that view to the view of the sole arbitrator in the CAS cases *Shkolina* and *Ukhov*. The ITIA Reply Brief emphasised that the doping in *Taye Girma Arit* case related to *qualification* for the Olympics, as opposed to performance in competition, but we do not see a distinction (and neither did the *Taye Girma Arit* panel, given their words “*or presumably competition in*”). We find that the fact that Ms Halep’s blood doping was targeted to her performance in the 2022 US Open was not an Aggravating Circumstance justifying an increase in her period of Ineligibility.

### **Period of Ineligibility and starting date**

380. Taking all our findings of Anti-Doping Rule Violations together, the period of Ineligibility imposed by this Tribunal on Ms Halep will therefore be four years.

381. Under TADP Article 10.13, that period of Ineligibility starts from the date of this Tribunal’s final decision, but credit is to be given under TADP Article 10.13.2 for the period of her Provisional Suspension since 7 October 2022, which has been respected by the Player. Accordingly, Ms Halep will serve a period of Ineligibility of four years from 7 October 2022 to 6 October 2026.

382. Under TADP Article 10.13.1, the period of Ineligibility may be deemed to have started at an earlier date where there have been substantial delays in the hearing process not attributable to the player charged. Ms Halep submitted that any period of Ineligibility should be deemed to have started on 29 August 2022. We find useful guidance in the CAS decision on the consolidated appeal *World Athletics v Salwa Eid Naser*, CAS 2020/A/7526 and *WADA v World Athletics & Salwa Eid Naser*, CAS 2020/A/7559, paragraph 219, where it was stated that “*substantial*” meant more than would normally be expected in the case under consideration; and that any substantial delay not attributable to the athlete (or player) could be taken into account, whether or not it resulted from factors which were both explicable and reasonable.

383. Ms Halep is certainly not responsible for any delay in the hearing and determination of this case. However, despite the Player’s repeated protestations to the contrary, neither is the ITIA nor anyone else involved. The case, involving both the Roxadustat Charges and the ABP Charge, has been complex both in its substance and procedurally. Given the complexity, there has been no more delay than would normally be expected. Accordingly, there is no justification for backdating the start of the period of Ineligibility under TADP Article 10.13.1.

### **Disqualification of results**

384. TADP Article 10.10 states:

*“Unless fairness requires otherwise, in addition to the Disqualification of results under Articles 9.1 and 10.1, any other results obtained by the Player in Competitions taking place in the period starting on the date the Sample in question was collected or other Anti-Doping Rule Violation occurred and ending on the commencement of any Provisional Suspension or Ineligibility period, will be Disqualified, with all of the resulting consequences, including forfeiture of any medals, titles, ranking points and Prize Money).”*

385. The ITIA has asked for disqualification of Ms Halep's results from 8 March 2022, when blood Sample 44 was collected, to 7 October 2022, the start of Ms Halep's Provisional Suspension.

386. A starting date of 8 March 2022 would depend on the Tribunal being comfortably satisfied that her ABP as shown following the collection of Sample 44 was the result of illicit blood doping. As appears in paragraph 365 above, we are not comfortably satisfied on that point, but we have found that based on her ABP, including particularly Sample 48 collected on 22 September 2022, the Player had committed a blood doping ADRV in preparation for the 2022 US Open. Her first (and as it turned out) last match at the US Open was on 29 August 2022, so we can be comfortably satisfied that she had committed an ADRV shortly or immediately before that match. We therefore disqualify all results obtained by her in competitions from 29 September 2022 to 7 October 2022. In practice that means just the US Open, as she has not competed at all since 29 September 2022.

## **H. COSTS**

387. The 2022 and 2023 TADP each include the following provisions on costs:

Article 8.5.3: *"The ITIA will pay the costs of convening the Independent Tribunal and of staging the hearing, subject to any costs-shifting order that the Independent Tribunal may make further to Article 8.5.4."*

Article 8.5.4: *"The Independent Tribunal has the power to make a costs order against any party, where it is proportionate to do so. If it does not exercise that power, each party will bear its own costs, legal, expert, hearing, and otherwise."*

### **Article 10.12 Financial Consequences**

Article 10.12.1: *"Where a Player or other Person commits an Anti-Doping Rule Violation, upon request by the ITIA the Independent Tribunal may order the Player or other Person to pay some or all of the costs associated with the*

*Anti-Doping Rule Violation (including, without limitation, those incurred by the ITIA in investigating or otherwise conducting Results Management in relation to the matter), regardless of the period of Ineligibility imposed (if any)."*

Article 10.12.2: *"The imposition of a costs order will not be considered a basis for reducing the period of Ineligibility or other Consequences that would otherwise be applicable under this Programme."*

388. The ITIA, in its opening brief in the ABP Proceedings dated 8 June 2023, asked the Tribunal to award the ITIA a significant contribution to its legal costs and expenses incurred in relation to these consolidated proceedings. However, in the written and oral submissions that bare request was not developed by the ITIA and was not addressed by the Player. In practical terms it would not have been seriously considered unless the ITIA had substantially succeeded on the charges against Ms Halep, as in the event it has.

389. It is clear that the Tribunal has jurisdiction to order a significant contribution towards the ITIA's legal costs and expenses. But before we decide on the ITIA's request the parties will have the opportunity of making written submissions as follows:

(1) By 20:00 BST (London time) on Monday 18 September 2023, the ITIA may file a written submission in support of its request for a significant contribution to its legal costs and expenses, including (i) the amount of its legal costs and expenses incurred to date; and (ii) the amount of contribution it now requests.

(2) By 20:00 BST on Monday 25 September 2023, the Player may file a written submission in response to the ITIA's request and submission on costs.

390. On receipt of those submissions the Tribunal may proceed to a decision on the ITIA's request (with or without any further directions as we may think fit).

391. Once we have made our decision on costs, the Tribunal will issue its final decision in these consolidated proceedings. This section H will be redrafted accordingly (and there will be very slight amendments to section I below). That will then be the final decision announced under article 4.1 of the Procedural Rules. In the meantime, the parties must not make any submissions which seek to reopen or reargue any of the points which we have already decided in this Decision on Liability and Sanctions.

## **I. RIGHT OF APPEAL**

392. In accordance with TADP Article 13, there will be a right of appeal exclusively to the Court of Arbitration for Sport, located at Palais de Beaulieu, Av. des Bergières 10, CH-1004 Lausanne, Switzerland (procedures@tas-cas.org), against the whole or any part of the Tribunal's final decision.

## **J. DECISION OF THE INDEPENDENT TRIBUNAL**

393. The Independent Tribunal decides:

- (1) The Player, Ms Simona Halep, has committed Anti-Doping Rule Violations under Article 2 of the Tennis Anti-Doping Programme 2022 by:
  - (a) The presence of the Prohibited Substance, Roxadustat, in her urine sample collected In-Competition on 29 August 2022, in breach of TADP Article 2.1; and
  - (b) Her Use of the Prohibited Substance, Roxadustat, on 29 August 2022, in breach of TADP Article 2.2.
  
- (2) The Player has committed an Anti-Doping Rule Violation in breach of TADP Article 2.2 by her Use of a Prohibited Substance and/or a Prohibited Method on or before 29 August 2022, as evidenced by her Athlete Biological Passport.

- (3) Under TADP Article 10.9.4.1, for the purposes of imposing sanctions the Player's Anti-Doping Rule Violations in paragraphs (1) and (2) are considered together as one single first Anti-Doping Rule Violation, for which this Tribunal imposes a period of Ineligibility of four (4) years.
- (4) That four-year period of Ineligibility will run from 7 October 2022 to 6 October 2026, credit being given under TADP Article 10.13.2 for her Provisional Suspension served since 7 October 2022.
- (5) Under TADP Article 10.10, all results obtained by the Player in competitions taking place in the period 29 August 2022 to 7 October 2022 are disqualified, with all resulting consequences, including forfeiture of any medals, titles, ranking points and prize money.
- (6) Costs still to be determined as indicated in section H above.



Nicholas Stewart KC (Chair)

On behalf of the Independent Tribunal

London

11 September 2023