CAS 2014/A/3759 Dutee Chand v. Athletics Federation of India (AFI) & The International Association of Athletics Federations (IAAF)

INTERIM ARBITRAL AWARD

delivered by the

COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President:

The Hon. Justice Annabelle Claire Bennett AO, Federal Court of Australia,

Sydney, Australia

Arbitrators:

Prof. Richard H. McLaren, attorney-at law in London, Canada

Dr Hans Nater, attorney-at-law in Zurich, Switzerland

Ad hoc Clerk:

Mr Edward Craven, barrister in London, United Kingdom

in the arbitration between

Ms Dutee Chand, Odisha, India

Represented by Mr James Bunting, Mr Carlos Sayao, and Hon. Morris J. Fish Q.C. of Davies Ward Phillips & Vineberg LLP in Toronto, Canada

Appellant

and

Athletics Federation of India (AFI), New Delhi, India

First Respondent

The International Association of Athletics Federations (IAAF), Monaco Cedex

Represented by Mr Jonathan Taylor and Ms Elizabeth Riley of Bird & Bird LLP in London, United Kingdom

Second Respondent

I. PARTIES

- 1. Dutee Chand (the "Athlete") is a 19 year-old female athlete of Indian nationality. During her career to date she has won a number of national junior athletics events in India. In addition, she won gold medals in the women's 200 metres sprint and the women's 4 x 400 metre sprint relay at the Asian Junior Track and Field Championships in Taipei in May 2014.
- 2. The Athletics Federation of India (the "AFI") is the national governing body for the sport of athletics in India.
- 3. The International Association of Athletics Federations (the "IAAF") is the international governing body of the sport of athletics, recognised as such by the International Olympic Committee. It has its seat and headquarters in Monaco. The IAAF recognises the AFI as its member federation for India.

II. OVERVIEW OF THE CASE

- 4. This case concerns a challenge to the validity of the IAAF Regulations Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition (the "Hyperandrogenism Regulations"). The Hyperandrogenism Regulations place restrictions on the eligibility of female athletes with high levels of naturally occurring testosterone to participate in competitive athletics. In particular, the Athlete challenges the Hyperandrogenism Regulations on the basis that: (a) they discriminate unlawfully against female athletes and against athletes who possess a particular natural physical characteristic; (b) they are based on flawed factual assumptions about the relationship between testosterone and athletic performance; (c) they are disproportionate to any legitimate objective; and (d) they are an unauthorised form of doping control. The IAAF rejects each of those arguments.
- 5. The case raises complex legal, scientific, factual and ethical issues. The parties' submissions draw upon a diverse range of expert scientific evidence, factual accounts of the evolution of the Hyperandrogenism Regulations and the experiences of female athletes who were subjected to their "gender testing" and "sex verification" predecessors, and philosophical arguments about the meaning of fairness in sport. The

length of this Award is a reflection of the complexity of those issues, and the exceptional care and detail in which they were presented to the Panel by the parties' representatives.

III. FACTUAL BACKGROUND

6. Below is a summary of the relevant facts and allegations based on the parties' written submissions, pleadings and evidence adduced at the CAS hearing on 23 – 26 March 2015. While the Panel has considered all the facts, allegations, legal arguments and evidence submitted by the parties in the present proceedings, it refers in its Award only to the submissions and evidence it considers necessary to explain its reasoning.

A. Background Facts

- 7. The Athlete was born in Odisha, India on 3 February 1996. She began competing in junior-level athletics competitions in 2007.
- 8. Since March 2012, the Athlete has been a resident athlete at the National Institute of Sports ("NIS") in Patiala, India. The NIS is a training facility for elite Indian athletes operated by the Sports Authority of India ("SAI"). The SAI is a public body that was established in 1982 by the Government of India's Ministry of Youth Affairs and Sports (the "Ministry"). The SAI performs a range of functions on behalf of the Ministry relating to the governance and promotion of sport in India and the training of elite athletes. It is not affiliated to the IAAF and is not subject to the IAAF's regulatory jurisdiction.
- 9. In 2013, the Ministry promulgated a Standard Operative Procedure to identify circumstances (female Hyperandrogenism) in which a particular sports person will not be eligible to participate in competitions in the female category (the "Standard Operative Procedure"). The Standard Operative Procedure created rules and procedures governing the investigation, diagnosis and eligibility to compete of hyperandrogenic female athletes in India. The document is binding on the SAI.
- 10. It is common ground that in late June 2014, the Director of the AFI, Mr M.L. Dogra, contacted the Athlete and asked her to meet him in Delhi on the way to a SAI training

centre in Bangalore. On 26 June 2014, Mr Dogra met the Athlete in Delhi. Aspects of the events that followed are a matter of dispute between the parties.

- 11. According to the Athlete, Mr Dogra asked her to undergo a "routine doping test". The following day, on 27 June 2014, the Athlete met the Chairperson of the AFI Medical Commission, Dr Arun Mendiratta, in Delhi. The Athlete claims Dr Mendiratta told her that the AFI was creating a "high performance profile" for her and they therefore needed to conduct a routine medical examination to check if she had any diseases. The Athlete claims she was told that, because no nurses were available to conduct a blood test, she would need to undergo an ultrasound examination instead. The Athlete says that she was confused by the examination and did not understand why an ultrasound scan was conducted in place of a blood test.
- 12. According to the AFI, the Athlete and another athlete underwent ultrasound examinations in Delhi after they had both complained of chronic abdominal pains. Dr Mendiratta said that in June 2014 several participants at the National Inter State Athletics Championships had expressed concerns to the AFI about the Athlete's appearance and questioned whether she should be permitted to compete in female athletics events. However he denied that the medical examination in Delhi had anything to do with investigating the Athlete's sex or gender or testing for possible hyperandrogenism.
- 13. On 30 June 2014, the AFI sent a letter about the Athlete to the SAI. The letter, which was signed by the Secretary of the AFI, Mr C.K. Valson, was entitled "Subject:- Gender Verification Issue". It stated:

It has been brought to the notice of the undersigned that there are definite doubts regarding the gender of an Athlete Ms. Dutee Chand. The athlete has won a Gold Medal in 200m (Women) and as well as 4X400 Relay (Women), in the recently concluded 17th Asian Junior Athletics Championships held at Chinese Taipei. During the above mentioned championships, also, doubts were expressed by the Asian Athletics Association regarding her gender issue.

As is aware [sic] that in the previous past also such cases of Female Hperandrogenism [sic] have brought embarrassment to the fair name of sports in India.

She is presently training at SAI Centre Bangalore, Karnataka.

14. The letter went on to say that the AFI was unable "to identify any suitable female Nodal officer" as required by the terms of the Standard Operative Procedure. The letter suggested that, in these circumstances, the SAI could perform a "Gender verification test" on the Athlete:

In view of the above you may like to conduct Gender verification test of Ms. Dutee Chand as per the established protocol, so as to avoid any embarrassment to India in the International arena at a later stage. The matter may be taken up on an urgent basis as the athlete is bound to leave on 18th July, 2014, for World Junior Athletics Championships.

- 15. It is common ground that following the medical examination in Delhi, the Athlete travelled on to an SAI training camp in Bangalore and was subjected to further medical examinations by the SAI. The Athlete stated that those tests included blood tests, clinical tests by a gynaecologist, karyotyping, an MRI examination and a further ultrasound examination.
- 16. According to the Athlete, on 13 July 2014 Dr Sarala of the SAI notified her that she would not be permitted to compete in the forthcoming World Junior Championships and would not be eligible for selection for the Commonwealth Games because her "male hormone" levels were too high.
- 17. On 15 July 2014, the Director-General of the SAI, Mr Jiji Thomson, issued a public statement announcing that an unnamed female athlete had been subjected to a gender test:

A gender test was conducted on a woman athlete in Bangalore. If she is there in the list of CWG [Commonwealth Games] participants, her name will have to be deleted from the list.

- 18. From 15 July 2014 onwards, a number of articles were published in the Indian press speculating that the Athlete had been made to undergo tests to determine her gender.
- 19. On 16 July 2014, the SAI issued a press release stating that an athlete had been found ineligible to participate in female events due to hyperandrogenism. According to a news article published in *The Hindu* newspaper (which was exhibited to Dr Mendiratta's witness statement) the press release stated that:

SAI has conducted this test following regulations set by international sport organisations like the IAAF and the IOC governing eligibility of females with hyperandrogenism. This test does not determine the athlete's gender. IOC and the IAAF have banned gender verification tests. We are simply trying to find out if the athlete has excess androgen in her body.

If the test results say she is ineligible to compete in the women's competition, that indicates she has excess androgen than what is specifies by the medical commission of the IAAF or by the medical board which helped create the 'Standard Operative Procedure to identify circumstances (female Hyperandrogenism) in which a particular sportsperson will not be eligible to participate in the female category in India.

Yes, we have conducted such a test. For confidentiality protocol, the name cannot be disclosed. The athlete will still be able to compete in the female category in future if she takes proper medical help and lowers her androgen level to the specified range.

- 20. The following day, the SAI made a further public statement about the Athlete's case. According to a transcript filed by the IAAF, Mr Thomson reiterated that the SAI had conducted a hyperandrogenism test, not a gender test. He stated that the test was part of "SAI protocol" and was "stipulated by the IAAF and the IOC". He added that, "the preliminary report indicates that she will not be able to compete in a female category. Maybe after some time she can take proper medical support and she will be able to participate in future events, but as of now she cannot participate".
- 21. After seeing press reports about the Athlete's case, Dr Payoshni Mitra made contact with the Athlete and offered her assistance. In late July 2014, the SAI nominated Dr Mitra to act as mediator and consultant on behalf of the Athlete. Dr Mitra's appointment was formally confirmed in a letter from the SAI dated 30 July 2014.
- 22. On 31 July 2014, Professor Bruce Kidd, the Vice President of the University of Toronto and a former Commonwealth athletics champion, wrote to the Director General of the SAI expressing his strong opposition to the decision to prevent the Athlete from competing in national and international athletics events. Professor Kidd's letter stated that there was "little scientific validity to the 'Hyperandrogenism test" and that "to date, it has only been used against women from developing countries". He also expressed significant concern that the IAAF had been counselling athletes with high testosterone levels to undergo corrective surgery or drugs treatment.

- On 14 August 2014, a meeting took place between the AFI, the SAI, the Athlete and Dr Mitra. Following that meeting, the SAI gave the AFI a copy of the Athlete's medical reports.
- 24. On 22 August 2014, Mr Thomson wrote to the President of the AFI, Mr Shri Adille Sumariwala, about the Athlete's case. The letter explained that the SAI's tests had concluded that the Athlete had hyperandrogenism and the SAI therefore recommended that she should be excluded from competing in female events:

As you are well aware, SAI had conducted a test on [the Athlete] for suspected Hyperandrogenism and the tests were found positive. We have recommended that she be excluded from participation in women's events till her hyperandrogen level is brought down to permissible limits. We have also promised that SAI will be ready to help the athlete to have medical assistance from any hospital of her choice. Her test reports were forwarded to the Secretary General, AFI, vide letter dated 14.08.2014 and the matter was discussed at great length in a meeting held in my office with Mr C.K. Valson, Secretary General, AFI, Dr Payoshni Mitra, our Consultant and [the Athlete]. In this meeting, it was decided that AFI will formally notify the athlete about her disqualification.

- 25. The letter went on to say that, "AFI is yet to notify [the Athlete] about her disqualification. I would request you to notify her immediately so that she can make an appeal against the decision." Mr Thomson suggested that the following points should also be addressed by the AFI:
 - i) The specific details of her alleged violation of policy along with copy of the policy issues alleged to have violated [sic].
 - ii) A deep regret for the fact that [the Athlete] was not clearly told about the test beforehand and the information was not kept confidential.
 - iii) An outline of the appeal processes available to her including the relevant documents along a [sic] statement that by mutual consent AFI & SAI would support an appeal directly to CAS.
- 26. On 26 August 2014, the AFI wrote to the SAI enclosing copies of the *IAAF Regulations*Governing Eligibility of Athletes Who Have Undergone Sex Reassignment to Compete
 in Women's Competition (the "IAAF Sex Reassignment Regulations") and the
 Explanatory Notes to the Hyperandrogenism Regulations. The AFI's letter added that
 the AFI had not compromised the confidentiality of the Athlete's case.

27. On 31 August 2014, the AFI delivered a letter to the Athlete (which was dated 29 August 2014) informing her that she was provisionally suspended from participating in any athletics events with immediate effect (the "Decision Letter"). The Decision Letter stated:

Madam

Based on your medical reports received from Sports Authority of India and a copy of the same has already been handed over to you by SAI in person, you are hereby provisionally stopped from participation in any Competition in athletics with immediate effect.

To be eligible for participation, you are further advised to follow the annexed IAAF guidelines (Copy enclosed).

Yours sincerely

(C.K. Valson)

Secretary, AFI

- 28. The Decision Letter did not contain any further information about the basis of the Athlete's suspension, the content of the medical reports referred to in the first sentence of the letter, or the Athlete's rights of appeal. According to the Athlete, the letter incorrectly enclosed the IAAF Sex Reassignment Regulations rather than the Hyperandrogenism Regulations.
- 29. On 18 September 2014, the Athlete sent a letter to the Secretary General of the AFI asking the AFI to reconsider the decision to revoke her eligibility to participate in all international or national athletics competitions. The letter stated, *inter alia*, that:

The high androgen level produced by my body is natural. I have not doped or cheated. If I follow the IAAF guidelines you have attached, I will have to undergo medical intervention in order to reduce my naturally-produced androgen level. Experts tell me that the basis for this policy is unscientific and that these interventions are invasive often irreversible and will harm my health now and into my future. I feel perfectly healthy and I have no health complaints so I do not want to undergo these procedures because the experts also tell me they are likely to have serious side effects. I also understand that these interventions will most likely decrease my performance level because of the serious side effects and because they will interfere with the way my body has worked my whole life. Also, I am unable to understand why I am asked to fix my body in a certain way simply for participation as a woman. I was born a woman, reared up as a woman, I identify as a woman and I believe I should be allowed to compete with

other women, many of whom are either taller than me or come from more privileged backgrounds, things that most certainly give them an edge over me.

I request that you allow me to compete again in national events without having to undergo medical intervention. I also request you to allow me to be a part of the Indian team in international competitions. The IAAF policy has a provision that says you can make me provisionally eligible while I contest my case.

I understand that IAAF may have asked you for my medical reports and records, but I request you not to share my private and confidential medical reports and information with the IAAF or any other organization without my consent.

I have spent nearly half of my life working hard to excel in athletics and to make my country proud. I hope I am allowed to continue to do so without feeling coerced to undergo medical intervention for participation as a woman.

Please allow me to run competitively. If you feel that you are compelled by the IAAF to go ahead with the suspension, I request you to support my appeal to the Court of Arbitration for Sport.

- 30. On the same day 18 September 2014 Mr Thomson wrote to Mr Valson reiterating the SAI's intention "to support [the Athlete] in her appeal to Court of Arbitration for Sport for reinstatement in competitive sports at the national and international levels". The letter asked the AFI to reconsider its decision to disqualify the Athlete. It added that: "the IAAF policy on hyperandrogenism is unscientific, unfair and unethical. The medical intervention recommended to reduce an athlete's natural androgen is also invasive, irreversible and harmful. We appreciate [the Athlete's] courage to appeal the decision."
- 31. The SAI's letter went on to note that the Athlete "has great potential of excelling in athletics internationally" and explained that SAI had therefore included her into a training programme at the National Institute of Sport's Centre of Excellence. It requested the AFI to support the Athlete's efforts to resume competing by allowing her to compete nationally and internationally without asking her to undergo any medical intervention. The letter added that, if the AFI felt compelled by the IAAF to proceed with the suspension, it should support the Athlete's appeal to the CAS.

B. The Issues

- 32. The issues that arise for determination by the CAS Panel in this appeal may be summarised as follows:
 - (a) Do the Hyperandrogenism Regulations discriminate impermissibly against certain female athletes on the basis of: (i) a natural physical characteristic; and/or (ii) sex?
 - (b) Should the Hyperandrogenism Regulations be declared invalid on the basis that there is insufficient scientific evidence: (i) that endogenous testosterone improves athletic performance in female athletes; and/or (ii) that 10 nmol/L is the scientifically correct threshold at which female athletes are in the "male range" of endogenous testosterone and therefore enjoy the benefits of male levels of androgens?
 - (c) Are the Hyperandrogenism Regulations disproportionate in the context of: (i) the fact they discriminate on the basis of a natural physical characteristic and/or sex; and/or (ii) the harm they cause to female athletes?
 - (d) Are the Hyperandrogenism Regulations invalid because they are a form of unauthorised anti-doping sanction in violation of Articles 4.3.3, 10 and 23.2.2 of the World Anti-Doping Agency Code?
 - 33. In addition to those issues, the Athlete raised a further issue concerning the AFI's failure to follow the procedures prescribed by the Hyperandrogenism Regulations when suspending her right to participate in competitive athletics. For the reasons described below, the Panel is not required to address that particular issue.
 - 34. The issues listed above give rise to three important related procedural issues concerning the burden and standard of proof. Specifically:
 - (a) Burden of proof Which party bears the burden of proof in relation to establishing the validity/invalidity of the Hyperandrogenism Regulations? Is the burden of proof the same in relation to each of the four grounds of challenge?

- (b) Standard of proof What standard of proof must the party who bears the burden of proof satisfy? Specifically, must the party establish its case (i) on the balance of probabilities; or (ii) to the comfortable satisfaction of the Panel?
- (c) Deference to the IAAF In considering the Athlete's challenge to the Hyperandrogenism Regulations, is the IAAF entitled to any deference or margin of appreciation in recognition of its particular responsibility and expertise as the worldwide regulator for the sport of athletics?
- 35. At the outset, it is important to record that the Panel is not called upon to answer this case in a vacuum. There are a number of matters that are accepted by the parties as part of the background and framework of the Hyperandrogenism Regulations:
 - (a) Athletics competition events are, for reasons of fairness, divided into events for male and female athletes.
 - (b) Female athletes participate in female but not male events. Likewise, male athletes participate in male but not female events.
 - (c) There is a substantial difference in athletic performance between elite male athletes and elite female athletes. Male athletes are, on average, faster and more powerful than female athletes.
 - (d) The division according to the sex of the athlete is therefore appropriate and is for the benefit of female athletes and their ability to engage in meaningful competition by competing on a level playing field.
 - (e) Although athletics events are divided into discrete male and female categories, sex in humans is not simply binary. As it was put during the hearing: "nature is not neat". There is no single determinant of sex. There are people with differences in sexual development ("DSDs") who do not biologically fall neatly into the traditional categories of women and men.
 - (f) Nevertheless, since there are separate categories of male and female competition, it is necessary for the IAAF to formulate a basis for the division

- of athletes into the male and female categories for the benefit of the broad class of female athletes. The basis chosen should be necessary, reasonable and proportionate to the legitimate objective being pursued.
- (g) It is inappropriate to subject athletes to gender verification; or to mere examination of external genitalia; or to chromosomal testing in order to determine eligibility to compete as women or for the purpose of making a determination about their sex or gender status.
- (h) Male advantage in athletics is primarily attributable to greater lean body mass ("LBM") in men. The difference in LBM between men and women begins at puberty.
- (i) Most males have significantly higher levels of endogenous (i.e. naturally occurring) testosterone than females.
- (j) Male and female athletes who take exogenous testosterone have an unfair advantage because exogenous testosterone improves athletic performance. The ban on exogenous testosterone is therefore justified for all athletes.
- (k) The criteria in the Hyperandrogenism Regulations that render a woman ineligible to compete in the female category are: first, a level of endogenous testosterone greater than 10 nmol/L; and then a physical examination which itself includes different criteria to assess androgen sensitivity/androgen insensitivity by the extent of virilisation. (Androgen sensitivity refers to the body's responsiveness to testosterone.)
- 36. In addition to the matters listed above, a number of important facts about this particular case are not in dispute. Dutee Chand is a woman. It is also not suggested that she has ever taken exogenous testosterone or any other banned or illegal substance. The case has proceeded on the assumption that Dutee Chand has an endogenous level of testosterone greater than 10 nmol/L although the actual level has not been established. She has not undergone the three-stage medical assessment process including any physical examination provided for in the Hyperandrogenism Regulations.

37. In addition, there is no suggestion that the IAAF or any of the individuals involved in drafting and implementing the Hyperandrogenism Regulations have acted in bad faith, either in relation to the enactment of the Regulations in general or in relation to the specific circumstances of the Athlete's case. The Athlete accepts that the IAAF adopted the Hyperandrogenism Regulations in good faith and in the genuine belief that the rules and procedures contained in the Regulations serve the best interests of the sport of athletics.

C. The relevant regulations

38. Before summarising the parties' respective submissions, the Panel sets out the relevant provisions of the IAAF and IOC governing statutes and the relevant IAAF regulations.

The Olympic Charter

- 39. The relevant Fundamental Principles of Olympism in the Olympic Charter provide:
 - (2) The goal of Olympism is to place sport at the service of the harmonious development of humankind, with a view to promoting a peaceful society concerned with the preservation of human dignity.
 - (4) The practice of sport is a human right. Every individual must have the possibility of practising sport, without discrimination of any kind and in the Olympic spirit, which requires mutual understanding with a spirit of friendship, solidarity and fair play.
 - (6) The enjoyment of the rights and freedoms set forth in this Olympic Charter shall be secured without discrimination of any kind, such as race, colour, sex, sexual orientation, language, religion, political or other opinion, national or social origin, property, birth or other status.¹

¹ The wording of this principle was amended by the 127th IOC Session on 8th December 2014. Prior to that change, principle (6) read: "Any form of discrimination with regard to...a person on grounds of race, religion, politics, gender or otherwise is incompatible with belonging to the Olympic movement." The Panel does not consider that the change in language has any impact on the outcome of this case.

IAAF Constitution

40. Article 3 of the IAAF Constitution sets out the objects of the IAAF. These include the following objectives in relation to discrimination and equal participation:

The Objects of the IAAF are:

[...]

- 2. To promote the sport of Athletics and its ethical values as an educational subject and life affirming and life enhancing activity.
- 3. To encourage participation in Athletics at all levels throughout the world regardless of age, gender or race.
- 4. To strive to ensure that no gender, race, religious, political or other kind of unfair discrimination exists, continues to exist; or is allowed to develop in Athletics in any form, and that all may participate in Athletics regardless of their gender, race, religious or political views or any other irrelevant factor.

The IAAF Regulations Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition

- 41. The IAAF enacted the Hyperandrogenism Regulations in April 2011. The Regulations establish "a framework for the determination of the eligibility of females with Hyperandrogenism to participate in International Competitions (as defined in IAAF Rules) in the female category" (Regulation 1.1). According to Regulation 1.4, the Hyperandrogenism Regulations "replace the IAAF's previous Gender Verification Policy and the IAAF has now abandoned all reference to the terminology "gender verification" and "gender policy" in its Rules".
- 42. The Hyperandrogenism Regulations are of "mandatory application" to all female athletes who compete or seek to compete in international athletics competitions. In addition, they are also "recommended as a guide to National Federations" for the management of cases that arise at national level (Regulation 1.2).
- 43. The Preface to the Hyperandrogenism Regulations contains the following explanation of the context and purpose of the regulatory regime:

Since 1928, competition in Athletics has been strictly divided into male and female classifications and females have competed in Athletics in a separate category designed to recognize their specific physical aptitude and performance.

The difference in athletic performance between males and females is known to be predominantly due to higher levels of androgenic hormones in males resulting in increased strength and muscle development.

It is also known from experience that there are rare cases of young females competing in Athletics today who are affected by hyperandrogenism which, if the condition remains undiagnosed or neglected, can pose a risk to health. Despite the rarity of such cases, their emergence from time to time at the highest level of women's competition in Athletics has proved to be controversial since the individuals concerned often display masculine traits and have an uncommon athletic capacity in relation to their fellow female competitors.

The Regulations set out to formulate a reasonable and suitably adapted approach by the IAAF to the management of such cases in Athletics and are predicated upon the following underlying principles:

- The early prevention of problems associated with hyperandrogenism;
- A respect for confidentiality in the medical process and the need to avoid public exposure of young females with hyperandrogenism who may be psychologically vulnerable;
- The evaluation of complex cases on an anonymous basis through the use of a panel of independent international medical experts in the field;
- A respect for the very essence of the male and female classifications in Athletics;
- A respect for the fundamental notion of fairness of competition in female Athletics;
- An acknowledgment that females with hyperandrogenism may compete in women's competition in Athletics subject to compliance with IAAF Rules and Regulations.

44. Regulation 1.3 provides that:

No female with hyperandrogenism shall be permitted to compete in the female category of an International Competition until her case has been evaluated by the IAAF in accordance with these Regulations.

45. Chapter 2 is entitled "The initial notification/investigation of cases under the Regulations". It sets out the circumstances in which, and the processes by which, a

female athlete may be investigated for possible hyperandrogenism. Regulation 2.1 states that:

Any female athlete with hyperandrogenism who seeks to compete in an International Competition shall be required to notify the IAAF so that her case can be evaluated in accordance with these Regulations. This applies both to athletes with hyperandrogenism who have been diagnosed and to those who are still in the course of diagnosis. Notification shall be made in strict confidence to the IAAF Medical Manager (a physician), either directly or via her National Federation's team doctor or other supervising physician.

46. Regulation 2.2 empowers the IAAF Medical Manager to undertake a confidential investigation if there are "reasonable grounds for believing" that a female athlete may have hyperandrogenism:

In addition, the IAAF Medical Manager may initiate a confidential investigation of any female athlete if he has reasonable grounds for believing that a case of hyperandrogenism may exist. The IAAF Medical Manager's reasonable grounds for belief in a case may be derived from any reliable source, including:

- 2.2.1 an athlete making an approach to the IAAF or her National Federation for advice or clarification on an associated medical condition, either in person or through her personal doctor or other appointed representative;
- 2.2.2 the results of a routine pre-participation or other medical examination conducted by an athlete's National Federation;
- 2.2.3 a report from a Doping Control Office following a routine doping control procedure;
- 2.2.4 the analytical results from a routine anti-doping test revealing an atypical steroid profile or abnormal profile within the Athlete's Biological Passport; or
- 2.2.5 information received by the IAAF Medical Delegate or other responsible medical official at a competition.
- 47. Chapter 3 contains rules concerning the "Confidential management of cases". All cases managed under the Hyperandrogenism Regulations must be treated in "strict confidence" (Regulation 3.1). As a necessary pre-condition of eligibility to complete, the athlete being investigated "shall consent to the disclosure of her medical information to such person or persons as may be required to review such information in accordance with these Regulations" (Regulation 3.2). The IAAF Medical Manager and members of the IAAF Medical Department involved in the management of cases under the

Regulations shall conduct all of their activities in "strict confidence" at all times (Regulation 3.3).

- 48. Chapter 4 contains provisions concerning the establishment and functioning of an Expert Medical Panel. The Panel consists of a pool of IAAF-appointed "independent medical experts" who are responsible for reviewing cases referred to it under the Hyperandrogenism Regulations (Regulation 4.1).
- 49. Chapter 5 establishes a three-stage medical assessment process for hyperandrogenism investigations under the Regulations. Regulation 5.1 provides:

Cases may be investigated under these Regulations according to the following three levels of medical assessment:

(i) Level 1 – Initial Clinical Examination

Level 1 provides for an initial clinical examination of the athlete and the compilation of specific clinical and anamnestic data.

(ii) Level 2 – Preliminary Endocrine Assessment

Level 2 provides for a preliminary endocrine assessment carried out on urine and blood samples (serum) collected from the athlete and analysed in an accredited laboratory.

(iii) Level 3 – Full examination and diagnosis

Level 3 provides for a full examination and whenever possible diagnosis of the athlete carried out by a specialist reference centre appointed by the IAAF.

Note: These Regulations merely set out an overall framework for the management of cases that might arise. The specific procedure to be adopted in each case will depend on the nature, timing and/or complexity of the individual case and these Regulations should be read accordingly. For example, depending on the circumstances of the case, the Level 1 and Level 2 examinations may be performed together, alternatively, the athlete may be referred directly to Level 3. If an athlete with hyperandrogenism has already been diagnosed prior to the entry into force of these Regulations, depending on the available data for the athlete, the IAAF Medical Manager may decide that no further medical assessment under these Regulations is required.

50. Regulations 5.2 – 5.6 set out the procedure for the "Level 1 - Initial Clinical Examination". The examination "shall be conducted in accordance with the Medical Guidelines" contained in Appendix 2 (Regulation 5.3). Before the examination begins,

the examining physician must explain the purpose of the examination and explain that it is part of a process to be conducted under IAAF Rules in accordance with the Hyperandrogenism Regulations (Regulation 5.4). Following the conclusion of the initial examination, the results of the examination and compilation of clinical and anamnestic data shall be transmitted confidentially to the athlete's designated physician and the IAAF Medical Manager (Regulation 5.6).

- 51. Regulations 5.7 5.18 govern the "Level 2 Preliminary Endocrine Assessment". At the second stage of the assessment process, an Athlete may be required to provide urine and blood samples for hormonal analysis at an accredited laboratory in accordance with the Medical Guidelines (Regulation 5.8). The laboratory's report must be transmitted confidentially to the athlete's designated physician and the IAAF Medical Manager (Regulation 5.12).
- 52. After Levels 1 and 2 are complete, the IAAF Medical Manager must conduct an initial review of any results obtained from the medical assessment in order to decide whether to refer the athlete's case for independent review by an Expert Medical Panel (Regulation 5.13).
- If a case is referred to an Expert Medical Panel, the Panel shall review the athlete's medical information and data and shall determine either that (i) no further medical assessment is required; or (ii) if there are "grounds to indicate an athlete with hyperandrogenism", to proceed to full examination and diagnosis under Level 3 (Regulation 5.21). If the Expert Medical Panel decides to refer a case to a full Level 3 examination, it may make a recommendation to the IAAF as to whether the athlete should be declared provisionally eligible to compete in women's competition while further assessments are undertaken. The IAAF Medical Manager must then make a decision on the athlete's provisional eligibility (Regulation 5.23).
- 54. Regulations 5.26 5.31 govern the procedure for the "Level 3 Full Examination and Diagnosis". If the Expert Medical Panel so determines, the athlete shall be required to submit to a full examination at an IAAF-approved specialist reference centre so that a "final and precise diagnosis of the athlete" may be carried out (Regulation 5.26). Before conducting the Level 3 examination, the examining physician must explain the purpose

of the examination, the nature of the testing and the potential consequences of the examination both for the athlete's health and for her eligibility in athletics. The athlete must provide "informed written consent" to the examination (Regulation 5.28).

- 55. The specialist medical centre where the Level 3 examination is undertaken "shall conduct a full examination on the athlete and shall carry out a diagnosis of the athlete in accordance with best medical practice". The examination "shall normally include the following different types of test: physical, laboratory (including genetic testing), imaging and psychological assessment" (Regulation 5.29). Following completion of the full Level 3 examination, the athlete's diagnosis and prescribed medical treatment, together with all results obtained from the examination, must be transmitted confidentially to the athlete's designated physician and the IAAF Medical Manager (Regulation 5.31).
- 56. Chapter 6 of the Hyperandrogenism Regulations is headed "Recommendation of Expert Medical Panel on Athlete's Eligibility". After the athlete's diagnosis has been carried out under the Level 3 assessment, if the athlete intends to continue competing in athletics then the IAAF Medical Department must forward to the Expert Medical Panel all further results obtained from the Level 3 examination to enable the Panel to make "an informed recommendation on her eligibility to compete in women's competition" (Regulation 6.1).

57. Regulation 6.5 provides that:

The Expert Medical Panel shall recommend that the athlete is eligible to compete in women's competition if:

- (i) she has androgen levels below the normal range; or
- (ii) she has androgen levels within the normal range but has an androgen resistance such that she derives no competitive advantage from having androgen levels in the normal male range.
- 58. The Regulation goes on to specify the lower limit of "the normal range":

Androgen levels for the purposes of paragraph 6.5 are measured by the levels of Total Testosterone in serum.

Normal male range Total Testosterone Levels - ≥ 10 nmol/L

(Underlining original)

59. Regulation 6.6 places a hyperandrogenic athlete under a burden of proving (where applicable) that her body is resistant to androgens and therefore her naturally elevated testosterone levels do not confer any competitive advantage:

The burden of proof shall be on the athlete to establish, where applicable, that she has an androgen resistance such that she derives no competitive advantage from androgen levels in the normal male range and the standard of proof in such a case shall be by a balance of probabilities.

- 60. Regulation 6.7 provides that when the Expert Medical Panel is making its recommendation in accordance with the criteria in Regulation 6.5, the applicable standard of proof "shall be to the comfortable satisfaction of the Panel".
- 61. Regulation 6.8 sets out the Expert Medical Panel's obligations if it decides that an athlete does not meet the criteria in Regulation 6.5:

If the Expert Medical Panel's recommendation is that the athlete does not meet the criteria in paragraph 6.5, it shall provide its reasons in writing and may further recommend:

- 6.8.1 conditions under which it would be acceptable for the athlete to compete in women's competition; and
- 6.8.2 a schedule of monitoring of the athlete's prescribed medical treatment with a view to the athlete returning to competition once she meets the conditions so determined [Return to Competition Monitoring]."
- 62. Under Regulation 7.1, the IAAF Medical Manager is responsible for making a final decision on the athlete's eligibility to compete, taking into account the recommendation made by the Expert Medical Panel.
- 63. Regulation 7.3 provides:

The IAAF may decide that the athlete shall be eligible to compete in women's competition subject to meeting any conditions for competition as recommended by the Expert Medical Panel. In this event, the athlete shall not be eligible to compete until such conditions have been met, including her compliance with any schedule of Return to Competition Monitoring.

64. The Hyperandrogenism Regulations contain a number of Appendices. Appendix 2 contains "Medical Guidelines for the Conduct of Level 1 and Level 2 Examinations". This includes an Introduction which explains that:

Hyperandrogenism in female athletes is a clinical condition that should always be thoroughly investigated to ensure a clear diagnosis.

Except for idiopathic hirsutism, virilisation results from the presence of abnormally high levels of androgens, the principal androgenic hormone being testosterone. The cause of the raised level may be either endogenous (e.g., a tumor or functional endocrine disorder) or it may be exogenous (oral or parenteral administration of synthetic androgens). There is a medical consensus supporting early diagnosis and follow-up of all cases.

Hyperandrogenism is associated with certain specific clinical features, including hyperseborrhea, acne and hirsutism. In more severe cases, there may be hoarseness and deepening of the voice, alopecia, muscular hypertrophy and clitoromegaly.

Moderate hyperandrogenism is not uncommon in women, and is usually linked to hormonal dysfunction. Its consequences will have different expressions according to the age of the patient and the date of onset. Polycystic Ovarian Syndrome (PCOS) is the most common diagnosis, often associated with menstrual disturbances and infertility. Early diagnosis can often help to improve these conditions, avoid metabolic disorders, and possibly reduce the risk of later cardiovascular events and gynaecological cancers.

The development of hyperandrogenism depends on both an excessively high level of circulating androgen and normal androgen sensitivity of the receptor tissues.

Appendix 2 goes on to provide a list of the main elements used for screening, evaluation and referral for more specialist care. The list directs attention to the individual's family history; birth history; pubertal history (including menstruation characteristics); medical history and medication. It also sets out a number of factors to be considered during a physical examination. These include a general examination of build, height, weight, skin and circulation. It also includes examination of pubertal signs (including breasts and public hair) and genitalia. The genital examination includes measurements and palpation of the vagina (which may only be conducted by a gynaecologist or paediatrician), clitoral enlargement, abnormal size of labiae minor or majora; and anogenital distance.

- 66. Under the heading "Key points Which clinical signs suggest pronounced and chronicle hyperandrogenism?" a number of indicia are listed. They include: deep voice; breast atrophy; no menstruation (or loss of menses since several months); increased muscle mass; body hair of male type; no uterus; clitoromegaly. Appendix 2 also contains a "Hirsutism scoring sheet" and a Tanner-Whitehouse Scale containing descriptions and illustrations of five grades of breast size and pubic hair.
- 67. The Hyperandrogenism Regulations are accompanied by Explanatory Notes. The Notes provide the following explanation of the rationale underpinning the Regulations:

The IAAF's role as the international governing body for the sport of Athletics is first and foremost to guarantee the fairness and integrity of the competitions that are organised under its Rules. Men typically achieve better performances in sport because they benefit from higher levels of androgens than women and this is predominantly why, for reasons of fairness, competition in Athletics is divided into separate men's and women's classifications. By extension, since it is known today that there are rare cases of females with [hyperandrogenism] competing in women's competitions, in order to be able to guarantee the fairness of such competitions for all female competitors, the new Regulations stipulate that no female with [hyperandrogenism] shall be eligible to compete in a women's competition if she has functional androgen levels [testosterone] that are in the male range.

Moreover, from the athlete's health perspective, there is scientific consensus as regards the importance of determining the presence (and source) of high levels of androgens in females. The early diagnosis of [hyperandrogenism] is considered critical to an effective therapeutic strategy.

68. The Explanatory Notes add that the Hyperandrogenism Regulations will be kept under review:

Will the Regulations be kept under review?

Yes. In approving adoption of the new Regulations last month, the IAAF Council specifically commented upon the need to keep them under review, notably, in line with any future developments made in the science in this area. The Regulations should therefore be seen as a 'living' document that will be subject to review and updating from time to time as may be necessary.

IAAF Competition Rules 2014-2015

69. The IAAF Competition Rules 2014-2015 regulate the conditions on which athletes may compete in athletics. Rule 22 governs ineligibility for international and domestic competitions. It provides:

The following persons shall be ineligible for competitions, whether held under these Rules or the rules of an Area or member:

Any athlete, athlete support personnel or other person:

[...]

(d) who does not meet the eligibility requirements set out in Rule 141 or the Regulations thereunder

70. Rule 141 provides:

Sex categories

- 3. Competition under these Rules is divided into men's and women's classifications. When a Mixed Competition is organised outside the stadium or in one of the limited cases set out in Rule 147, separate men's and women's classification results should be declared or otherwise indicated.
- 4. An athlete shall be eligible to compete in men's competition if he is recognised as a male in law and is eligible to compete under the Rules and Regulations.
- 5. An athlete shall be eligible to compete in women's competition if she is recognised as a female in law and is eligible to compete under the Rules and Regulations.
- 6. The Council shall approve Regulations to determine the eligibility for women's competition of
 - (a) females who have undergone male to female sex reassignment; and
 - (b) females with hyperandrogenism.

An athlete who fails or refuses to comply with the applicable Regulations shall not be eligible to compete.

The World Anti-Doping Code

71. The World Anti-Doping Code (the "WADA Code") is the governing document of the World Anti-Doping Program. The Code seeks to "ensure harmonized, coordinated and

effective anti-doping programs at the international and national level with regard to detection, deterrence and prevention of doping".

72. Part One of the WADA Code establishes mandatory anti-doping rules and principles. Article 4 makes provision for the publication of a "Prohibited List" of banned substances. The Prohibited List identifies substances and methods that are prohibited at all times because of their potential to enhance competitive performance or to mask other performance-enhancing substances (Article 4.2.1). Article 4.3 sets out the criteria that WADA must consider when it is deciding whether to include a substance or method on the Prohibited List. Article 4.3.3 provides that:

WADA's determination of the Prohibited Substances and Prohibited Methods that will be included on the Prohibited List and the classification of substances into categories on the Prohibited List is final and shall not be subject to challenge by an Athlete or other Person based on an argument that the substance or method was not a masking agent or did not have the potential to enhance performance, represent a health risk, or violate the spirit of sport.

- 73. Article 10 regulates the possible sanctions for anti-doping violations. Article 10.2 provides that in cases concerning the presence, use or possession of prohibited substances, the penalty for a first violation shall be two years' ineligibility.
- 74. Article 23 contains provisions concerning implementation of the WADA Code. Article 23.2.2 provides:

The following Articles (and corresponding Comments) as applicable to the scope of the anti-doping activity which the Anti-Doping Organization performs must be implemented without substantive change (allowing for any non-substantive changes to the language in order to refer to the organization's name, sport, section numbers, etc.):

- Article 1 (Definition of Doping)
- Article 2 (Anti-Doping Rule Violations)
- Article 3 (Proof of Doping)
- Article 4.3.3 (WADA's Determination of the Prohibited List)
- Article 10 (Sanctions on Individuals)

No additional provision may be added to a Signatory's rules which changes the effect of the Articles enumerated in this Article.

IV. PROCEEDINGS BEFORE THE COURT OF ARBITRATION FOR SPORT

- 75. On 26 September 2014, the Athlete filed her Statement of Appeal with the CAS Court Office pursuant to Article R48 of the Code of Sports-related Arbitration (the "CAS Code"). Within such Statement of Appeal, the Athlete nominated Professor Richard H. McLaren as an arbitrator and elected to proceed in English.
- On 6 October 2014, the CAS Court Office wrote to the parties acknowledging receipt of the Athlete's Statement of Appeal and directing the Athlete to file her Appeal Brief within 15 days of the expiry of the time limit for the appeal. The letter invited the Respondents jointly to nominate an arbitrator. In addition, it invited all parties to indicate whether they preferred the arbitration to remain confidential throughout the proceedings.
- 77. On the same day 6 October 2014 the Athlete's legal representative wrote to the CAS stating that the appeal "raises important issues of public interest and general application" and that the Athlete therefore did not agree to the arbitration proceedings being confidential (save in respect of her personal medical records, which she wished to remain private).
- 78. On 21 October 2014, the Respondents jointly nominated Dr Hans Nater as an arbitrator.
- 79. On 7 November 2014, the CAS Court Office wrote to the parties to confirm that, since the Respondents had not objected to English as the language of the arbitration procedure, all written submissions should be filed in English and any exhibits in any other language should be accompanied by an English translation.
- 80. On 17 November 2014, following agreed upon extensions of time, the Athlete filed her Appeal Brief with the CAS Court Office pursuant to Article R51 of the Code.
- 81. On 24 November 2014, the parties were informed that the panel appointed to decide this arbitration was as follows:

President:

The Hon. Justice Annabelle Claire Bennett

Arbitrators:

Professor Richard H. McLaren

Dr Hans Nater

82. On 25 November 2014, the Athlete filed a request for provisional relief with the CAS Court Office. The Athlete sought an order permitting her to compete in athletics events until a decision was rendered in her appeal. The request stated that the Athlete was "under significant pressure to undergo medical intervention from her major sponsor". It explained that after several months of being suspended from competing, the Athlete was giving serious consideration to undergoing medical treatment instead of pursuing her appeal. In these circumstances, provisional measures were said to be necessary in order to protect the Athlete from irreparable harm.

- 83. On 28 November 2014, the CAS notified the parties that Mr Edward Craven, barrister in London, United Kingdom, had been appointed to act as *ad hoc* clerk in the CAS proceedings.
- 84. On 3 December 2014, the IAAF wrote to the CAS in response to the Athlete's request for provisional relief. The letter contained a short overview of the IAAF's position concerning the validity of the Hyperandrogenism Regulations. The letter went on to state that, without prejudice to its position on that issue, the IAAF did not object to the Athlete participating in national-level competitions while awaiting the outcome of the CAS proceedings. The letter confirmed that, following discussions with the AFI, the AFI's position was the same.
- 85. The same day, the CAS wrote to the parties stating that, in light of the Respondents' agreement to permit the Athlete to compete in national-level events, the Athlete was permitted to compete at all national-level events pending the issuance of a Final Award in the proceedings.
- 86. On 18 December 2014, the Secretary of the AFI wrote a letter confirming that the Athlete would be permitted to compete in state-level and national-level athletics events pending the determination of her appeal by the CAS.

- 87. On 22 January 2015, the Athlete filed an application requesting a public hearing of the CAS proceedings. The application requested that the hearing before CAS take place in public and that the material filed by the parties be made publicly accessible.
- 88. On 4 February 2015, the IAAF wrote to CAS stating that the IAAF and AFI had objected to the Athlete's request for a public hearing and that, as a result, the CAS had no power to order a public hearing.
- 89. On 6 February 2015, following agreed upon extensions of time, the IAAF filed its Answer pursuant to R55 of the Code.
- On 16 February 2015, the IAAF requested the CAS to order the Athlete to produce certain documents, namely the recommendations that Dr Payoshni Mitra had submitted to the Indian Government in connection with the creation of the Government's "Standard Operative Procedure to identify circumstances (female hyperandrogenism) in which a particular sports person will not be eligible to participate in competitions in the female category". The Athlete responded by letter dated 17 February 2015. The letter stated that the Athlete agreed to the disclosure of the documents, however it reiterated the Athlete's position that the formation and content of the Standard Operative Procedure was irrelevant to the issues in the appeal.
- 91. On 17 February 2015, the CAS notified the parties that, barring an agreement between the parties, the Athlete's request for a public hearing was denied in accordance with Articles R44.2 and R57 of the CAS Code.
- 92. On 6 March 2015, the Athlete filed a motion under Article R56 of the Code seeking permission to file a witness statement from Ms Madeleine Pape, an Australian track and field athlete. The Athlete submitted that the new witness evidence satisfied the "exceptional circumstances" test for admissibility under Article R56 since: (a) the statement responded to the material filed by the IAAF which suggested, for the first time, that the "community of athletes" supports the Hyperandrogenism Regulations; (b) there had been a significant imbalance in the amount of time allocated to the parties to prepare their appeal materials.

- 93. On 13 March 2015, the IAAF wrote to CAS objecting to the admission of Ms Pape's witness statement. The IAAF submitted that there were no exceptional circumstances that would warrant filing the new witness evidence under Article R56 of the CAS Code. The IAAF asserted that the Athlete had mischaracterised the IAAF's case; had already had sufficient time to deal with the points covered in the statement when she filed her appeal papers; and was illegitimately seeking to use the statement as a vehicle to make further submissions and to adduce further scientific evidence in addition to what had already been submitted to the CAS.
- 94. On the same day, the Athlete filed a further Expert Report from Professor Holt and Dr van Anders. The Report addressed specific aspects of two of the witness statements filed by the IAAF.
- 95. On 18 March 2015, the Athlete submitted a signed copy of the Order of Procedure. The same day, the Athlete submitted a two-page witness statement from Ms Natasha Singh, the Manager of Marketing for the Anglian Medal Hunt Company ("Anglian"). Ms Singh's statement described the circumstances in which she accompanied the Athlete to a medical examination in Delhi in June 2014.
- 96. On 19 March 2015, the IAAF submitted a signed copy of the Order of Procedure.
- 97. On 20 March 2015, the Panel admitted the statement of Ms Pape.
- 98. On 23 26 March 2015, a hearing was held at the CCAS Court Office in Lausanne, Switzerland. The Panel was assisted by Mr Brent J. Nowicki, Counsel to the CAS, and Mr Edward Craven, Ad Hoc Clerk, and joined by the following:

For the Athlete:

- Mr Jim Bunting
- Mr Carlos Sayao
- Hon. Morris J. Fish Q.C.

For the IAAF:

- Mr Jonathan Taylor
- Ms Elizabeth Riley

- Mr Thomas Capdeville
- Dr Pierre-Yves Garnier

The AFI did not appear at the hearing and did not file any written submissions in response to the Athlete's Appeal Brief.

- 99. The following witnesses gave oral evidence at the hearing: (listed in the order of appearance)
 - Ms Dutee Chand
 - Dr Arun Mendiratta (by video)
 - Ms Natasha Singh
 - Professor Arne Ljungqvist
 - Professor Thomas Murray (by video)
 - Dr Payoshni Mitra
 - Professor Maria José Martinez-Patiño
 - Dr Katrina Karkazis
 - Ms Paula Radcliffe M.B.E. (by video)
 - Dr Sari van Anders (by video)
 - Professor Richard Holt
 - Professor Martin Ritzen
 - Professor Angelica Lindén Hirschberg
 - Dr Stéphane Bermon
 - Mr Nick Davies (by video)
 - Ms Madeleine Pape (by video)
- 100. Ms Joanna Harper participated in the hearing but did not give oral evidence.
- 101. At the inception of the hearing the parties confirmed that they had no objection to the constitution of the Panel and at the conclusion of the hearing the parties confirmed that their right to be heard had been fully and fairly respected.
- 102. On 26 March 2015, the Panel directed, with the concurrence of the counsel for the parties, that the Athlete would be permitted to compete in the Asian Athletics Championships on 3 7 June 2015. Such direction was confirmed with the parties by letter dated 10 April 2015.

V. SUBMISSIONS OF THE PARTIES

103. The parties' submissions, in essence, may be summarised as follows.

The relief sought

- 104. The Athlete's Statement of Appeal asks the CAS to grant the following relief:
 - (a) the Hyperandrogenism Regulation (sic) be declared invalid and void; and
 - (b) the Decision Letter be set aside and she be declared eligible to compete.
- 105. During the course of the hearing, the parties reached agreement that if the Panel were to invalidate the Hyperandrogenism Regulations, then the IAAF would communicate the outcome of the judgment to all of its member federations, who would then be required to amend their national implementing rules accordingly to reflect the invalidity of the Regulations. In light of that agreement, the parties agreed that it is unnecessary for the Panel to make a formal ruling upon request (b).

Preliminary issue: The burden and standard of proof

The Athlete's position

- 106. At the outset of the hearing, the Panel requested the parties to clarify their position in relation to the burden and standard of proof. In response, the Athlete's counsel accepted that the Athlete bore the onus of establishing that the Hyperandrogenism Regulations breach higher-ranking rules (namely the IAAF Constitution, the IOC Charter and the laws of Monaco). It is not disputed that the standard of proof is the balance of probabilities.
- 107. In relation to the specific issue of discrimination, the Athlete accepts that she bears the burden of proof in establishing unlawful discrimination. However, she submits that if a party establishes that a measure has a prima facie discriminatory effect, the burden shifts to the party responsible for the measure to justify the discrimination. Accordingly, if the Athlete succeeds in establishing that the Hyperandrogenism Regulations are prima facie discriminatory then the burden shifts to the IAAF to establish that the discriminatory measure is a necessary and proportionate means of achieving a legitimate aim. The Athlete submits that the IAAF must establish that justification to the comfortable satisfaction of the Panel.
- 108. In relation to the question of deference, the Athlete submits that where a regulation is inconsistent with a higher-ranking legal rule such as a constitutional principle or the

Olympic Charter – the CAS jurisprudence establishes that the regulation must be declared invalid (citing <u>IRIFF v FIFA</u>, CAS 2008/A/1708 and <u>United States Olympic Committee v International Olympic Committee</u>, CAS 2011/O/2422). Since the critical question is whether a lower-ranking rule conflicts with a higher-ranking rule, the Athlete contends that the IAAF is not entitled to any special deference or margin of appreciation in defending the Hyperandrogenism Regulations.

The IAAF's position

- 109. The IAAF agrees that the Athlete bears the onus of establishing that the Hyperandrogenism Regulations are invalid. The IAAF also agrees that if (which it accepts) the Regulations are *prima facie* discriminatory, the burden shifts to the IAAF to justify that discrimination.
- 110. The IAAF accepts that its view of what constitutes a sporting imperative, and its assessments of necessity and proportionality, must be honestly and reasonably held. However, it submits further that provided those conditions are satisfied, it is irrelevant that other persons may take a different view. In the IAAF's submission, the judgment of a sports governing body must not be interfered with unless it is shown to be "evidently and grossly disproportionate" (FIFA & WADA, CAS 2005/C/976 & 986, para 143) or "irrational or perverse or otherwise outside the margin of discretion" available to the regulator (Sheffield United v FAPL, FAPL Arbitration Award, 3 July 2007, para 38).
- 111. Accordingly, the IAAF submits that the burden is on the Athlete to show that a reasonable person acting in good faith could not take the view that the eligibility rule is necessary and appropriate. It says that she is unable to do this. Alternatively, even if the IAAF bears the burden of establishing the validity of the Regulations, in light of the broad margin of appreciation that regulators enjoy in this context, the IAAF says that it has to do no more than persuade the Panel that the assumptions underlying the Hyperandrogenism Regulations are supported in good faith by competent scientists.

Issue 1: Discrimination

The Athlete's submissions

- 112. The Athlete submits that the Hyperandrogenism Regulations violate the antidiscrimination provisions contained in the Olympic Charter, the IAAF Charter and international human rights law. Specifically, the Athlete submits that the Hyperandrogenism Regulations discriminate unlawfully against some female athletes on the basis of: (a) a natural physical characteristic; and/or (b) sex.
- 113. In relation to (a), the Athlete submits that the Hyperandrogenism Regulations discriminate against certain athletes based on a natural and essentially immutable physical characteristic, namely the quantity of testosterone their bodies produce without any artificial intervention. Any performance advantage that those athletes enjoy is the product of a natural genetic gift, which should not be viewed differently from other natural advantages derived from exceptional biological variation. Athletes are not prohibited from competing in sport because they possess other natural genetic advantages for example height, lung capacity, foot size or visual acuity above a certain limit. On the contrary, athletes who achieve sporting success are usually those who fall outside normal parameters. There is therefore no principled or permissible reason for prohibiting a female athlete from competing because of an unusual natural genetic trait, even if that trait confers an advantage over fellow female competitors who lack that trait.
- In relation to (b), the Athlete submits that the Hyperandrogenism Regulations discriminate against women, as there is no testosterone limit applicable to male athletes. Male athletes with testosterone levels falling above the upper limit of the "normal" range of male testosterone are permitted to compete without having to satisfy any medical criteria or to undergo any medical examination or treatment as a precondition to eligibility. Female athletes unlike their male counterparts must therefore satisfy an additional eligibility criterion before they are permitted to compete. The differential treatment between male and female athletes constitutes discrimination on grounds of sex and therefore contravenes the anti-discrimination provisions of the IAAF Constitution, the Olympic Charter and the laws of Monaco.
- In support of this argument, the Athlete points out that Monegasque law requires the IAAF to take all appropriate measures to eliminate discrimination against women.
 Under a Monegasque Ordinance dated 16 June 2005, the United Nations Convention on

the Elimination of All Forms of Discrimination Against Women was "fully executed" as part of Monegasque law. Article 13(c) of the Convention requires State Parties to

...take all appropriate measures to eliminate discrimination against women in other areas of economic and social life in order to ensure, on a basis of equality of men and women, the same rights, in particular... [t]he right to participate in recreational activities, sports and all aspects of cultural life.

116. The Athlete submits that, having established that the Hyperandrogenism Regulations have a clear discriminatory impact, the onus shifts to the IAAF to justify the discrimination. For these purposes, the Athlete accepts that pursuing fairness in sport is a legitimate objective. However, she disagrees with the IAAF's argument that the Regulations are designed to preserve a "level playing field" for the benefit of elite female athletes. She submits that a multitude of biological, psychological, sociological and economic factors influence athletic performance. It is therefore impossible to single out a particular factor. The Athlete challenges the IAAF's reliance on the perception of fairness held by the "community of athletes", pointing out that different athletes hold different views, and no single viewpoint can be attributed to the large and diverse body of elite female athletes.

The IAAF's submissions

- 117. The IAAF accepts that the Hyperandrogenism Regulations are a sex-based eligibility restriction and are therefore *prima facie* discriminatory on grounds of sex. Consequently, it accepts that it bears the burden of establishing that the discriminatory effect of the Regulations is justified as a necessary and proportionate means of achieving a legitimate objective. The IAAF submits that the principle of equal treatment requires like cases to be treated alike; however it also permits differentiation between objectively different situations where such differential treatment is necessary to protect fair competition. It says that it is with this principle firmly in mind that the Regulations must be assessed.
- 118. In light of the IAAF's concession, properly made, it is established that the Hyperandrogenism Regulations are *prima facie* discriminatory. The Panel addresses the issue of whether that discrimination is justified under Issue 3 below (see paragraphs 500 to 538).

Issue 2: The scientific basis of the Hyperandrogenism Regulations

The Athlete's submissions

- 119. In her written submissions, the Athlete submits that the Hyperandrogenism Regulations are founded on two fundamentally flawed factual premises, namely that: (a) elevated levels of natural testosterone give elite female athletes a performance advantage; and (b) medical science is presently capable of delineating distinct testosterone ranges for male and female athletes.
- 120. The Athlete contends that each of those propositions is wrong and not supported by the best available science. She therefore submits that the Hyperandrogenism Regulations should be declared void unless the IAAF can positively establish that both propositions are correct.
- 121. In relation to issue (a), two separate sub-issues were identified during the course of the hearing, namely: (i) whether there is any causal relationship between testosterone levels and athletic performance; and (ii) whether endogenous (i.e. naturally occurring) testosterone has the same physiological effect as exogenous testosterone (i.e. testosterone which is artificially introduced into the body from an external source).
- 122. In support of her argument in relation to proposition (a)(i), the Athlete relies on expert evidence that:
 - There is no convincing casual relationship between high endogenous testosterone and enhanced athletic performance in female athletes;
 - There are no published scientific studies that link athletic performance with testosterone concentration in women with hyperandrogenism; and
 - Factors other than endogenous testosterone are sufficient to account for differences in athletic performance between male and female athletes.
- 123. On a general level, the Athlete submits that the scientific evidence makes it clear that endogenous testosterone cannot be the basis for successful athletic performance. For example:

- Some high-level athletes have very low levels of testosterone, indicating that
 high testosterone is neither necessary nor sufficient to achieve top athletic
 performance.
- Some female athletes use hormonal contraceptives, which have the effect of lowering androgens but which do not adversely affect athletic performance.
- Some elite-level female athletes have complete or partial androgen insensitivity syndrome ("AIS"). Those individuals' bodies are either completely or partially unresponsive to testosterone. There is also an over-representation of female athletes with XY chromosomes within the elite athlete population. A number of those athletes have AIS, which means their enhanced levels of testosterone have no effect on athletic performance. The fact athletes with AIS are able to succeed at the highest level of professional sport indicates that testosterone must have no (or very limited) performance enhancing effects.
- 124. In relation to issue (a)(ii), the Athlete accepts that exogenous testosterone does improve athletic performance. The important question, she contends, is whether endogenous testosterone has the same effect. The Athlete submits that the human body reacts differently to exogenous testosterone and endogenous testosterone. The former involves the introduction of a new biochemical agent that upsets the body's equilibrium by dislodging its natural hormonal stasis, whereas the latter does not. Accordingly, the Athlete contends that data concerning the performance enhancing effects of exogenous testosterone do not allow the same conclusion to be drawn in respect of endogenous testosterone.
- 125. In support of her argument against proposition (b), the Athlete relies on expert evidence that:
 - The ranges of male and female testosterone levels overlap naturally;
 - Women who have testosterone levels in excess of the IAAF's threshold of 10 nmol/L fall within the normal female range for testosterone levels;

- The threshold of 10 nmol/l is flawed because there are no scientific norms for testosterone levels in healthy individuals across cultures;
- The 10 nmol/L threshold is flawed because testosterone levels are naturally dynamic and vary in individuals in response to an array of environmental, physiological and social factors.

The IAAF's submissions

- 126. For its part, the IAAF contends that the scientific evidence establishes that:
 - Testosterone is a significant determinant of athletic performance.
 - The physiological effects of exogenous testosterone and endogenous testosterone are identical.
 - Differences in testosterone levels are the most significant factor in explaining the performance differences between male and female athletes.
 - It is possible to identify a "female" range for normal testosterone levels. Female
 athletes do not have testosterone levels beyond that range unless they suffer
 from a difference of sexual development ("DSD") or have been doping.
- 127. The IAAF contends there is a strong body of scientific opinion that the main cause of male athletes' power, size and strength advantages over female athletes is the significantly higher levels of testosterone that males generate during and after puberty. This is evidenced, amongst other things, by the numbers of male and female athletes who illegally self-administer exogenous testosterone to build up their size, strength and power. However in rare cases, female athletes may have conditions which, through no fault of their own, cause their bodies to produce male rather than female levels of testosterone. Those conditions raise a concern that the affected athletes have a performance advantage over female athletes with normal levels of testosterone. Implicit in this submission is that this performance advantage equates to the male-over-female advantage.

- 128. The IAAF relies on the evidence of several expert scientific witnesses. On the basis of their understanding of the relevant scientific data, they conclude that higher testosterone levels in men are "the most important factor" in explaining the significant difference in physical performance between elite males and female athletes. According to their evidence, no other known factors demonstrate such a clear-cut difference between men and women. Accordingly, testosterone levels are "the best discriminating factor between male and female performance in sports".
- 129. The IAAF contends that this scientific assessment of the physiological function and athletic significance of testosterone is widely held within the scientific community. The IAAF's Answer Brief included extracts from a number of published scientific papers. To give three examples:
 - In 2008 Handelsman and Gooren wrote that: "segregation into separate but equal competitions aims to allow women a chance to win in events where the hormonally determined superiority of men in height, weight and strength would make it otherwise virtually impossible for women to win against men... The biological basis for gender segregation in sports is the consequence of long-term endogenous androgen exposure of men after puberty." (Hormones and sport, Asian Journal of Andrology (2008) 10, 348-350).
 - In 2010 Tucker and Collins wrote that: "performance differences between males and females... are attributed primarily to the hormone testosterone, produced in substantially higher concentrations by males at the onset of puberty, leading to increased muscle mass; increased cardiovascular and lung capacity; and increased strength, speed and power" (The science of sex verification and athletic performance, Int J Sports Physiol Perform, 2010, 5(2), 127 at 131 and 134).
 - In 2013 Sanchez et al stated that: "there is a trait that is known to influence one's athletic performance and which happens to be sexually dimorphic: Androgens. Although females produce androgens mainly secreted in their adrenal glands their androgen levels are markedly lower than the levels in males. Furthermore, androgens are known to influence one's athletic capabilities,

especially by increasing muscular development and strength." (The New Policy on Hyperandrogenism in Elite Female Athletes is not about "Sex Testing", Sex Res, 50, 112 at 3).

- 130. The IAAF defends the use of a testosterone threshold of 10 nmol/L on the basis of a number of considerations including: (i) studies which show a correlation between endogenous testosterone and sports performance; (ii) the proven substantial performance-enhancing effects of the testosterone administered to female athletes in the German Democratic Republic in the 1960s to 1980s; (iii) the fact that significant numbers of female athletes continue to dope themselves with testosterone because of its performance-enhancing benefits; (iv) the disproportionate representation of hyperandrogenic athletes in the elite female athlete population; and (v) data showing decreases in performance by elite hyperandrogenic female athletes following testosterone-suppression treatments; and (vi) the threshold of 10 nmol/L is a level that, in order of magnitude above the "normal" range for women, is within the "normal" range for men.
- 131. The IAAF also referred to data from two large population studies from international athletics competitions at Moscow in 2013 (the "Moscow data") and Daegu in 2011 (the "Daegu data"). According to the IAAF, the data show that under resting conditions, the normal range of testosterone levels in elite female athletes is the same as the range found in the general population (i.e. between 0.1 and 3.08 nmol/L). The IAAF is not aware of any data which show that a non-doped female athlete with normal gonadal and adrenal function could come anywhere close to reaching serum levels of testosterone of 10 nmol/L.
- 132. The IAAF also relied upon a view expressed by Professor Murray, who refrained from offering an opinion on any empirical questions concerning the physiological effect of endogenous testosterone, but proffered the following three general observations:
 - First, he commented that to the extent that scientific evidence supports the view
 that testosterone levels are a plausible marker for male performance advantage,
 then absent any more effective alternative it is justified to use testosterone levels
 to determine eligibility to compete in women's athletics.

- Second, he stated that the Athlete's submissions go too far in demanding that the IAAF must establish that 10 nmol/L is a "scientifically correct" threshold at which female athletes enter the male range of testosterone levels.
- Third, Professor Murray identified an apparent tension between the Athlete's
 suggestion that there is no scientific evidence that endogenous testosterone
 improves athletic performance and the Athlete's assertion that
 hyperandrogenism should not be treated differently from other natural
 advantages derived from biological variation.

Expert evidence

- 133. The panel was assisted by written reports and oral testimony from a number of expert witnesses who gave evidence for the parties. In advance of the hearing, two of the experts retained by the Athlete (Dr van Anders and Professor Holt) and one of the experts retained by the IAAF (Professor Ritzen) participated in a conference call to discuss the scientific issues covered by their expert reports. The three experts subsequently reported that they had reached agreement on the following three propositions:
 - (a) The amount of LBM is important for athletic performance (at least in some disciplines).
 - (b) Exogenously administered testosterone leads to an increase in LBM particularly when accompanied by physical activity.
 - (c) Either pharmacological or surgical reduction in testosterone leads to a reduction in LBM in men.
- 134. Accordingly, these propositions are not in dispute between the parties.

Professor Richard Holt (expert witness retained by the Athlete)

135. Professor Richard Holt produced a written expert report dated 14 November 2014. Professor Holt is a medical doctor with specific expertise in endocrinology. He is a Professor of Diabetes and Endocrinology at the University of Southampton. He has

previously advised a number of anti-doping agencies including WADA, the United States Anti-Doping Agency (USADA) and UK Anti-doping. Professor Holt produced his report in co-operation with Professor Peter Sonksen, another academic medical doctor with expertise in the field of endocrinology (Professor Sonksen did not testify at the hearing.). In addition to that Report, shortly before the hearing Professor Holt and Dr Sari van Anders produced a joint Reply Expert Report that responded to aspects of the IAAF's expert scientific evidence.

- 136. In his report, Professor Holt explained why, in his opinion, the Hyperandrogenism Regulations are "scientifically unsound". Professor Holt identified two scientific flaws in the assumption that elevated endogenous testosterone in female athletes confers a competitive advantage. First, endogenous testosterone does not explain the difference between male and female athletic performance. Second, there is no convincing evidence that endogenous testosterone enhances athletic performance in female athletes, including those with hyperandrogenism.
- about a recent multinational research project aimed at developing a test for growth hormone abuse in sport. The results of the study were published in the peer-reviewed Journal of Clinical Endocrinology and Metabolism. (See Healy et al, Endocrine profiles in 693 elite athletes in the post competition setting, Clin Endocrinol (Oxf (2014) 81(2):294-305)). The Healy study compared 24 variables between elite male and female athletes, including hormone levels and body fat. It found that a woman's LBM is, on average, proportionally and absolutely much lower than that of a man's. Healy et al assert the average 10kg difference between men and women's LBM sufficiently and exclusively accounts for the "observed differences in strength and aerobic performances seen between the sexes." As such, the authors say, there is no need to "hypothesize" that testosterone levels are a significant determinant of sport performance.
- 138. Professor Holt's premise was that endogenous testosterone is not an appropriate criterion on which to differentiate men from women competing in elite sport because there is an overlap in testosterone concentration between the sexes. He expressed the view that the value of 10 nmol/L as the lower limit of the "normal male range" is flawed

- and that the corresponding assumption that female athletes having total testosterone in serum above 10 nmol/L is also "scientifically untenable".
- 139. Professor Holt was also of the view that LBM is insufficient to account for differences in performance between elite male and elite female athletes. He said that endogenous testosterone is not an appropriate criterion on which to differentiate athletic performance.
- 140. Professor Holt addressed three questions:
 - (a) Do elevated endogenous testosterone levels lead to enhanced performance in female athletes?
 - (b) Does a value of 10 nmol/L total testosterone in serum represent the lower limit of "normal male range" for elite athletes?
 - (c) Are there other natural physical traits that are screened for by international sports federations as a basis for preventing an athlete from competing?
- 141. Professor Holt's expert report relied on the article by Healy et al and the results showing a very wide range of testosterone levels in both elite male and female athletes. The outcome is a complete overlap of endogenous testosterone levels between the sexes. He noted that, as reported in that article, 11 of 234 female athletes had endogenous testosterone levels above 8 nmol/L and all but one of these women had normal LH and FSH "which would suggest that at worst these results could only be explained by doping in one of the participants". Professor Holt relied on the scattering of results for female athletes with 32 of the 324 (17%) above the upper limit of the female reference range of 2.7 nmol/L. He argued that this conflicts with the assumption that it is possible to distinguish between men and women on the basis of serum testosterone and said that it showed that there is no clear separation between the endogenous testosterone levels of elite male and elite female athletes. He pointed out that, while on average men have higher testosterone than women, there are some women with high testosterone and some men, even elite athletes, with low testosterone. He drew on the analogy of height which, he pointed out, cannot be used alone to determine sex. He advanced the hypothesis that

- differences in athletic performance are not caused by sex differences in testosterone levels but by other factors.
- 142. Professor Holt accepted the differences in LBM recorded in the Healy study and that such differences are in keeping with the differences in world records. He also pointed to other factors likely to influence performance in female and male athletes, such as age, height and genetic factors, psychological factors and nutrition.
- 143. Professor Holt seemed to accept a reference range for women of less than 2.7nmol/L and for men between 8.4 and 29 nmol/L but noted that testosterone varies with age and said that there are insufficient data to define a reference range for elite athletes. Healy, the first to publish such a profile, reported that 16.5% of male elite athletes had serum testosterone values below 8.4 nmol/L and 13.7% of elite female athletes had serum testosterone above 2.7 nmol/L. He noted that in Bermon *et al*, the reported 99th percentile for testosterone in women was 3.08 nmol/L, excluding women with DSDs for whom the median level was 18.3 nmol.
- 144. He also said that in the Healy study, there was no correlation between testosterone levels and LBM in either men or women. LBM, he said, is determined largely by height and mass, both genetically determined.
- 145. Professor Holt believed that the Healy study is the first study of testosterone levels and endocrine profiles in elite athletes to be published in a peer-reviewed scientific journal. In his opinion, the results of the study showed that, "although the majority of values were within the expected reference ranges for each sex" there was "a very wide range of testosterone levels in both elite male and female athletes" which resulted in "a complete overlap of endogenous testosterone levels between the sexes".
- 146. In his report, Professor Holt stated that the wide dispersal of results conflicts with the assumptions which underpin the Hyperandrogenism Regulations, namely that it is possible to distinguish between men and women on the basis of serum testosterone levels. He explained that the results of the Healy study establish that "there is no clear separation between the endogenous testosterone levels of elite male and elite female athletes". This supports the theory that differences in athletic performance between males and females are not attributable to sex-based differences in testosterone levels,

but are instead due to other factors. In his view, the average difference in LBM is commensurate with the differences in male and female athletics world records. In addition, athletic performance is also likely to be influenced by age, height and genetic factors, psychological factors and nutrition.

- 147. Professor Holt stated that the overlap of testosterone levels between the sexes called into question whether a "male range" can be meaningfully distinguished from a "female range". On average men have more testosterone than women; however some women have high testosterone levels, while some men have low testosterone. Furthermore, even with elite male athletes the evidence does not demonstrate that 10 nmol/L is the lower end of the "normal male range". In this regard, Professor Holt stated that there are statistically significant differences in testosterone levels between participants in different sports.
- 148. On a more general level, Professor Holt said there are "insufficient data" on elite athletes to establish a proper reference range for men or women. To establish a scientific causal relationship, it would be necessary first to demonstrate that testosterone levels in a large cohort of elite female athletes correlate to athletic performance. However, even then such evidence would only establish association, not causation. Professor Holt noted that in 2013, Berman et al acknowledged that, "there are few published studies on the influence of endogenous testosterone and athletic performance in women". In 2014, they similarly noted that: "[t]he lack of definitive research linking female hyperandrogenism and sporting performance is problematic and represents another point of the controversy".
- 149. In his expert report, Professor Holt listed a number of other physical traits that have been proven to confer performance advantages on athletes. These include: (i) an inherited genetic defect in the EPO receptor, which results in high haemoglobin levels; (ii) tall stature, which offers advantages in a number of sports such as basketball and rowing; (iii) short stature, which offers an advantage in power-lifting and weight-lifting; (iv) low body mass index, which is advantageous for long-distance running and cross-country skiing; and (v) high lung capacity and large hands and feet, which are advantageous in swimming. Professor Holt concluded his report by stating that, apart from high natural testosterone in female athletes, neither he nor Professor Sonksen was

- aware of any natural physical trait that is screened for by any international sporting federation on the basis that it confers a competitive advantage.
- 150. In the Reply Expert Report, Professor Holt and Dr van Anders analysed the Daegu data and the Moscow data. According to their analysis, the Daegu data revealed there were 13 non-doped female athletes with testosterone levels above 3.08 nmol/L (the value cited by the IAAF's experts as the upper limit of the "female range"). In addition, there were four men with testosterone levels below 3.08 nmol/L and 198 men with testosterone below 10 nmol/L. The Dageu data confirmed Professor Holt's and Dr van Anders' opinion that there is an overlap between the testosterone levels of elite male and elite female athletes. The Moscow data tell a similar story. After removing doped female athletes, six women had testosterone levels above 3.08 nmol/L. Two male athletes had testosterone levels below 3.08 nmol/L and 131 men had testosterone below 10 nmol/L. Accordingly, Professor Holt and Dr van Anders concluded that the Moscow data also demonstrated an overlap between the sexes, although it was "not as pronounced as that shown by the Daegu data, in all likelihood due to the application of the Regulations".
- During his oral testimony, Professor Holt reiterated that there was "undoubtedly an overlap" between testosterone ranges for male and female athletes. For example, he stated that a significant number of men have testosterone levels lower than 10 nmol/L. There are also some men with testosterone levels in the so-called female range. The overlap was, he said, seen clearly in the study by Healy et al. Professor Holt acknowledged that the samples used in the Healy et al study had not been obtained for medical purposes and that no clinical data had been collected together with those data. He conceded it was "certainly possible" that some of the women with high testosterone levels may have been taking drugs. However, all of the participants had made a self-declaration that they were not taking drugs and, since the study was conducted voluntarily and anonymously, in his view it was likely they were telling the truth. Moreover, the study had been published in a prestigious peer-reviewed endocrinological journal.
- 152. Professor Holt said that the biggest difference between his analysis and that put forward by the IAAF's experts was whether to include outliers when defining the normal

reference range for endogenous testosterone levels. In Professor Holt's opinion, outliers ought to be included unless there is a good reason to exclude them. Elite athletes are, by definition, outliers. Professor Holt accepted that for clinical diagnostic purposes it would be appropriate to define the normal reference range as two standard deviations from the mean level of testosterone. However, he said, the reference range in sport performs a different and quite separate function that warrants a different approach. Professor Holt observed that testosterone levels are not generally measured in normal healthy individuals. Therefore, there are not enough samples to determine whether everyone with over 10 nmol/L endogenous testosterone must have a disorder. Moreover, Professor Holt suggested that not all DSDs require clinical attention and therefore some females with high testosterone levels may never visit an endocrinologist.

- 153. In relation to the Daegu data, Professor Holt noted that not all women in the 10 nmol/L plus range had a clinical DSD diagnosis or were shown to be doping. The Daegu data were in his opinion consistent with the Healy data.
- 154. On the issue of testing for androgen insensitivity, Professor Holt explained that a number of hormonal conditions can cause hormonal resistance. The clinical, endocrinal and molecular assessment of androgen insensitivity is very imprecise. There are several hundred mutations of androgen receptors and certain receptors have a greater effect than others. In his view, this variability and imprecision makes a 10nmol/L criterion unworkable.
- 155. According to Professor Holt there is "absolutely no doubt" that athletes who have doped with exogenous testosterone have experienced performance benefits. However, there is no demonstrated correlation between endogenous testosterone and LBM. In his opinion, exogenous testosterone and endogenous testosterone operate differently within the "extraordinarily complex" endocrinological system.
- 156. Professor Holt stated that a multitude of biological and sociological factors account for the difference between male and female athletic performance. Professor Holt noted that in general terms, men have approximately 10% more LBM than women. It is a "reasonable... hypothesis" that testosterone is the explanation for the difference. However, there are certainly a number of other factors that may also be important. For

example, different levels of growth hormone – which affects muscle mass and fat mass – may be an alternative or additional explanation. In Professor Holt's opinion, the available evidence does not yet establish that testosterone is the reason why men significantly outperform women in athletics competition. In Professor Holt's view, the IOC and IAAF did not undertake the appropriate studies prior to the enactment of the Hyperandrogenism Regulations. Accordingly, he concluded that "[t]he best available science does not support the assertion that differences in endogenous testosterone levels explain differences in performance between elite men and female athletes".

- 157. At the end of his oral testimony, Professor Holt drew a comparison between the evolution of growth hormone testing and the Hyperandrogenism Regulations. He said that tests for growth hormone were developed during the 1990s, but that they were not implemented until 2012. During the intervening period, scientists worked hard to establish the scientific proof needed to justify the implementation of a growth hormone testing regime. The present state of the scientific evidence in relation to the role of endogenous testosterone on athletic performance is, in his view, similar to the state of knowledge about the effects of growth hormone in the 1990s. In Professor Holt's opinion, the current state of evidence is "rudimentary" and there is a long way to go before the evidence can withstand satisfactory scientific scrutiny.
- 158. Professor Holt emphasised the absence of data demonstrating a causal link between elevated endogenous testosterone levels and enhanced performance in female athletes or, in particular, in elite female athletes. He said that extrapolation of the link between the administration of exogenous testosterone (at supra physiological levels) and athletic performance is not supported by the available science. He challenged the methodology and conclusions in Bermon *et al.* He also drew a distinction between "causation" and "association" in describing the kinds of tests that would be necessary positively to establish the link.

Dr Sari van Anders (expert witness retained by the Athlete)

159. Dr van Anders submitted a written expert report dated 14 November 2014. Dr van Anders is a tenured associate professor of psychology and women's studies at the University of Michigan. Dr van Anders has published a large number of peer-reviewed

articles related to testosterone and other topics. She has particular research expertise in social neuroendocrinology, which examines the relationship between hormones and social behaviour.

- 160. Dr van Anders began her report by explaining that three factors influence the effect of endogenous testosterone on a person's body, namely: (a) testosterone levels; (b) androgen receptor function; and (c) androgen receptor count/location. Factor (b) is static but varies between different individuals. Factors (a) and (c) are both dynamic (i.e. they change in response to internal, environmental and social factors) and also vary between people.
- 161. Dr van Anders listed a large number of factors that have a direct impact on variability of testosterone in individuals. They include: seasonality; time of day; sleep pattern and duration; age; medication, drugs and health; stress levels; body composition, muscle mass and weight; exercise; competition; relationship status and sexual activity; parental status; menstruation; hormonal contraceptives. Dr van Anders stated that "the vast majority" of research on testosterone has been conducted on men of European descent living in major cities. In her view it is "not clear" how far these findings may be generalised to other groups of individuals.
- 162. Dr van Anders' report compared the physiological effects of exogenous and endogenous testosterone. She stated that exogenous testosterone sometimes has the opposite effect of endogenous testosterone. For example, while the former increases the number of androgen receptors; the latter decreases them. In addition, increases in endogenous testosterone do not lead to the same enhancement of muscle growth as exogenous testosterone. It follows that in her opinion, "effects of high exogenous testosterone cannot be generalised to high endogenous testosterone".
- 163. According to Dr van Anders, the existing scientific research does not establish that endogenous testosterone is the basis for successful athletic performance. Authors frequently claim that higher testosterone levels account for higher athletic performance in men than women, while providing no scientific evidence in support. In her view, the scientific research shows that "endogenous testosterone cannot be the basis for successful athletic performance". She pointed out that there are elite-level male and

female athletes with low testosterone levels, that some athletes use hormonal contraceptives which lower androgens, and that some elite female athletes have complete or partial androgen insensitivity syndrome.

- 164. Dr van Anders' report discussed, briefly, the common association between testosterone and cultural notions of "masculinity". She explained that, although testosterone is tied to sex across many species including humans, cultural ideas about masculinity incorrectly assume that testosterone underlies all aspects of masculinity, whereas in humans, "testosterone is linked to competition, rather than masculinity, despite assumptions to the contrary". She relied on scientific research that shows that "masculinity is a social-level construct that is not dependent on testosterone". Moreover, "even maleness, an evolved heritable construct, is only partly related to testosterone".
- 165. In the conclusion to her report, Dr van Anders explained that because testosterone is dynamic and varies markedly, it is not possible to set a static "normal" male range or "normal" female range. While the Hyperandrogenism Regulations are based on a distinction between a discrete male range that does not overlap with a discrete female range, in fact there is a "considerable overlap". Dr van Anders identified three reasons why in her view the Regulations are "scientifically unsound", "intrinsically flawed" and "not based on the current state of scientific knowledge":
 - First, testosterone is dynamic. This means that individuals have their own testosterone ranges that vary depending on a wide range of factors.
 - Second, endogenous testosterone does not define maleness or femaleness.
 - Third, there are no scientific norms for testosterone levels in healthy women and men – in part because these norms would not reflect the dynamic nature of individual testosterone levels.
- 166. During her oral evidence, Dr van Anders questioned the evidential basis for the view of the IAAF's expert witnesses that healthy women do not have endogenous testosterone levels of 10 nmol/L. She commented that high androgen levels are not *per se* abnormal or evidence of a health problem. Women who present for clinical attention are often

individuals with abnormalities; however there may also be perfectly healthy women with high androgen levels who do not ever come to the attention of endocrinological clinicians. Dr van Anders stated that there were a number of possible DSDs which are not of clinical significance and would not require clinical treatment, but which result in naturally elevated testosterone levels.

- 167. Dr van Anders drew attention to the paucity of data concerning testosterone ranges. While she did not expect many women to have high testosterone levels, it did not follow that every woman who does must have a DSD or be involved in doping.
- 168. In relation to assessing androgen insensitivity, Dr van Anders stated that the appraisal of physical characteristics in the assessment process imports cultural norms about (for example) deepness of voice. In her opinion, subjective judgments about an athlete's appearance should not necessarily play any role in the clinical diagnosis.
- 169. In her oral testimony, Dr van Anders also stated that the suggestion that testosterone accounts for the difference between male and female athletic performance was a "false and problematic" assumption. While testosterone may seem like the prime suspect, she says that it is possible that other factors for instance gender-socialisation during puberty may account for the difference. Dr van Anders also noted that women with hyperandrogenism who have testosterone levels within the "male" range do not perform at the same level as men within that range.
- 170. In relation to the difference between endogenous and exogenous testosterone, Dr van Anders stated that it was known that exogenous testosterone affects sexual desire, whereas endogenous testosterone does not. She explained that the two sources of testosterone involve different delivery mechanisms, with different consequences for neural activity.
- 171. Dr van Anders cited a 2005 study by Sader *et al* in support of the proposition that the effects of exogenous testosterone are sometimes opposite to effects of endogenous testosterone. Specifically, she claimed that endogenous testosterone increases the binding sensitivity of androgen receptors, whereas exogenous testosterone decreases it. The Sader study found that on average, androgen receptor expression was consistently higher in young healthy males than young healthy females. Dr van Anders' oral

testimony focused on the subject group of female-to-male transsexuals, as they were administered exogenous testosterone. Their androgen receptor level was markedly lower than that of young healthy males. Females who had been endogenously exposed to testosterone through a bone marrow transplant showed an androgen receptor level comparable to that of healthy young males, much higher than that of healthy young females. Dr van Anders compared these effects to deduce that the effects of endogenous and exogenous testosterone can be opposite. Dr van Anders also cited a 2011 study by Crewthler *et al* for the proposition that endogenous increases in testosterone do not lead to the same enhancement of muscle growth as exogenous increases do.

Dr Katrina Karkazis (expert witness retained by the Athlete)

- 172. Dr Katrina Karkazis produced a written expert report dated 13 November 2014. Dr Karkazis is a senior research scholar in the field of bioethics at Stanford University. She has a doctorate in medical and cultural anthropology. She has published books and peer-reviewed publications on the cultural and social aspects of disease; clinical and research ethics; medical treatment for intersex infants; and the treatment of female athletes with hyperandrogenism. In her expert report, Dr Karkazis explained why she is "strongly opposed" to the Hyperandrogenism Regulations, criticising both the scientific basis of the Regulations and the fairness-based justification for the rules relied on by the IAAF.
- 173. Dr Karkazis referred to a number of published academic articles. In Out of Bounds? A Critique of the New Policies on Hyperandrogenism in Elite Female Athletes (The American Journal of Bioethics, 12(7) 3-16 (2012)) the authors (who include Dr Karkazis) disputed the connection between testosterone and athletic performance, stating that there is "no evidence" that successful athletes have higher testosterone than less successful athletes. They noted that while clinical studies show that testosterone helps individuals to increase their muscle size, strength and endurance, it does not follow that higher endogenous testosterone will cause improved athletic performance. Individuals have "drastically different" responses to testosterone, which is "just one element in a complex neuroendocrine feedback system". Nearly all research on testosterone and athletics has been conducted in men. Moreover, while there is "a 10-fold gap" in male and female endogenous testosterone levels, the differences in athletic

- performance are significantly smaller. In summary, she says, there is "a great deal of mythology" about the physical effects of testosterone.
- 174. In response to questioning by the IAAF's counsel, Dr Karkazis confirmed that she was not an endocrinologist or a medical doctor and, as a bioethicist, she did not have experience in diagnosing or treating medical patients. However, she did have clinical experience of working with individuals with a range of intersex conditions and providing input into their care.

Professor Martin Ritzen and Professor Angelica Lindén Hirschberg (expert witnesses retained by the IAAF)

- 175. Professor Ritzen and Professor Hirschberg produced a joint expert report dated 30 January 2015.
- 176. Professor Ritzen is an emeritus professor at the Department of Women's and Children's Health at the Karolinska Institutet in Stockholm. He has specialised in the field of paediatric endocrinology for more than 40 years and has published a large number of scientific papers about male reproduction and sex differentiation.
- 177. Professor Hirschberg is a professor of obstetrics and gynaecology at the Karolinska Institutet and a senior consultant at the Department of Obstetrics and Gynaecology at Karolinska University Hospital. She has published a large number of scientific papers about disorders of sexual development, effects of testosterone treatment, oral contraceptives, and other issues concerning gynaecological endocrinology.
- 178. Professor Ritzen and Professor Hirschberg are both members of the 14-person expert panel responsible for reviewing cases submitted to the IAAF under the Hyperandrogenism Regulations.
- 179. In their joint report, Professor Ritzen and Professor Hirschberg explained the reasons why they "strongly reject" the Athlete's argument that the Hyperandrogenism Regulations are scientifically flawed and the suggestion that the medical treatments contemplated under the Regulations are harmful to hyperandrogenic athletes.

- 180. The joint report began by explaining the process of sex development and the conditions that cause female hyperandrogenism. In overview, during the development of a foetus, the primitive gonad has the potential to develop into either testicles or ovaries. If certain genes are present the gonad will develop along the male path and form a testis. If this does not happen, the gonad will proceed along the female path and develop into an ovary. When a testis is formed, the organ secretes testosterone and the anti-Müllerian hormone (AMH). Those hormones, in turn, cause their respective receptors to stimulate the development of the male internal and external organs. In the absence of testosterone, or if the receptor does not function, the external genitalia will develop on the female path.
- 181. After testosterone is converted into dihydrotestosterone (DHT) in the body, the DHT causes the external genitalia to develop in a male direction. It follows that if the testes cannot make testosterone, or if the foetus is insensitive to testosterone and DHT (or if the testosterone cannot be converted to DHT for some reason), the external genitalia will not masculinise fully. A baby in that position may be assigned a female gender at birth, even if she carries male sex chromosomes (XY). On the other hand, if a foetus with female chromosomes (XX) is exposed to androgenic hormones her external genitalia will be masculinised (sometimes to the extent that she is mistaken for a male at birth). Some DSDs can result in the birth of a female with XY chromosomes and undescended but functioning testicles.
- 182. It follows that there are a number of conditions that may cause hyperandrogenism in adult women. These include polycystic ovary syndrome (PCOS); congenital adrenal hyperplasia (CAH); 5-alpha-reductase deficiency type 2; complete androgen insensitivity (CAIS); partial androgen insensitivity (PAIS); ovotesticular DSD; and aromatase deficiency.
- 183. In their report, Professor Ritzen and Professor Hirschberg identified a number of issues on which they disagreed with the expert opinion of Professor Holt and Dr van Anders:
 - First, they contended that Professor Holt and Dr van Anders had erroneously
 interpreted the Hyperandrogenism Regulations as using testosterone as a way to
 distinguish women from men. This is wrong: the Regulations make it clear that

the sex of an athlete must never be questioned. Instead, the purpose of the Regulations is to address the position of female athletes who, due to a special condition, have functional levels of serum testosterone that are usually only seen in males.

- Second, in relation to the role of testosterone as a cause of superior athletic performance, Professor Ritzen and Professor Hirschberg stated that there are "undoubtedly a variety of physical and psychological attributes" that contribute to athletic success. However, higher testosterone levels is "the most important factor" explaining the difference in physical performance found between male and female athletes.
- 184. Professor Ritzen and Professor Hirschberg explained that before puberty, males and females have similar levels of testosterone and similar body composition. However, from the onset of puberty, the male body produces significant amounts of testosterone in the testes whereas the female body normally does not. The increased testosterone causes increased lipolysis, protein synthesis and muscle fibre growth. As a result, boys gain significantly more LBM than girls. Since adult men have an average of approximately ten times more testosterone than adult women, this creates a significant physical advantage for men. In addition, testosterone causes increases in bone tissue and red blood cells and influences certain behavioural patterns, such as the drive to compete. All of this helps to enhance athletic performance.
- 185. Professor Ritzen and Professor Hirschberg explained that exposure to male levels of testosterone causes virilisation in women with normal androgen receptor sensitivity. This occurs whether a woman's chromosomes are XY or XX and whether the elevated testosterone levels arise from undescended testes or from adrenal or ovarian disorders. Virilisation has a number of symptoms including deepening of the voice, breast atrophy, increased body hair growth, acne, increased muscle volume, amenorrhea and elitoromegaly.
- 186. Professor Ritzen and Professor Hirschberg stated that since testosterone is a major determinant of LBM, which in turn determines strength, that the hormone is "the best discriminating factor" between male and female athletic performance. They said that

there is "no doubt" that female athletes with more than 10 nmol/L testosterone will have a "significant advantage" over female athletes with normal testosterone levels. They say this view is supported by a wealth of direct and indirect evidence and is "widely held in the scientific community". Professor Ritzen and Professor Hirschberg referred to a number of studies that establish "proven correlations" between endogenous testosterone levels and performance. For example, a study by Cardinale & Stone (2006) demonstrated a positive correlation between testosterone concentration in blood and the explosive strength of both female and male athletes.

- 187. Professor Ritzen and Professor Hirschberg said there is a proven relationship between the use of exogenous testosterone and increased strength and athletic performance. For example, in 2015 Bermon et al reported that of the 156 female athletes currently serving bans for doping offences, 100 were using androgenic anabolic steroids. Of those 100, 57 had been caught using either testosterone or testosterone-related compounds. The authors of the study concluded that "it is unlikely that so many cheating female athletes would keep on using such banned but detectable studies if they had no performance-enhancing effects." According to Professor Ritzen and Professor Hirschberg there is "no biochemical difference between endogenous and exogenous [testosterone]". In their opinion, once exogenous testosterone is in the bloodstream, the molecule is the same and the androgen receptors cannot distinguish between exogenous and endogenous testosterone. In their opinion, Dr van Anders' claim to the contrary was not supported by evidence and based on flawed reasoning.
- 188. In relation to the threshold of 10 nmol/L in the Hyperandrogenism Regulations, Professor Ritzen and Professor Hirschberg stated that the resting serum testosterone levels of healthy elite female athletes always fall well below 10 nmol/L. In support, they cited studies based on general population data and elite athlete data. In relation to the latter, a report by Bermon *et al* (2014) analysed the testosterone levels in all female athletes participating in the 2011 World Championships in Daegu. According to Professors Hirschberg and Ritzen, this showed that when female athletes with DSDs or who are doping are excluded, serum testosterone levels in female athletes never reach 10 nmol/L. The 99th percentile for the female group was 3.08 nmol/L a long way short of the 10 nmol/L limit. Three female athletes without a diagnosis of DSD or doping had testosterone levels in excess of the limit. However, according to Professors

- Hirschberg and Ritzen, those athletes were "highly suspected of doping, even if the full proof was not obtained".
- 189. Professors Hirschberg and Ritzen stated that most elite female athletes have levels of endogenous testosterone between 0.1 and 3.08 nmol/L. The normal range for the male population begins at around 10.5 nmol/L. While ethical considerations preclude a randomised placebo-controlled study, there is "plenty of good evidence, both direct and indirect" to support the proposition of significant advantage.
- 190. Professor Ritzen and Professor Hirschberg disagreed with Dr van Anders' assertion that even if there are distinct male and female ranges of serum testosterone, the selection of a limit of 10 nmol/L as the low end of the normal male range is unsustainable:
 - First, they explained that while testosterone levels do vary within individuals
 according to environmental, internal and social factors, such variations are
 included in the mean of the published cohorts.
 - Second, there is no evidence of significant variations between ethnic groups.
 - Third, while testosterone levels can vary from time to time in all individuals, this does not occur to extreme levels. In their view, the probability of a healthy woman reaching 10 nmol/L is practically zero.
- 191. Professors Hirschberg and Ritzen disagreed with Professor Holt and Dr van Anders' analysis of the study by Healy *et al.* They co-authored a paper rebutting the Healy study. This rebuttal noted that the authors of the Healy study were not able to investigate the clinical status of the individuals who had these values, since the samples were obtained anonymously. As a result, it could not be excluded that the 11 women who had more than 8 nmol/L of testosterone were either doped or had a DSD. Moreover, the study did not explain the low testosterone levels of some of the male athletes. According to Professors Hirschberg and Ritzen, one possible explanation may be due to the timing of the sample collection, which was within two hours after competing. (Exhaustion can reduce testosterone levels in men.)
- 192. According to Professor Ritzen and Professor Hirschberg's joint report, there is therefore no basis for attacking the 10 nmol/L limit. If anything it is "arguably too generous,

leading to the possibility of 'false negatives'". In contrast to the IAAF's Hyperandrogenism Regulations, the IOC's hyperandrogenism rules do not specify a lower limit for the normal range of male serum testosterone. Professor Ritzen and Professor Hirschberg understood that this is because the IOC considers that the normal male range may extend below 10 nmol/L. While they agreed with the IOC's approach from a scientific perspective, they noted that the IAAF's rules have the benefit of establishing "a clear objective criterion".

- 193. In relation to the health consequences of testosterone-lowering medical treatment, Professor Ritzen and Professor Hirschberg noted that Dr Karkazis and Dr van Anders are not clinicians. Professor Ritzen and Professor Hirschberg stated that hormonal contraceptives are the simplest and most direct way to lower testosterone levels. This treatment is, they point out, generally well tolerated and has few side effects.
- During her oral testimony Professor Hirschberg disagreed with Professor Holt about whether there is an overlap in the normal ranges of male and female testosterone. Leaving aside abnormal situations such as hyperandrogenism (which causes high levels of testosterone in females) and over-training (which can cause abnormally low levels of testosterone in both male and female athletes), there is usually a clear-cut difference between male and female testosterone levels. Professor Hirschberg accepted that some males have under 10 nmol/L endogenous testosterone. However she said that the discussion of the lower boundary of the male range was "a non-issue" since the salient question is whether a woman with healthy ovaries and adrenal function would ever have testosterone over 10 nmol/L.
- 195. Professor Ritzen agreed with Professor Hirschberg on this point. In his opinion the chance of a healthy woman having a testosterone level of 10 nmol/L is "zero". Professor Ritzen had never seen a woman with that level of testosterone without a pathological condition. Professor Hirschberg had likewise never seen a woman with healthy ovaries and normal adrenal glands with such a high level of endogenous testosterone. In response to Professor Holt's suggestion that it is possible that healthy women with high testosterone levels never present themselves for clinical attention, Professor Hirschberg stated that unless those individuals were androgen resistant then they would have

- symptoms of virilisation (e.g. deeper voice, increased body hair, breast atrophy) which would lessen the likelihood of them escaping clinical attention.
- 196. In relation to the Daegu data, Professor Ritzen explained that all but three of the female athletes with high levels of testosterone had a DSD. The three athletes in question all came from the same country. There was therefore a "strong suspicion" they were doped. Professor Hirschberg added that the hormone profile in those athletes' blood and urine samples also indicated doping.
- 197. In response to a question from the Panel about the process of assessing androgen insensitivity, Professor Ritzen stated that it is "easy" to determine complete insensitivity since the athlete will present no signs of virilisation at all. However, it is more difficult to determine partial androgen insensitivity. There is no specific test that can enable a precise quantification of the degree of partial insensitivity and exact grading is therefore "very difficult". Professor Hirschberg agreed that determining insensitivity involved a combination of physical evaluation and endocrine testing. He acknowledged the process is "very complicated".
- 198. In relation to the connection between testosterone and the difference between male and female athletic performance, Professor Hirschberg agreed that, "we don't have much evidence" and there was no "definitive proof" of the link. Professor Hirschberg accepted that men and women have different levels of human growth hormone. Nevertheless, in her view, the available science suggests that testosterone is "the most important factor" that could explain the difference.
- 199. Professor Hirschberg's position is that cells in the human body cannot distinguish between endogenous and exogenous testosterone. Both forms of testosterone are identical in molecular terms and must bind with androgen receptors. However, she explained that comparing the two is "very difficult" because there are many factors which must be controlled for. The factors include the level of testosterone-regulating protein in the body and the duration of exposure to increased levels of testosterone. Nevertheless, the clinical response to both forms of testosterone is "exactly the same".
- 200. Professor Ritzen suggested that there was no positive evidence to support Professor Holt and Dr van Anders' theory that high levels of exogenous testosterone affect the body's

homeostasis in a way the endogenous testosterone does not. During the course of his oral evidence, Professor Ritzen drew an 'S'-shaped dose response curve to illustrate the typical reaction of the human body to increasing levels of exogenous testosterone. According to that analysis, the relationship is not linear. At the lower and upper levels, it is difficult to prove a relationship between testosterone and muscle mass. However, if the increase in the dose of testosterone is from 3 to 5 or 10 nmol/L, 'S'-shaped response curve is such that the difference in muscle mass between the average woman and those on 10 nmol/L of testosterone will be great. Similarly, an increase at the highest levels of testosterone, such as for men with very high levels of testosterone, would not have a significant effect. Professor Ritzen stated that he would expect the same dose-response curve to apply to endogenous testosterone; however he conceded there were no data to prove this.

- 201. In his oral testimony, Professor Ritzen explained why the IAAF decided to use 10 nmol/L as its cut-off for allowable testosterone level. He stated that one alternative diagnosis to hyperandrogenism that accounts for high levels of testosterone in women is PCOS. These women were found to have an average testosterone level of 4.5nmol/L. Adding three standard deviations to this number, to make it 7.5 nmol/L, would apply to only approximately 16 athletes out of 1000. To ensure that the Regulations only apply to athletes with hyperandrogenism, Professor Ritzen proposed adding an extra two standard deviations to the threshold. This resulted in the 10 nmol/L currently in place. He also noted that the 10 nmol/L also coincided with the normal clinical "male range" of testosterone levels. Professor Ritzen's belief that there is no overlap between normal male and female testosterone levels is foundational to setting this amount as a cut-off. The reasoning is as follows: if statistically there is no overlap between men and women's testosterone levels, then a woman with 10 nmol/L of testosterone is an outlier with an advantage which results in the competition being unfair.
- 202. Notably, in his oral testimony, Professor Ritzen said that he is not in favour of a fixed cut-off as the sole criterion, as he believes the clinical examination of androgen sensitivity is also of significant importance. Professor Ritzen recognised that for legal purposes, the IAAF has chosen a cut-off level. In contrast, the IOC's policy is for female athletes suspected of having elevated levels of testosterone to undergo an individual examination.

203. Professor Hirschberg concluded her oral testimony by discussing the effects of oral contraceptives on endogenous testosterone levels. She explained that all women who take combined oral contraceptives experience reduced levels of testosterone. Oestrogen-dominated contraceptives have a particularly significant effect and are "extremely effective to reduce testosterone". Professor Hirschberg gave an example from her clinical experience where a female patient used oral contraceptives to reduce her endogenous testosterone level from around 22 nmol/L to around 1 nmol/L.

Dr Stéphane Bermon (expert witness retained by the IAAF)

- 204. Dr Bermon produced an expert report dated 29 January 2015. Dr Bermon is the current President of the International Society of Exercise and Immunology. Dr Bermon has been a member of the IAAF's Medical & Anti-Doping Commission since January 2006. In 2009, he joined the IAAF working group responsible for reviewing the IAAF's policies in light of the problems highlighted by the case of Caster Semenya.
- 205. Dr Bermon noted that elite male athletes consistently outperform elite female athletes by a substantial margin. Using data from all directly comparable events, the average performance difference between the two is 12.64%. The available evidence establishes that this difference is not attributable to nurture; instead it is due to the fact that elitemale athletes are typically faster, stronger, taller, and have greater reach and leverage and a greater ratio of muscle-to-weight than women. The difference arises as a result of the greater muscle mass and greater power that males develop during puberty. That difference, in turn, is "mainly due to the anabolic and androgenic effect of the vastly higher levels of testosterone that males start to produce from puberty onwards".
- 206. Dr Bermon disagreed with the Athlete's criticisms of the scientific foundation of the Hyperandrogenism Regulations. He cited two large population studies by the IAAF which establish that the normal range of endogenous testosterone in females (including elite female athletes) is "much lower (by several standard deviations)" than the limit in the IAAF Regulations. In addition, he referred to the fact that: (a) elite female athletes in the German Democratic Republic experienced "immediate and enormous improvements" in athletic performance after receiving exogenous testosterone; (b) elite female athletes continue to use exogenous testosterone illicitly to improve athletic

performance; (c) females with DSDs are disproportionately represented in the elite female athlete population compared to the general population; (d) a number of studies establish a positive link between testosterone levels and explosive power; and (e) those hyperandrogenic athletes who have received treatment to suppress their testosterone levels have been unable, on their return to competition, to match their best pre-treatment results.

- 207. Dr Bermon questioned the Athlete's reliance on the study by Healy *et al* (2014). In particular, leaving aside questions over methodology, Dr Bermon asked whether the authors of that study were able to exclude doping or hyperandrogenism in the female athletes and hypoandrogenism in the male athletes. Dr Bermon endorsed the analysis and conclusions contained in the joint expert report by Professor Ritzen and Professor Hirschberg.
- 208. In his oral evidence, Dr Bermon stated that ten of the female athletes with abnormally high testosterone levels in the Dageu data were either doped or had DSD conditions. He explained that, after removing these athletes from the data pool, 99% of the female athletes had a testosterone level under 3.08 nmol/L. Nine female athletes were over that level. Six of those female athletes had testosterone levels between 3 and 4 nmol/L. Of those six, one was an athlete with a DSD who was permitted to compete, but who had not been very compliant with her prescribed medical treatment.

The sixth had retired in 2012 and Dr Bermon did not have any further information about her.

209. In relation to the three female athletes with values between 10 and 12 nmol/L,

- 210. Dr Bermon stated that his analysis of the Daegu data revealed an over-representation of women with DSDs among the population of elite female athletes. This was consistent with the fact that women with PCOS (who have elevated levels of testosterone) are also over-represented in the elite female population. The Daegu data showed a hyperandrogenism incidence rate of 7.1 per 1,000 female athletes. By contrast, the figure for the incidence rate in the general population is around 1 in 20,000. Accordingly, the incidence rate in the elite female population is about 140 times greater than in the general population. Dr Bermon described this "recruitment bias" as "very meaningful". He added that there was "a recruitment bias in the recruitment bias" since undeveloped countries tended to have more elite athletes with certain DSDs than developed countries. The reason, he suggested, was that DSD conditions were less likely to be diagnosed at an early stage in undeveloped countries.
- 211. Dr Bermon further explained that data had also been collected from male athletes at Daegu. However, in contrast to the samples from female athletes, the male athletes' samples were not tested using mass spectrometry, which Dr Bermon described as "the gold standard for measuring hormones".
- 212. In relation to the Moscow data, Dr Bermon stated within the female athlete population there were two "very high outliers" with between 28 and 43 nmol/L of testosterone. There were "serious reasons" to believe those athletes had DSDs. In addition, three doped athletes had readings between 7 and 11 nmol/L. Once those five athletes were removed, the testosterone levels of the elite female population were roughly the same as in the general population. Dr Bermon stated that there were "quite a significant number of males" with under 10 nmol/L testosterone. Some of those individuals were believed to be hypogonadic, either as a result of anabolic steroid use, overtraining or an underlying medical condition.
- 213. When asked why men are not tested for high levels of testosterone, Dr Bermon gave two reasons. First, there are two categories for male and female and not three: male, female and "super-male" (i.e. a separate category for males with abnormally high athletic performance). Secondly, because of the dose response curve, a male with high levels of testosterone may not derive a particular advantage in the same way that a female does.

- 214. Dr Bermon was asked directly about published and expressed views that there is no link between testosterone levels and differences in athletic performance and about the view he has expressed that the science is unable to support this conclusion. He accepted that the evidence was indirect and said that it was not possible to obtain direct evidence as that would involve giving testosterone to healthy women in the normal range. He also referred to other analyses that could be helpful but had not been carried out, in part because of a need for a wide distribution of data that has not been available. He described three cases where decreased athletic performance was observed after suppression of testosterone levels, but explained that there has not been a proper analysis correlating rankings and testosterone levels, for want of data.
- 215. Dr Bermon confirmed that threshold of 10 nmol/L had been selected on the basis that it was five standard deviations away from the typical testosterone levels of females with PCOS. Dr Bermon was asked whether it was possible that, since some males have testosterone levels under 10 nmol/L, and some (non-outlier) females have testosterone levels of 4 nmol/L, the use of testosterone to delineate between the two categories of athletics competition could become statistically invalid. Dr Bermon conceded that if outliers were taken into account then there was a "mild overlap" between the male and female ranges. He added that it is possible that in the future it may be necessary to lower what is the normal male range in an athletic population. He maintained, however, that testosterone is presently "the best available parameter" to explain the performance difference between men and women. He added that testosterone should not be considered in isolation, since the clinical assessment of virilisation is equally important. Virilisation, assessed by an expert panel, is necessary to ascertain total or partial androgen insensitivity. There are difficulties in ascertaining a specific percentage or degrees of androgen resistance and Dr Bermon says that the benefit of the doubt is given to the athlete. Dr Bermon's understanding as to when the benefit of the doubt is given to the athlete is not completely consistent with the Hyperandrogenism Regulations.

Professor Arne Ljungqvist (expert witness retained by the IAAF)

216. Professor Ljungqvist produced an expert report dated 29 January 2015. Professor Ljungqvist was previously an elite international athlete before training as a medical doctor. He was the Chairman of the IAAF's Medical and Anti-Doping Commission for

24 years between 1980 and 2004 and Chairman of the IOC's Medical Commission for 11 years between 2003 and 2014. He has held a number of senior roles at WADA including serving as a member of the WADA Foundation Board and the WADA Executive Board; a Chairman of the WADA Health, Medical & Research Committee and the WADA Vice-President.

- 217. According to Professor Ljungqvist's report, the athletic differences between the sexes are due in large part to the fact that from puberty onwards a male's testes produce much higher levels of testosterone than a female's ovaries. Testosterone affects the entire body, in particular by increasing muscle size and increasing the oxygen-carrying capacity of the blood. It is for this reason that some athletes (both male and female) illicitly self-administer testosterone to boost athletic performance.
- 218. Professor Ljungqvist disagreed with the Athlete's argument that there are not distinct male and female ranges of endogenous testosterone. In this regard, Professor Ljungqvist cited a paper that he had co-authored with Professor Ritzen rebutting the paper by Healy et al relied on by the Athlete. He also rejected the argument that there is no evidence that endogenous testosterone is performance-enhancing. While he explicitly deferred to the expert opinion of Professors Ritzen and Hirschberg, Professor Ljungqvist noted that the WADA List of Prohibited Substances prohibits both the administration of synthetic exogenous hormones and also the administration of substances that promote the production and release of endogenous hormones (including testosterone). As a former Chairman of the WADA Health, Medical & Research Committee, Professor Ljungqvist was able to confirm that the latter category was prohibited because those endogenous hormones are considered to have performance-enhancing effects.
- 219. During his oral evidence, Professor Ljungqvist said that based on his experience in antidoping control, exogenously ingested testosterone has a greater effect on women than men. In answer to a question from the Panel concerning the difference between endogenous and exogenous testosterone, Professor Ljungqvist said he was unable to say whether the evidence indicated that a human body that is constantly exposed to testosterone may somehow adjust to it.

- 220. In relation to the assessment of androgen insensitivity, Professor Ljungqvist said it was not possible to quantify the magnitude of athletic advantage enjoyed by a particular athlete based an assessment of physical virilisation.
- 221. In response to questioning by the Panel, Professor Ljungqvist confirmed that the IAAF does not routinely test the endogenous testosterone levels of all female athletes. He also confirmed that a female athlete with over 10 nmol/L testosterone (who would be deemed to be within the "male" range) is not permitted to compete in the male category. Similarly, a male athlete with less than 3 nmol/L is not permitted to compete in the female category. In addition, he confirmed that no other exclusionary rule applies to other genetic traits or biological characteristics such as hand size.
- 222. Professor Ljungqvist was careful not to speak outside his area of expertise. He did, however, provide an insight into the reasoning of the IAAF in adopting the Hyperandrogenism Regulations. Professor Ljungqvist was actively involved from the 1980's in the categorisation of males and females for the purposes of sport and was actively involved in the rejection of gender verification and in the introduction of the Regulations and in the discussions in Miami between various experts which preceded their adoption. Professor Ljungqvist's evidence in this regard noted the following views:
 - The Regulations were adopted after many 'consensus meetings';
 - The IAAF felt that there was a responsibility to the athletes, including to protect athletes from speculations as to their sex;
 - The IAAF over time has continued to look for a test involving the best available science with the least possible embarrassment to the athlete;
 - The process that led to the current Regulations was originally focused on athletes with DSDs;
 - There was a concern that men did not compete in women's events;
 - The accepted view has been that women with complete androgen insensitivity
 would have no competitive advantage and the view has been that even partial
 androgen insensitivity could have an advantage of only "minor
 importance". This is despite the fact that there seems to be an over-

representation of people with partial or complete androgen insensitivity in the elite athlete population.

- 223. Professor Ljungqvist's view is that only a woman in the male range with fully functional androgen receptors would in all likelihood have a competitive advantage, but this would have to be assessed on a case-by-case basis.
- 224. The presence of testosterone in the body is, in his view, the same whether it is taken by way of doping or whether it is in the natural state and present from birth.
- 225. The effect of testosterone doping, specifically exogenously ingested testosterone, in women is more significant than testosterone doping in men. In answer to a question from the Panel as to whether this leads to a conclusion that a body constantly exposed to testosterone may somehow adjust to it, Professor Ljungqvist commented that this was a matter for scientists. However, he could see no scientific reason why a person should respond differently to exogenous and endogenous testosterone.
- 226. When asked directly by the Panel, Professor Ljungqvist said that the Hyperandrogenism Regulations are scientifically sound, as known to science today. He also said that where the competition is divided into male and female categories and there is an intersex population, scientists with whom he has consulted say that these Regulations are the best that can be done. At present, there is no intersex category. There is, however, a distinction between the male and female ranges of testosterone and this characterises the difference between males and females. At this time, this is the best criterion available.
- 227. When asked why there was no exclusion for other genetic traits such as hand size, Professor Ljungqvist said that such characteristics do not qualify the person as male or female and that it is perfectly acceptable to have a diversity of body characteristics inside a competition group.
- 228. At the end of his testimony, Professor Ljungqvist was asked whether the Hyperandrogenism Regulations were scientifically sound. Professor Ljungqvist answered in the affirmative, but acknowledged there had been "a history of ignorance" with respect to their predecessors. Notwithstanding that history, Professor Ljungqvist was confident that testosterone is the "best parameter we have" for explaining the

differences in male and female athletic performance. He added that if it were proven that high endogenous testosterone levels do not confer a performance advantage then there would be no justification for the Hyperandrogenism Regulations.

Issue 3: Proportionality

- 229. The issue of proportionality arises both as a freestanding ground of challenge and in relation to the specific question of whether the IAAF can justify the discriminatory effect of the Hyperandrogenism Regulations (arising under Issue 1).
- 230. The parties did not make submissions on the existence or content of the laws of Monaco as to proportionality. The Panel does note, however, that the detrimental impact of a measure must be proportionate, in that it must not exceed that which is reasonably required in the search of the justifiable aim. This principle applies notwithstanding the wide discretion given to a Federation to determine its affairs and regulations. The Panel accepts the legitimate objective of the IAAF to organise competitive athletics to ensure fairness in athletic competition. It is legitimate and necessary to divide athletes into male and female categories. This is because male athletes have such an advantage over female athletes that competition between the sexes is not fair.

The Athlete's submissions

231. The Athlete submits that the harm caused by the application of the Hyperandrogenism Regulations is grossly disproportionate to any benefits the rules are designed to achieve. In particular, the Hyperandrogenism Regulations may result in: (a) stigmatisation of female athletes caught by the Regulations; (b) serious damage to the self-esteem and gender-identity of female athletes with hyperandrogenism; (c) female athletes undergoing medical tests without fully informed consent; and (d) female athletes undergoing unnecessary medical procedures with serious long-term side effects. Moreover, she says, the Hyperandrogenism Regulations are inherently unfair because they prevent female athletes from competing as females because of a natural physical characteristic that is no different in principle from the many other physical, psychological, social and economic factors that contribute to elite athletic performance.

- 232. The Athlete accepts that pursuing fairness in sport is a legitimate objective. However, she disagrees that pursuing a level playing field is a legitimate aim. In her view, the very concept of a level playing field is an illusory and meaningless concept having regard to the extraordinary breadth of different factors that contribute to athletic performance.
- 233. In his opening submissions, the Athlete's counsel contended that the Hyperandrogenism Regulations were the latest instalment in a series of deeply flawed regulations dating back over 50 years, all of which have caused very significant harm and displayed grossly insufficient respect for women. Although the content and procedures are different, he submitted that the present Hyperandrogenism Regulations inflict the same indignity, stigma and harm on women as their forbearers.
- 234. In support of her argument, the Athlete relies on evidence describing the stigmatisation experienced by athletes who have been investigated under the Hyperandrogenism Regulations (or their "gender testing" and "sex verification" predecessors). According to the Athlete, the Hyperandrogenism Regulations incite scrutiny, suspicion and fear of particular body types and particular modes of gender presentation. Intrusive investigations of this nature can affect an athlete's self-perception and identity as a woman, and may also cause other people to question her identity. Moreover, the Hyperandrogenism Regulations may increase the pressure on female athletes to conform to stereotypical expectations of "feminine" behaviour and appearance for fear of being investigated and prevented from competing.
- 235. While the Hyperandrogenism Regulations require any investigation to remain confidential, the Athlete submits that there is no guarantee that this will be achieved. The Athlete points out that the investigation process can take months to complete, during which time the athlete is unable to participate in competitive events. An athlete's absence from competition is likely to arouse suspicion. She contends that although the investigation process is supposed to be confidential, there is an inevitable risk of public speculation or disclosure that the athlete is being investigated for hyperandrogenism. In addition, the fact that the Hyperandrogenism Regulations enable anyone to raise doubts about an athlete to an IAAF medical director may result in leaks of private medical

- information and may encourage "whispering campaigns" which trigger formal investigations into particular athletes.
- 236. In this regard, the Athlete submits, there have been numerous examples where the identity of athletes under investigation has been leaked to the public. The Athlete's Appeal Brief refers to several examples where female athletes have experienced public humiliation and shame as a result of the public disclosure of an investigation. In two of those cases, it is said that the athletes were so distressed that they became suicidal.
- 237. The Athlete also submits that the Hyperandrogenism Regulations mean that athletes are likely to undergo medical procedures to reduce their testosterone levels that are neither medically necessary nor the result of free and informed consent on the part of the athlete. A female athlete who declines or fails an assessment under the Hyperandrogenism Regulations is barred from competing in any event unless she is able to reduce her testosterone levels below 10 nmol/L. She maintains that there is therefore a serious risk that elite-level athletes who have devoted their whole lives to sport will feel an overwhelming compulsion to undergo any surgical or pharmacological treatment that enables them to continue competing, regardless of its medical necessity or possible side-effects. This is particularly serious since some medical interventions to reduce testosterone levels may have serious and permanent health consequences.
- 238. The Athlete likens the Hyperandrogenism Regulations to a hypothetical rule which imposes a maximum permissible hand size for female basketball players, beyond which they would be deemed to fall within the "male range" and therefore ineligible to compete in female competitions. A rule of that nature would plainly be discriminatory and unjustifiable. Exactly the same is true, she submits, of the Hyperandrogenism Regulations.
- 239. In the course of his submissions, the Athlete's counsel pointed out that whereas eligibility rules such as weight categories and age categories always give every sportsperson the opportunity of competing in a certain category, the Hyperandrogenism Regulations are fundamentally different since they prevent some female athletes from competing *at all* unless they undergo medical intervention to bring their level of a particular naturally-occurring hormone down below a particular threshold.

- 240. The Athlete submits that the facts of her case serve as a good illustration of the harm that the Hyperandrogenism Regulations are apt to cause. The investigation into the Athlete's testosterone levels was leaked to the media, leading the Athlete to be publicly shamed and humiliated by intrusive and hurtful questions about her femininity. The Athlete was told she required medical intervention and, were it not for the assistance of Dr Mitra, the Athlete would not have understood her rights.
- 241. The Athlete further submits that, since the Hyperandrogenism Regulations are only "recommended as a guide to National Federations in Athletics" in relation to national-level cases, the Hyperandrogenism Regulations create an inconsistent and unfair patchwork of compliance by different countries around the world. This, she says, compounds the inherently disproportionate nature of the Hyperandrogenism Regulations.

The IAAF's submissions

- 242. The IAAF submits that the Hyperandrogenism Regulations pursue the legitimate objective of protective fairness in competitive athletics by ensuring that elite female athletes are able to compete on a level playing field. The IAAF submits that the Hyperandrogenism Regulations are both a necessary and proportionate means of achieving that objective. The IAAF maintains that the benefits of the Hyperandrogenism Regulations therefore outweigh any harms and that the discriminatory effects are amply justified.
- 243. The IAAF identifies two types of benefit achieved by the Hyperandrogenism Regulations:
 - First, the Regulations address the concerns of the majority of female athletes,
 while still giving hyperandrogenic athletes an opportunity to compete. This
 helps the IAAF to incentivise women to make the significant sacrifices
 necessary to excel in athletics, while discouraging female athletes from feeling
 that they must dope in order to compete.
 - Second, the Regulations help the IAAF to protect the health of hyperandrogenic athletes, by facilitating an expert diagnosis of their condition (at the IAAF's

expense), enabling the affected athlete to obtain appropriate and beneficial medical treatment for her condition.

- 244. The IAAF submits that the restriction on a hyperandrogenic athlete's ability to compete must be weighed against "the need to be fair... to the vast majority of female athletes who are within the (much lower) normal female range". Those athletes, the IAAF says, would consider it unfair to compete with women whose bodies respond in different and stronger ways to training and racing to the bodies of female athletes with normal testosterone levels. In this respect, the IAAF relies on the evidence of Professor Thomas Murray, who stated that if women are to be treated as a "protected class" in athletics competition for reasons of fairness, then the IAAF must police the sex divide "to safeguard the promise of fair competition offered by the division of disciplines into sexspecific events". In light of testosterone's performance-enhancing effect, the IAAF says that it has "an ethical obligation to assure that women athletes who desire to compete against other women do not have to compete against athletes with hormone-related performance advantages commonly associated with men".
- 245. The IAAF rejects the Athlete's argument that elevated endogenous testosterone levels are no more "unfair" than numerous other natural advantages derived from exceptional biological variation (such as height, lung capacity, vision, foot size etc.). It contends that it is irrelevant that the high testosterone levels of hyperandrogenic athletes are not the product of cheating and are merely the consequence of natural biological factors. The IAAF endorses Professor Murray's contention that each sport is entitled to determine what factors make competition unfair and therefore warrant the adoption of clear dividing lines.
- 246. The IAAF also draws support for its position from a paper by Tucker and Collins entitled *The science of sex verification and athletic performance* (Int J Sports Physiol Perform, 2010;5:127-139). The authors of that paper draw a comparison between elevated testosterone levels (which go directly to the root of the male-female division in athletics competition) and other physical traits (which do not). According to the paper, gender categories exist for the very reason that performance differences between males and females call for two separate categories of competition. It follows that sports authorities "must defend equality of competition in the female category when the

equality is questioned as a result of a physiological factor that challenges the basis for the gender categories in the first place". In the authors' opinion, simply dismissing DSDs such as hyperandrogenism as naturally occurring advantages would compromise the integrity of sport, since it would be "analogous to having a system, where weight classifications exist, but then waiving the weight limit for certain individuals who cannot reduce their weight enough to fit into the required category".

- 247. The IAAF denies that the Hyperandrogenism Regulations discriminate impermissibly against female athletes because of the absence of any equivalent eligibility restriction on male athletes with unusually high endogenous testosterone levels. The IAAF relies on the evidence of Professor Murray, who states that he is unaware of any evidence of a strong correlation between male athletes with exceptional levels of testosterone levels and enhanced performance in sport. In the absence of such evidence and unlike the present circumstance where female athletes have supported a regulation for hyperandrogenism, he says that "the complete lack of any clamour among male competitors for separate competitions according to testosterone levels" means that the discrimination argument is not made out. In any event, since the purpose of the Hyperandrogenism Regulations is to protect women from having to compete against athletes with the hormonal advantages of men, Professor Murray says that it is difficult to see how equal treatment requires an analogous policy to protect men competing against other men.
- 248. In relation to the other disadvantages and risks identified by the Athlete, the IAAF makes a number of responses:
 - (a) First, it rejects the argument that the Hyperandrogenism Regulations imply that female athletes with hyperandrogenism are not really women. The IAAF points to the fact that the Hyperandrogenism Regulations expressly and emphatically disavow the concept of "sex testing" and "gender verification". According to the IAAF, the Hyperandrogenism Regulations expressly acknowledge the femaleness of the Athlete, not the reverse.
 - (b) Second, the IAAF rejects the suggestion that the Regulations are implemented in the same manner as the previous gender verification policies. In contrast to

the previous regime, no tests are done to determine the sex of an athlete. Moreover, the IAAF denies that "anyone" can instigate an investigation into an athlete. Only the IAAF medical director may start an investigation. He/she may only do so if there are "reasonable grounds" derived from a "reliable to source" to consider that an athlete may be hyperandrogenic. A competitor of an athlete (or a member of her entourage) would not be regarded as a reliable source. Anyone who attempts to use the Hyperandrogenism Regulations to harass or injure another athlete would face disciplinary sanctions.

- (c) Third, it is wrong to suggest (as Dr Karkazis does) that a majority of the indicators of hyperandrogenism identified by the Hyperandrogenism Regulations are entangled with "deeply subjective and stereotypical Western definitions of femininity". The indicators in the Hyperandrogenism Regulations are not used to determine which female athletes should be investigated. Instead, they are only used once it has been decided that an investigation should be conducted: only at that point do the medical guidelines come into play. Furthermore, the guidelines are closely based on the American Association of Clinical Endocrinologists' Medical Guidelines for the Clinical Practice for the Diagnosis and Treatment of Hyperandrogenic Disorders (2001) and on the Consensus Document on the Management of Intersex Disorders.
- (d) Fourth, there is no issue of stigmatisation unless the fact that an athlete is being investigated and/or has been diagnosed as hyperandrogenic following such investigation is made public. The Hyperandrogenism Regulations expressly emphasise the need for "respect for confidentiality in the medical process" and "the need to avoid public exposure of young females with hyperandrogenism who may be psychologically vulnerable". The Hyperandrogenism Regulations include a chapter specifically devoted to "Confidential management of cases" and require that notification of cases to the IAAF must be done "in strict confidence to the IAAF Medical Manager (a physician), either directly or via her National Federation's team doctor or other supervising physician". There have been over 30 cases to date under the Hyperandrogenism Regulations. No one outside the IAAF knows the identity, nationality or any personal

information of any of those athletes. The IAAF has never leaked any confidential information about any hyperandrogenism cases, whether under the Hyperandrogenism Regulations or otherwise. Any breach of the confidentiality provisions would be a breach of the IAAF Code of Ethics, resulting in significant sanctions against the perpetrator.

- (e) Fifth, the Athlete is wrong to suggest that the surgical or pharmacological suppression of testosterone levels may produce serious medical side effects. In many cases the treatment involves a simple contraceptive pill, similar to those taken by many women worldwide. The IAAF points out that hyperandrogenism conditions create potentially very serious health risks, which make early diagnosis and treatment very important. The conditions can lead to virilisation that may cause the individual serious anxiety about the formation of future intimate and/or sexual relationships. In some cases, there may be an increased risk of cancer. In regular clinical medicine, females with hyperandrogenism who wish to prevent further virilisation generally have two options: (i) hormonal treatment to suppress androgens; or (ii) gonadectomy/surgical removal of the source of the androgens. Exactly the same is true under the Hyperandrogenism Regulations. The hormonal option usually involves an oral contraceptive, which generally involves few side effects. In none of the cases under the Hyperandrogenism Regulations was an athlete required to undergo gonadectomy. Some hyperandrogenic athletes have undergone surgical procedures for personal reasons that are entirely unconnected to the implementation of the Hyperandrogenism Regulations.
- (f) Sixth, it is wrong that female athletes caught by the Hyperandrogenism Regulations do not provide full informed consent and are at risk of coercion. The Hyperandrogenism Regulations are very clear about the need for informed consent. The IAAF is not involved in the diagnosis or treatment processes. It has never been suggested that any surgical procedure was necessary in order to be eligible to compete.
- 249. In his closing submissions, the IAAF's counsel asked hypothetically what would happen if there was no regulation at all and the IAAF simply accepted that an athlete's sex under

the law was determinative of their eligibility to compete in the female category. He noted that some countries (for example Argentina and Denmark) provide that an individual's self-designation is automatically determinative of his/her legal status as a male or female, enabling a person with exclusively male characteristics to self-declare as a female. He submitted that the Hyperandrogenism Regulations are a necessary and proportionate means of protecting the level playing field from the potential effects of national laws like that.

250. For all these reasons, the IAAF submits the Hyperandrogenism Regulations are plainly a necessary and proportionate means of ensuring fairness in athletic competition and protecting the health of hyperandrogenic athletes.

Dr Katrina Karkazis (expert witness retained by the Athlete)

- 251. In her expert report, Dr Karkazis explained why she is "strongly opposed" to the Hyperandrogenism Regulations. In particular, it is her opinion that:
 - (a) The Hyperandrogenism Regulations stigmatise and harm female athletes who are investigated for suspected hyperandrogenism;
 - (b) It is unfair to treat endogenous testosterone differently to all other physiological variations that affect athletic performance;
 - (c) The Hyperandrogenism Regulations have a disproportionate burden on women from the Global South region;
 - (d) The Hyperandrogenism Regulations may cause healthy women to undergo harmful medical interventions in order to become eligible to compete; and
 - (e) The Hyperandrogenism Regulations raise serious concerns about coercion.
- 252. Dr Karkazis explained that the Hyperandrogenism Regulations are based on an assumption that sex segregation in sports means that all competitors can (and must) be scientifically segregated into two distinct categories, male and female. However, in her opinion the Hyperandrogenism Regulations imply that an athlete's general legal classification as either male or female is insufficient for the specific purpose of athletics classification. Instead, the Hyperandrogenism Regulations suggest that it is necessary

to look behind an individual's formal legal status as either "male" or "female" and to identify a further yardstick to determine whether an athlete is female for the purposes of competing in female athletics events.

- 253. The Hyperandrogenism Regulations seek to depart from the previous approach to "gender verification" by claiming that testosterone is a scientifically valid marker for sex segregation. However, despite that intention, Dr Karkazis stated that there is a widespread perception that the Hyperandrogenism Regulations are a "gender verification" tool. In her opinion, there are at least two possible reasons for this:
 - First, the perception may be partly caused by misunderstanding about the complexity of sex. Contrary to what is commonly thought, sex determination is not a straightforward exercise and there are no fewer than six markers of sex (chromosomes, gonads, hormones, secondary sex characteristics, external genitalia and internal genitalia). No one marker is decisive. The markers are not themselves binary and there is substantial variation both within and across individuals. The extent of physical variance across human bodies is therefore considerably more complex than the binary categories of male and female imply.
 - Second, the perception that the Hyperandrogenism Regulations are a form of "gender verification" is reinforced by the fact that the Regulations cite sex segregation as a reason for their existence, and by the fact that in practice the Regulations are applied in the same manner as the earlier "gender verification" and "sex testing" policies.
- 254. In Dr Karkazis's opinion, the widespread perception that the Hyperandrogenism Regulations are an aspect of "gender verification" or "sex testing" has resulted in significant stigma for athletes who are the subject of investigations under the Regulations. Media reports often suggest that the purpose of an investigation is to determine whether an ostensibly female athlete is, in fact, not a woman. She said that the manner in which investigations are instigated under the Hyperandrogenism Regulations compounds the stigma. The Regulations state that women with hyperandrogenism "often display masculine traits and have an uncommon athletic capacity in relation to their fellow female competitors". In Dr Karkazis' view, this

- creates a risk that exceptionally talented athletes and athletes whom others deem insufficiently "feminine" will be subject to intense scrutiny.
- 255. Dr Karkazis described how high androgens produce what are commonly understood as "masculine" physical traits. In her view, the Hyperandrogenism Regulations imply that "these 'surface' masculinities on a woman's body are signs of a deeper 'true' masculinity (or even maleness) and thus incite scrutiny and suspicion around particular types of bodies and modes of gender presentation." This, in turn, increases the pressure on female athletes to conform to expectations of "feminine" appearance. Dr Karkazis commented that more than half of the indicators specified in the Hyperandrogenism Regulations to determine which female athletes should undergo investigation are "entangled with deeply subjective and stereotypical Western definitions of femininity".
- 256. Dr Karkazis also stated that the fact that anyone can raise doubts about an athlete to an IAAF Medical Director creates a danger that investigations may be triggered by whispering campaigns about a particular athlete, as well as the possibility that private health information will be leaked. Dr Karkazis stated that the IAAF itself has been involved in disclosing information about athletes under investigation. In 2008, for example, an IAAF official confirmed to reporters that the athlete Caster Semenya was under investigation. Accordingly, she says, the Hyperandrogenism Regulations are not capable of being applied in a manner that properly respects athletes' rights to privacy.
- 257. For all these reasons, Dr Karkazis said, the process of investigation is "shocking and stigmatizing" to the athlete concerned. An investigation can affect an athlete's self-identity and their relationships with members of their family, their sport and the wider community. The harm is aggravated by voyeuristic press reports and "diagnosis by media". Dr Karkazis described the types of grave harm that female athletes have suffered, including termination of family relationships, loss of employment and even attempted suicide.
- 258. In addition to the harms associated with the stigmatising effect of the Hyperandrogenism Regulations, Dr Karkazis said there is a risk that female athletes with hyperandrogenism will undergo coerced medical interventions in order to regain their eligibility to compete. Medical interventions to reduce testosterone are complex

and may entail serious health side effects that diminish quality of life and involve significant physical dangers. According to Dr Karkazis, her empirical research on intersex individuals demonstrates that informed consent "is often lacking for medical decisions relating to hyperandrogenism".

- 259. Moreover, poor women from the Global South appear to be the population most affected by the Hyperandrogenism Regulations. The disproportionate impact on women from certain regions and ethnic groups increases the concerns about lack of informed consent, particularly as women from poorer socio-economic backgrounds may be affected by additional pressures which arise from the fact that their families, teams and nations may be particularly reliant on them competing.
- 260. Lastly, Dr Karkazis criticised the fact that under the Hyperandrogenism Regulations testosterone is treated differently to all other natural physical traits. In her opinion there is no reason to treat hyperandrogenism differently to other biological advantages derived from exceptional biological variation. She contrasted the treatment of testosterone with other biological advantages commonly present in groups of elite athletes. For example: (i) some runners and cyclists have rare mitochondrial conditions that give them extraordinary aerobic capacity and resistance against fatigue; (ii) some basketball players have a hormonal condition known as acromegaly, which results in exceptionally large hands and feet; (iii) the proportion of elite baseball players with perfect vision is significantly higher than amongst the general population; and (iv) some elite athletes have genetic variations that respectively increase muscle growth/efficiency and blood flow to skeletal muscles. None of these traits are the subject of eligibility restrictions.
- 261. In Dr Karkazis' view, since hyperandrogenism is a naturally occurring phenomenon there is no reason to treat it differently to any other exceptional biological variation in the human body. Nor, in her view, is there any reason to treat it any differently to the myriad of other unregulated technological, financial and social factors that affect sporting performance.
- 262. In support of the conclusions in her report, Dr Karkazis referred to a number of published academic articles. In *Out of Bounds? A Critique of the New Policies on*

Hyperandrogenism in Elite Female Athletes (The American Journal of Bioethics, 12(7) 3-16 (2012)) Dr Karkazis and her co-authors described the evolution of sex and gender testing in sport, beginning with the practice of "nude parades" and genital examinations and moving on to sex chromosome testing, "manual/visual" checking and SRY gene test. According to the authors, the history of sex testing shows that "female athletes have always been under suspicion, and women with intersex traits have often been scapegoats for broad anxiety about the gender contradiction inherent in the very concept of an elite female athlete".

263. On the basis of these considerations, the authors considered that the Hyperandrogenism Regulations are both "illogical and unfair". They concluded that elite athletes "never begin on a fair playing field", since if they were not exceptional in one way or another they would never have made it to a prestigious international athletic arena. Athletic excellence is the product of "a complex entanglement of biological factors and material resources". In the authors' view, the Hyperandrogenism Regulations seek to "do the impossible" by trying to isolate testosterone from all other relevant factors and to determine the impact that it alone has on athletic advantage. The authors therefore concluded as follows:

Considerations of fairness support an approach that allows all legally recognized females to compete with other females, regardless of their hormonal levels, providing their bodies naturally produce the hormones. While a legal definition of sex opens up a scrutiny of its own, it is currently the single best sex categorization measure we have to rely on. It is true that countries may define sex in different ways, but this variability is not necessarily bad; it allows countries to do so how they see fit... We need to move beyond policing biologically natural bodies and the resultant exceptional scrutiny of extraordinary women.

264. In her oral testimony, Dr Karkazis expanded upon the harms described in her expert report. Dr Karkazis reiterated her view that the Hyperandrogenism Regulations are very similar to the predecessor policies and constitute a form of sex testing. She discussed the psychological harm that an athlete can suffer when the fact of an investigation is publicised. On this point, Dr Karkazis noted that much of the media reporting on the Athlete's appeal to the CAS wrongly referred to the Athlete having failed a gender test.

- 265. Dr Karkazis drew upon her professional experience of working with elite female athletes to describe the extraordinary dedication, focus and singularity of purpose that are required to succeed at the highest levels. Removing an elite athlete's ability to compete can result in a sudden personal "derailment" with serious psychological consequences for the woman in question. Dr Karkazis did not disagree with the proposition that diagnoses of hyperandrogenism may potentially benefit certain athletes, by identifying previously unknown medical conditions. For example, testing for hyperandrogenism may lead to the discovery of an undetected tumour in the undescended testes. However, in her opinion, the Hyperandrogenism Regulations operate coercively by making athletes' eligibility to compete conditional on undergoing medical treatment to reduce high levels of naturally occurring testosterone. The potential benefits of a medical diagnosis cannot justify that erosion of informed consent.
- 266. In response to further questioning, Dr Karkazis confirmed that she was not challenging the importance of having a male/female divide in athletic competition. When asked by the IAAF's counsel whether eligibility to compete should depend exclusively upon an athlete's self-declaration about their sex, Dr Karkazis replied that countries had their own legal definitions and she doubted whether it was appropriate for sports' governing bodies to usurp or override those rules. Dr Karkazis added that it was unclear precisely what problem the Hyperandrogenism Regulations were seeking to address. She was unaware of any concerns about male athletes masquerading as female athletes and pointed out that if that did become a problem, then appropriate steps could be taken to address that. However, she stated, the Hyperandrogenism Regulations are not an appropriate means of addressing that issue.

Paul Melia (expert witness retained by the Athlete)

267. Mr Paul Melia produced a written expert report dated 14 November 2014. Mr Melia is the President and Chief Executive Officer of the Canadian Centre for Ethics in Sport ("CCES"), Canada's national anti-doping agency. In addition to its doping control functions, the CCES also has a wider a mandate which includes protecting the integrity of sport from other unethical threats and promoting sport that is fair, safe and open to all.

- 268. Mr Melia's report set out the reasons why the CCES believes that the Hyperandrogenism Regulations are "objectionable on moral, ethical and legal grounds" as well as being difficult to implement at national level and also being potentially illegal in some countries.
- 269. In relation to discrimination, Mr Melia's report explained that the CCES opposes the exclusion of individuals from sport based on any natural physical trait or feature. In his view, the Hyperandrogenism Regulations are no less discriminatory than prohibiting a women with gigantism from playing women's basketball on the basis that she falls within the "male range" for height. In addition, the Hyperandrogenism Regulations discriminate against women by subjecting female athletes to a restriction that does not exist for men. In contrast to the position with female athletes, there is no level of naturally produced testosterone above which a man would be considered to have an "unfair advantage" to compete against other men.
- 270. In relation to proportionality, the CCES believes the Hyperandrogenism Regulations are disproportionate because the concern that hyperandrogenic athletes jeopardise the integrity of sport is not substantiated by scientific evidence or history. The predecessor to the Hyperandrogenism Regulations the sex verification policy resulted in "harassment, humiliation and emotional pain for the athletes caught up in the resulting web of suspicion". Similar policies have caused "acute, and in some instances, catastrophic" harm to athletes. Mr Melia stated that the facts of the present case illustrated the damage that policies of this nature can cause: media coverage demonstrates that the Athlete's sex and gender have been questioned, resulting in emotional torment and stigma for the Athlete and her family. Mr Melia suggested that, faced with a real prospect of being subjected to an investigation of this nature, female athletes may be dissuaded from pursuing sport altogether.
- 271. According to Mr Melia, the unfairness inherent in the Hyperandrogenism Regulations is compounded by the patchwork compliance in different countries around the world. In Canada, the CCES has "serious reservations" about the propriety and legality of any attempt to implement the Hyperandrogenism Regulations. In its view, applying the Hyperandrogenism Regulations in Canada could result in a breach of national or provincial human rights and anti-discrimination legislation. The CCES does not support

- the Hyperandrogenism Regulations and would refuse to participate in any testing or procedures mandated under them.
- 272. In support of the CCES's position, Mr Melia's report summarised the conclusions of a 2012 CCES study entitled Sport in Transition: Making Sport in Canada More Responsible for Gender Inclusivity. The study focussed on the application of sex verification policies to intersex and transgender athletes. It noted, inter alia, that scientific research could not identify a definite line at which certain sex-typical characteristics confer a competitive advantage. The study stated that since between 200 and 300 genes affect sport performance, "testing any single sex-typical marker is just too limited to ever provide a conclusive basis for exclusion, or categorical proof of advantage". The study concluded that, "the greatest and potentially most damaging unfairness would be to continue to marginalize or exclude athletes with variations of sex development". Sex testing had historically been used to address a "virtually non-existent" threat to fair competition, while "the actual harms experienced by athletes from such testing have been acute, and in a few instances, catastrophic".
- 273. The IAAF waived its right to cross-examine Mr Melia, but stated that it did not thereby accept the contents of his statement.

Professor Thomas Murray (expert witness retained by the IAAF)

- 274. Professor Thomas Murray produced a written expert report dated 30 January 2015. Professor Murray is a senior academic in the field of bioethics. He is President Emeritus at the Hastings Center and is a Visiting Professor at the School of Medicine of the National University of Singapore. Since its inception in 2004, Professor Murray has chaired the WADA Ethics Review Panel.
- 275. In relation to the issues of discrimination and proportionality, Professor Murray's report contained a detailed discussion about whether fairness requires that hyperandrogenic athletes should be allowed to compete even if their condition confers a performance advantage. In Professor Murray's opinion, the essence of competitive sport is that a contest is "fair and meaningful" in the sense that "its outcome is uncertain and will be determined by the factors that are prized and valued by the sport (e.g. talent and dedication) and not by other factors". It follows from this that it is inevitable that lines

must be drawn to ensure fair and meaningful play. Those lines must delineate categories of competition; establish rules of permissible and impermissible conduct; and define what is fair and what is unfair.

- 276. Professor Murray stated that the justification for eligibility and classification schemes "is grounded in the values and meanings within the sport, the desire to create fair and meaningful contests in which success is determined by the dedicated perfection of natural talents or similar formulations". He referred to the International Paralympic Committee's classification scheme, which includes 10 impairment categories (some of which are sub-divided according to the severity of the impairment). The Committee justifies the system on the basis that, to ensure fairness, there must be a system that ensures winning is determined by "skill, fitness, power, endurance, tactical ability and mental focus", which are "the same factors that account for success in able bodied athletes". According to Professor Murray, those values are fully consistent within the "spirit of sport" described in the WADA Code, which expressly refers to "the pursuit of human excellence through the dedicated perfection of each person's natural talents".
- 277. Professor Murray's report went on to argue that a sport and its stakeholders have the right to decide what values they want to celebrate and promote; then to draw lines to ensure that their competitions emphasise such values and make them the determinant of success. In this regard, "What is unfair is decided, to a large extent, by the community of athletes and other stakeholders who understand and love the sport... The limitations each sport chooses for itself reflect a shared understanding of what that sport is meant to display and reward." While in one sense the rules of sport are arbitrary, in another sense they are far from arbitrary since "they must pass muster with the community of those who play and love that sport." According to Professor Murray, new rules will only attain that approbation if they "keep alive what it values, what natural talents enable athletes to excel, and what, in the end, is meaningful about participating and winning."
- 278. Professor Murray listed a number of factors that are commonly used to divide competitions into different categories. Age, for example, is used to divide competition so as to ensure that one side does not have "such a huge advantage that there is no doubt who will win". Weight categories may also serve to ensure meaningful competition:

most people would think it "ludicrous", for example, for a flyweight boxer to have to fight a heavyweight boxer. It is a constant challenge for sports to decide what variations among athletes are sufficiently important to justify separate classifications. In Professor Murray's opinion, different categories are justified "if they are necessary to permit similarly situated athletes an opportunity to compete with the outcome determined by what sport considers to be meaningful difference".

- 279. Professor Murray's report went on to explain that, on this basis, height is not used as an eligibility rule for competition even though it confers clear advantages in basketball and volleyball (and may be advantageous in other events) because "the athletes and other stakeholders apparently do not consider height advantage to be unfair, or to undermine or detract from the essential characteristics that they value in the sport".
- 280. Professor Murray stated that there is a clear consensus that competitive sports (at least those where power and strength are important) should be divided into male and female categories. If women are a "protected class" of competition for reasons of fairness, then regulations are necessary to "police the divide". In Professor Murray's opinion, the IAAF has "an ethical obligation" to ensure that female athletes who desire to compete against other females do not have to compete against athletes with hormone-related performance advantages commonly associated with men. This does not involve any judgment on the self-identified sex or dignity of the athlete in question; it is simply concerned with regulating eligibility in the interests of fair and meaningful competition.
- 281. In addition, Professor Murray suggested that it is "likely" that some female athletes would feel pressure to resort to doping with exogenous anabolic androgens in order to "level the playing field" with competitors who have naturally high levels of endogenous testosterone. He cited the Lance Armstrong case as an example of "how powerful the drive to keep up with one's competitors can be" and "how readily athletes can rationalize and excuse their doping".
- 282. Professor Murray disagreed with the Athlete's argument that since performance-enhancing effects of endogenous testosterone are not cheating, it is unfair to treat endogenous testosterone differently to other performance-enhancing natural physical traits. In Professor Murray's view, there can be unfairness even if there is no intention

to cheat. For example, "If a cross-country runner takes a short-cut, she has not run as far as her competitors and so must be disqualified, even if she has done so completely innocently and by mistake". Similarly, an athlete who unknowingly ingests a performance-enhancing substance must be disqualified from a race, notwithstanding his or her personal blamelessness.

- 283. According to Professor Murray, an arbitrary line (such as the 10 nmol/L threshold) can be justified if it satisfies two conditions. First, the rule must be helpful or necessary to enable meaningful competition. Second, the line must be reasonable and drawn in a place that is defensible in light of the available alternatives. In his opinion, the IAAF's policy on hyperandrogenism unquestionably satisfies the first of these requirements, since the line seeks to ensure fair and meaningful competitions for women who lack the performance advantages typically enjoyed by male athletes. In relation to the second requirement, his view is that this will be satisfied if the scientific and clinical data do not clearly refute the rationale for using a particular testosterone level to draw the line, and no obviously better way of drawing the line can be identified.
- 284. In relation to the issue of discrimination, Professor Murray stated that endogenous testosterone can be distinguished from other natural physical traits on the basis of a principled distinction between: (a) "those variations that the particular sport regards as part of the bundle of attributes constituting 'natural talents' that should play a role in determining whose performance is superior", and (b) "those variations, such as in age, weight, level of impairment, or male-type musculature, for which the sport expressly establishes separate classifications in order to assure fair and meaningful competitions".
- 285. Professor Murray disagreed that the Hyperandrogenism Regulations treat women in an impermissibly disfavourable way compared to men. The purpose of the Regulations is to protect women from having to compete against other women with the hormonal advantage of men. Professor Murray stated that evidence of a correlation between testosterone levels and enhanced athletic performance amongst men was lacking. In those circumstances, and because there is "no clamour among male competitors for separate competitions according to testosterone levels", the absence of an equivalent

- eligibility rule for male athletes does not mean that the Hyperandrogenism Regulations are discriminatory against women.
- 286. In relation to the question of proportionality, Professor Murray agreed with Dr Karkazis that the history of sex testing/gender verification had, until recently, "been characterized by poor science and insufficient, often grossly insufficient, respect for women athletes". He agreed that it is untenable to suggest that every person can be unambiguously assigned as either male or female. He also agreed that it is important to treat all individuals with respect and to ensure that individuals who are subjected to the Hyperandrogenism Regulations have their rights, privacy and wellbeing protected. Professor Murray considered that the Hyperandrogenism Regulations represented a substantial change in direction from the earlier, defective policies. The Hyperandrogenism Regulations accept that anyone who self-identifies as a woman may compete in the female category, subject only to the endogenous testosterone eligibility criterion. It is his view that the procedures under the Regulations "show proper concern for and respect for the privacy and well-being of the affected athlete".
- 287. In relation to the issue of coercion, Professor Murray accepted that the pressures on a hyperandrogenic female athlete may be "similar in intensity" to the pressures placed on competitors who were competing against competitors who were doping. However "the dynamic is utterly different". In the case of hyperandrogenism, the need for a choice between undergoing medical treatment to reduce testosterone level or foregoing competing in female events "comes from a concern for fairness and is neither undue, unnecessary nor unfair".
- 288. Professor Murray concluded his report by addressing the consequences of invalidating the IAAF's policy on hyperandrogenism. He considered that as long as certain sports permit women to compete separately from men, some policies and procedures will be necessary to determine eligibility to compete in the women's category. One option would be to accept a person's statement that she is a woman. Another would be to accept certain forms of identification document. However, these options suffer from the drawbacks of being open to misrepresentation and being likely to affect similarly situated individuals very differently. Accordingly, from the perspective of fairness and creating a level playing field, Professor Murray's opinion is that it is not unreasonable

to limit competition in women's events to individuals who are not benefiting from the androgenising effect of male levels of testosterone. Thus, in Professor Murray's view, "if the IAAF policy on hyperandrogenism is reasonably consistent with available clinical and scientific evidence, is administered scrupulously to protect the privacy, dignity and well-being of athletes evaluated under the policy, and contributes materially to the ability to stage fair and meaningful competitions for women athletes, it deserves to be upheld."

Professor Murray testified by telephone at the hearing. During his brief oral testimony he reiterated his view that fairness in sport requires rules that facilitate meaningful competition between participants who are "similarly situated" with respect to those characteristics that the sport regards as central. In his opinion, the Hyperandrogenism Regulations are a reasonable means of enabling non-hyperandrogenic female athletes to compete successfully. In response to questions by the Athlete's counsel, Professor Murray stated that he received a modest payment for his work on the IAAF Ethics Commission and for his contribution to the present case, although it was not suggested to him that the contents of his evidence were in any way influenced by the payment. Professor Murray added that it is important for regulations to be consistent with current understandings of best available science.

Professor Ljungqvist (expert witness retained by the LAAF)

- 290. In his report Professor Ljungqvist explained why he believes that the Hyperandrogenism Regulations are a necessary and proportionate means of ensuring fair competition amongst elite female athletes.
- 291. Professor Ljungqvist's report began by summarising the history of regulation in this area.
- 292. According to Professor Ljungqvist, all relevant data in particular sporting world records establish that in sports where power, strength and size are relevant, elite male athletes significantly outperform elite female athletes. Since there is now parity of resources between the two groups of athletes, it follows that the differential performance must be caused by nature not nurture. As a consequence, he says, it is generally accepted that there must be separate competitive categories for male and female athletes.

- Without those separate categories, the essence of sport which Professor Ljungqvist characterised as "a level playing field, leading to true equality of outcome" would be compromised, with detrimental consequences to female participation in elite sport.
- 293. From at least the 1960s there was a general concern that some countries might try to win more medals through the use of male athletes masquerading as females. This perceived threat led to the implementation of "sex testing" or "gender verification" tests. Initially these involved a crude physical examination of a female athlete's anatomy. This was quickly replaced by chemical sex chromatin testing, which used mouth swabs to determine whether an athlete had XX or XY chromosomes. Those tests were predicated on the assumption that all female athletes had XX chromosomes while all male athletes had XY chromosomes. Subsequent advances in science and medicine showed this to be flawed, and it became clear that the binary division made in sport between males and females is not replicated in nature. In particular, some people are intersex, meaning they do not neatly fall into one category or another.
- 294. Through enhanced medical and scientific understanding, the sports governing bodies came to appreciate that there are not two discrete categories of sex. Instead, there is a spectrum ranging from male at one end to female at the other. In the case of intersex athletes who lie between the two, "gender verification" is extremely complicated if not impossible. The existing testing procedures were therefore deemed unfit for purpose, given their potential to single out the wrong athletes and cause them harm. In any event, fears about male athletes masquerading as females had receded in the modern climate.
- 295. In 1992, the IAAF formally abandoned sex testing / gender verification. In place of general screening, it retained the authority to undertake medical examination on an *ad hoc* basis in a case if an issue arose. The IOC continued screening all female participants in the Olympic Games until 1998. In 1999, it followed the IAAF and discontinued its programme of mandatory chromosome-based gender verification testing.
- 296. In 2003, the IOC Medical Commission established an expert panel to review the rules and procedures regarding sex reassignment in sport. Professor Ljungqvist was a member of that panel. The panel's final recommendations were set out in the IOC's

Medical Commission's Stockholm Consensus Statement on sex reassignment in sports. Under the Statement, an athlete who has undergone male-to-female sex reassignment is eligible to compete in the female category: (a) provided that reassignment occurred before puberty; or (b) if the reassignment occurred after puberty, the gonads have been removed and the athlete has undergone oestrogen replacement therapy for a sufficient length of time to remove as much as possible of the advantage derived from the earlier exposure to male levels of testosterone.

- 297. Professor Ljungqvist stated that the case of Caster Semenya in 2009 demonstrated the problems of following an ad hoc policy in this area. In early 2010, the IAAF and IOC therefore held a joint meeting of medical experts and others to consider, inter alia, eligibility restrictions in respect of intersex athletes and athletes with disorders of sex development. According to Professor Ljungqvist, there was consensus that the issues relating to DSD conditions were not concerned with sex or gender verification, but rather with how to deal fairly with athletes with excessive productions of androgens. Following further meetings with experts, stakeholders and interested parties the IOC Medical Commission recommended that the IOC should adopt rules to determine the eligibility of hyperandrogenic athletes to compete in the female categories. The IOC Executive Board accepted that recommendation. In 2012, the IOC adopted Hyperandrogenism Regulations for the 2012 Olympic Games in London. In 2013, the IOC adopted hyperandrogenism regulations for the 2014 Winter Olympics in Sochi. These regulations were largely the same as the 2012 regulations for the London Olympics.
- 298. The IOC regulations expressly state that, "Nothing in the Regulations is intended to make any determination of sex." The regulations established a process for opening investigations into suspected cases of hyperandrogenism at the Olympic Games. In such cases, an expert panel comprising a genetic expert, a gynaecologist and an endocrinologist must evaluate the case in order to determine: (i) whether the athlete is hyperandrogenic; and (ii) if so, whether the condition confers a competitive advantage. In contrast to the IAAF's Hyperandrogenism Regulations, the IOC regulations do not prescribe a specific eligibility threshold of 10 nmol/L. The reason for this is the IOC's belief that "some athletes may enjoy a performance advantage even with concentrations of endogenous testosterone in serum lower than 10 nmol/L".

299. During his oral testimony, Professor Ljungqvist agreed that a range of factors such as funding, nutrition, training methods and coaching all affected athletes' performance. He acknowledged that athletes from different countries had access to different resources, and that it is not possible to compare the advantages that an athlete derives from training resources and the advantage derived from high levels of natural testosterone. He acknowledged that his own thinking had evolved over time but steadfastly defended his opinion that the Hyperandrogenism Regulations effectively serve the best interests of the community of athletes.

Dr Stéphane Bermon (expert witness retained by the IAAF)

- 300. Dr Bermon gave evidence for the IAAF, as a participant in the development of the Hyperandrogenism Regulations and also as an expert in this field. In his statement, Dr Bermon stated that since the Hyperandrogenism Regulations were enacted in April 2011, the IAAF has dealt with cases under the Hyperandrogenism Regulations. Dr Bermon, who described himself as "the 'go to' person for all matters relating to and arising under the [Hyperandrogenism Regulations]", has been actively involved with all of those cases.
- 301. In his statement, Dr Bermon explained why he believed that the Hyperandrogenism Regulations are necessary, proportionate and fair. Without the Hyperandrogenism Regulations, he said, the available data suggest that certain events in particular middle distance finals "would likely become dominated by female athletes with hyperandrogenism and athletes who are doping". This may encourage other athletes to dope in order to be able to compete at that level.
- 302. Dr Bermon began by setting out the IAAF's key objectives and its overriding responsibility to do everything in its power to guarantee fair condition. In this respect, Dr Bermon considered that fairness requires that "the only determinant of success is individual talent and determination".
- 303. In relation to the proportionality of the Hyperandrogenism Regulations, Dr Bermon expressed strong disagreement with Dr Karkazis. Contrary to what Dr Karkazis suggested, Dr Bermon said the Hyperandrogenism Regulations do not imply that female athletes with hyperandrogenism are "not really women". The Hyperandrogenism

Regulations expressly reject the concept of "sex testing" and "gender verification". They make it clear that if an athlete is regarded as female in law, she is eligible to compete in women's competition. The Hyperandrogenism Regulations do not mandate any tests to determine an athlete's sex. Nor is it correct to say that "anyone" can instigate an investigation of an athlete: an investigation may only be opened by the IAAF Medical Manager (and only if there are "reasonable grounds" based on a "reliable source" for doing so).

- 304. Dr Bermon disagreed that the Hyperandrogenism Regulations encourage suspicion of female athletes whose appearances do not conform to gender stereotypes. The specific indicators of hyperandrogenism listed in the Hyperandrogenism Regulations are not used to determine which athletes should undergo investigation. Instead, they are only used where an investigation has been opened. The guidelines are closely modelled on the American Association of Clinical Endocrinologists' Medical Guidelines for the Clinical Practice for the Diagnosis and Treatment of Hyperandrogenic Disorders (2001).
- 305. Dr Bermon also disagreed that the identity of athletes under investigation will inevitably be made public. The Hyperandrogenism Regulations are extremely clear about the need for strict confidentiality. The IAAF is, he said, "absolutely committed" to upholding the confidentiality of the athletes concerned. No one outside the IAAF knows the identity of the athletes, their nationality, or even the number of cases involved. It follows, in his view, that Dr Karkazis' concerns in this regard are "entirely unfounded".
- 306. In relation to the issue of physical harm, Dr Bermon noted that medical treatment for hyperandrogenism is entirely separate from the question of eligibility to compete in female athletics events. Hyperandrogenism can involve potentially serious health risks, making early identification and diagnosis very important.
- 307. Dr Bermon said that the Hyperandrogenism Regulations are explicit about the need for informed consent. Informed consent was obtained from all athletes who have undergone investigation and subsequent treatment under the Regulations. At no time was any surgery presented as necessary in order to be eligible to compete. According

to Dr Bermon, no athlete has ever been forced to do anything that she did not want to do, nor has athlete subsequently complained that she was.

- 308. Dr Bermon expressed his view that the functional testosterone limit under the Hyperandrogenism Regulations is "very conservative" and only captures female athletes with "very high testosterone levels, well above the normal female range". This is demonstrated by the fact that the median testosterone level for female athletes is 0.69 nmol/L and the 99th percentile for female athletes is 3.08 nmol/L. The Hyperandrogenism Regulations therefore incorporate a "significant margin" which ensures that they "only apply to female athletes with a DSD [disorder of sexual development] condition or doped female athletes".
- 309. Based on his experience of the Hyperandrogenism Regulations in practice, Dr Bermon made the following observations:
 - Of the had dealt with under the Hyperandrogenism Regulations, involved doping offences. The other athletes underwent investigation for hyperandrogenism. They athletes had more than 10 nmol/L of serum testosterone. They all underwent treatment to reduce their testosterone levels to less than 10 nmol/L. Following treatment all athletes experience a decrease in athletic performance. The extent of the decrease varied among individuals. Of the athletes who received treatment "[a]pproximately half" returned to a high level of international competition, while the others "did not repeat their initial level of performance and then retired". All of the remaining cases are ongoing.
 - Some athletes experienced minor side effects following surgical treatment; however these were successfully treated by the use of oral contraceptives.
 - The IAAF always ensures that athletes receive the necessary information in order to make a properly informed decision.
- 310. In relation to the specific circumstances of the Athlete's case, Dr Bermon repeated that the Athlete's case was not referred to the IAAF under the Hyperandrogenism

Regulations. Nor was it handled by the AFI in accordance with the Hyperandrogenism Regulations. Instead, it was handled by the SIA under the Standard Operative Procedure. Notwithstanding this, Dr Bermon had offered the IAAF's assistance to the Athlete. In August 2014, he wrote to Dr Karkazis offering to ask the Chair of the IAAF Expert Medical Panel, Professor Ritzen, to review the case file on an anonymous basis to confirm the Athlete's diagnosis and (if necessary) recommend treatment options. Dr Karkazis responded that the Athlete was receiving the help she required from the SAI and/or the AFI and it was not clear what other help she might need.

- 311. In the course of his evidence, Dr Bermon was asked why he believed it is intrinsically unfair for a woman who has naturally occurring high levels of testosterone to compete as a woman against other women. Dr Bermon responded that the unfairness arose from the fact that such athletes derive a "very important advantage" from their hyperandrogenic condition. In the sport of athletics it typically takes male and female athletes between 10 and 15 years of dedicated training to reach the level of world champion. However, hyperandrogenic female athletes can achieve this level of performance in less than a year. Dr Bermon questioned whether it was fair for an athlete to become a national, continental and world champion "out of the blue" in such a short period of time.
- 312. Dr Bermon was also asked to explain why endogenous testosterone should be singled out from among the manifold advantageous genetic variations and subjected to specific eligibility restrictions. He agreed with the premise of the question and suggested it was possible that in future athletes might be classified according to other genetic traits too.
- 313. Dr Bermon was asked to explain why, if endogenous testosterone is so relevant to athletic performance, male athletes are not subjected to the same eligibility and testing regime. Dr Bermon gave two reasons. First, he stated that there were only two categories of athletics competition: male and female. There is no third "super male" category. Second, while there are some male athletes with unusually high levels of endogenous testosterone, they do not enjoy the same performance advantage over their fellow competitors as do female athletes with unusually high levels of testosterone.

- 314. Under cross-examination by the Athlete's counsel, Dr Bermon agreed that it is not easy to determine androgen insensitivity or virilisation. Assessments cannot place a specific percentage value on the degree of androgen insensitivity. It is not possible to quantify the performance advantage that any individual athlete derives from her hyperandrogenic condition. Dr Bermon stated that in a marginal case, the IAAF Medical Panel would give the athlete the benefit of the doubt, although he acknowledged that this was not reflected in the wording of the Hyperandrogenism Regulations. Dr Bermon acknowledged the existence of a number of publications that expressed a contrary view, however he maintained his conclusions notwithstanding those papers.
- 315. Dr Bermon explained the results in the Daegu study and some of the assumptions made with respect to some of the outliers. It was clear that without the outliers, there is a definite difference in testosterone levels between the normal male range and normal female range. For females, the 99th percentile was 3.08 nmol/L, meaning that 99% of females were under this level. If the outliers were taken into account, there was what Dr Bermon called "a mild overlap". There were some males with values of less than 4 nmol/L who, Dr Bermon said, were thought to be hypogonadic which could result from the use of anabolic steroids or by overtraining or a medical condition. There were a significant number of males under 10 nmol/L.
- 316. Dr Bermon was asked to comment on the following: if the male range were lowered and the female range, without outliers, was up to 4 nmol/L, then assuming that there was normal variation and timing of testing compared to activity, would the delineation between male and female be statistically not valid? His response was that a "huge amount of work" would need to be done to investigate the males under 10nmol/L to see if the levels of testosterone were normal or pathological. However, he emphasised that the figure of 10 nmol/L was adopted by starting with the normal female range and then moving five standard deviations above the mean to fix a conservative threshold for identifying hyperandrogenic female athletes.
- 317. During the course of his oral testimony, Dr Bermon discussed the processes of measuring virilisation in order to ascertain the existence of total or partial androgen insensitivity. He acknowledged there are difficulties in ascertaining a specific

- percentage on degrees of androgen resistance. He stated that in cases of doubt the benefit of the doubt is given to the athlete.
- 318. Dr Bermon recognised that, in the future, there may be other categories considered relevant to account for genetic advantages but, he pointed out, today we only have two categories: male and female.

Professor María José Martínez-Patiño (expert witness retained by the IAAF)

- 319. Professor María Martínez-Patiño produced an expert report dated 30 January 2015. Professor Martínez-Patiño is a former elite-level female athlete. She is a national athletics coach and a Professor at the Faculty of Sciences in Education and Sport at Vigo University in Spain. Since 2013 she has served as an independent expert on the IOC's Medical Commission. As part of that role, she is involved in monitoring the IOC's hyperandrogenism rules.
- 320. In her report, Professor Martínez-Patiño explained how, during her career as a young elite athlete, she was subjected to gender-verification testing. In 1985, she "failed" the Barr body test and was declared ineligible to compete in the women's competition because of a genetic condition relating to her chromosomes. As a result, she experienced significant public criticism; her private medical information was disclosed to the world; and her status as a woman was widely questioned. Professor Martínez-Patiño later successfully challenged her ineligibility and was ultimately permitted to continue competing in women's athletics events. The experience was, however, a sad and painful one with significant and enduring personal consequences.
- Martínez-Patiño said that she defended the existing hyperandrogenism rules. Professor Martínez-Patiño said that she defended the existing hyperandrogenism rules. Professor Martínez-Patiño stated that, while the Hyperandrogenism Regulations could be improved in some respects (most notably in the areas of confidentiality, privacy and education) she supported the "spirit and approach" of the current regime. While acknowledging that she is not an expert in endocrinology, she said that she agreed with the majority of experts that the different testosterone levels in men and women provide men with a competitive advantage.

- 322. In Professor Martínez-Patiño's opinion, the Hyperandrogenism Regulations therefore serve to ensure equality in sport by enabling female athletes to compete on a level playing field in conditions that are fair and equal. In her opinion, when assessing the fairness of the Hyperandrogenism Regulations, it is necessary to consider both the women who are directly affected by the eligibility rule and also the women who are not hyperandrogenic and who wish to compete on an equal basis. In her view, the Hyperandrogenism Regulations are necessary in order for athletic competition to be carried out with equality.
- 323. In her oral testimony, Professor Martínez-Patiño was asked about a paper she had authored in which she explained her opposition to the Hyperandrogenism Regulations. Professor Martínez-Patiño explained that before she was a member of the IOC Medical Commission her opinion was shaped by her own personal experience of being subjected to gender testing under the Barr body test. However, over time her understanding of the science and medical evidence underpinning the Hyperandrogenism Regulations evolved. She had also had the opportunity to consider the perspective of high profile sportswomen and to understand the importance of ensuring a level playing field in professional sport.
- 324. Professor Martínez-Patiño explained the emotional toll of her own experience. She explained how the facts of her case had been made public after a doctor leaked the results of her medical tests to journalists. As a result of the disclosure, her partner left her and her status as a woman was the subject of worldwide discussion and speculation. Professor Martínez-Patiño stressed the overriding importance of preserving athletes' confidentiality, which was an area that the IAAF and IOC could and must improve. She suggested that disciplinary sanctions should be available whenever an individual breached that confidentiality. In addition, Professor Martínez-Patiño stated that psychologists should be involved when women are investigated under the Hyperandrogenism Regulations.
- 325. Despite her own deeply painful experience, Professor Martínez-Patiño expressed confidence that the Hyperandrogenism Regulations are a necessary and appropriate means of ensuring a level playing field for elite female athletes. In response to questioning by the Athlete's counsel, Professor Martínez-Patiño stated that the process

of undergoing medical investigation and testing does not cause an adverse psychological impact for an athlete. Instead, it is the questioning of a woman's status as a woman that causes harm.

Joanna Harper (witness who gave evidence for the IAAF)

- 326. Ms Joanna Harper produced a witness statement dated 22 January 2015. Ms Harper describes herself as a medical physicist. For over 30 years she competed in distance running events in the male category. After undergoing a process of gender transition, since 2005 she has raced in the female category.
- 327. In her statement, Ms Harper described her own experience of undergoing testosterone suppression as part of hormone replacement therapy (HRT) designed to reduce her testosterone levels from male levels to female levels. According to Ms Harper, she was "noticeably slower" within one month of starting testosterone suppression. (Her witness statement compared her finishing times for various athletics event before and after undergoing HRT.) This reduction in speed persisted after undergoing a gonadectomy.
- 328. Ms Harper subsequently collated data from seven other transgender runners. All had "much slower times" competing as females than when they competed as males. Those athletes' time differences were so great that their aged-graded performances (a mathematical method of comparing race times by men and women of all ages) stayed "virtually constant". The results of Ms Harper's study have been published in the Journal of Sporting Cultures and Identities. She concluded that, "the data indicate that, at least for distance running, manipulating [testosterone] levels is enough to change a person's athletic performance from competitive male to equally competitive female".
- 329. In addition, Ms Harper stated that her experience and those of other women athletes "suggest that exogenous and endogenous [testosterone] affects athletic performance in a very similar manner". Accordingly, the studies which link exogenous testosterone to increased athletic performance have "significant applicability to the huge hormonal advantages enjoyed by some intersex women".
- 330. Ms Harper stated that the "extreme and rapid" changes in speed that transgender women experience once they suppress testosterone indicate how important testosterone is to

performance. In her opinion, it is unreasonable to compare the athletic benefits of testosterone with the athletic benefits of other physical features such as larger hands. In her view, testosterone is "without doubt, the single most important differentiating factor between male and female athletic achievement". Accordingly, functional testosterone level is the best criterion for determining eligibility to compete in women's sport.

- 331. While there is little direct evidence enabling a comparison between exogenous and endogenous levels of testosterone and the effect on athletic ability, Ms Harper's evidence and the study that she has done and is about to publish, and the conclusions that can be drawn from that study, are relevant. Ms Harper acknowledges that it is an extrapolation from the effect of lowering endogenous levels of testosterone in transgender athletes to the general female population but she believes that the extrapolation is reasonable. That supports her opinion, she says, that testosterone is not the only factor but is the single most important differentiating factor, and the most appropriate parameter to distinguish, between male and female athletes. After transgender surgery, the body produces less endogenous testosterone and this accorded with reduced athletic ability.
- 332. In relation to the question of fairness, Ms Harper stated that it is "a very difficult thing to decide exactly what is or is not fair". However in her opinion, the best way to achieve a level playing field for female athletes is "to require all woman athletes to be hormonally similar".
- 333. In relation to the issue of medical consent, Ms Harper "very strongly" agreed with the Athlete that it is wrong for intersex women to be coerced into undertaking surgery in order to continue participating in competitive sport. She said that it was "questionable at best" whether young women in that position can give informed consent for medical interventions within the current procedures. However, Ms Harper did not agree that the harmful effects of chemical hormone manipulation are as severe as the Athlete suggested. Ms Harper underwent 18 months of chemical testosterone-suppression and, except for some diuretic effects, she experienced no adverse consequences. She has also spoken with several other female athletes who reported that they have undergone testosterone-suppression without any major side effects.

Paula Radcliff MBE (witness who gave evidence for the IAAF)

- 334. Paula Radcliffe produced a witness statement dated 26 January 2015. Ms Radcliffe is an exceptionally accomplished elite-level long-distance runner. She has won gold medals at the European Championships, World Championships and Commonwealth Games and is the current women's world record holder for the 10km, 25km and marathon events. Ms Radcliffe has been a member of the IAAF Athletes' Commission since around 2009. In 2013, she participated as an IAAF athlete representative in the IOC's review of its hyperandrogenism regulations.
- 335. In her witness statement, Ms Radcliffe described the overriding need for athletes to feel that they are competing on an equal footing and that competition is fair and meaningful. She described the multitude of sporting regulations designed to ensure fairness, ranging from rules against deliberate cheating (e.g. anti-doping rules) to the use of age, weight and gender categories that are "designed to ensure success is determined solely by talent and dedication, and not by 'unfair' advantage".
- 336. In relation to the separation of male and female athletes, Ms Radcliffe described the "huge gap" in athletic performance between elite men and elite women athletes. If men and women competed in one category then, she said, competition would not be fair and meaningful, because the men would always outperform women. Ms Radcliffe stated that, while she is not a scientist, she understood that experts consulted by the IAAF believe that the difference in performance is predominantly due to the increased levels of testosterone found in males.
- 337. Ms Radcliffe was clear in her statement that the Hyperandrogenism Regulations are not about gender or sex, nor are they concerned with deliberate cheating. Instead, they are concerned with "preserving fair and meaningful competition, based on what is fair from a sporting perspective". The Regulations are, in her view, focused on the very reasons for the significant performance gap between males and females. Ms Radcliffe would have "genuine concerns about the fairness" of having to compete against females with testosterone levels in the male range. She explained that elevated testosterone levels "make the competition unequal in a way greater than simple natural talent and dedication". While sympathetic to the feelings of hyperandrogenic athletes, she stated:

"the concern remains that their bodies respond in different, stronger ways to training and racing than women with normal testosterone levels, and that this renders the competition fundamentally unfair".

- 338. For these reasons, Ms Radcliffe fully supported the approach under the Hyperandrogenism Regulations. She believed that many other athletes share her views. She cited the reaction to the case of Caster Semenya, in respect of whom "many athletes" were "extremely concerned that she had an unfair advantages and that as a result she was able to compete at a level that they simply were not". In Ms Radcliffe's opinion, the current approach under the Hyperandrogenism Regulations is both necessary and fair and strikes an "appropriate balance" between the various interests involved.
- 339. In her oral evidence, Ms Radcliffe confirmed that her support for the Hyperandrogenism Regulations was based on the scientific opinions of the experts cited in her report and was reinforced by her own experience of growing up and competing as a female athlete. Ms Radcliffe also confirmed that during her career she had consulted with physiologists and a nutritionist and had also engaged in high altitude training all with a view to maximising her recovery rate and overall athletic performance.
- 340. In response to questioning by the Panel, Ms Radcliffe stated that as she was not a scientist, she was unable to express a view about whether allowing a female athlete to compete with an endogenous testosterone level of 8 nmol/L (i.e. just under the 10 nmol/L threshold) would upset the level playing field. However, she felt that it was important that a line be drawn somewhere and said that she understood that it was not possible for a person without a DSD to have a level of endogenous testosterone above the limit set in the Hyperandrogenism Regulations.

Nick Davies (witness who gave evidence for the IAAF)

341. Nick Davies produced a witness statement dated 28 January 2015. Mr Davies is the IAAF's Deputy General Secretary General and has been the IAAF's Communications Director since 2002. Mr Davies' witness statement was filed in response to a passage in the Athlete's Appeal Brief, which suggested that Mr Davies had leaked information about the Caster Semenya case to the media in 2009:

There are numerous examples in which the identity of athletes under investigation has been leaked to the public, including in the case of Dutee discussed below. Indeed, leaks have been committed even by those affiliated with the IAAF. IAAF official, Nick Davies, for example, confirmed the investigation into Caster Semenya to reporters prior to the women's 800 metre final at the Berlin World Championships, fuelling headlines around the world. As reported by the New York Times: '[Davies] said the I.A.A.F. had decided to confirm the existence of the investigation [into Semenya] only when asked about it in Berlin by reporters. "The choice is that you lie, which we don't like to do," said Davies, acknowledging that it was unfortunate that Semenya's privacy had been violated.

- 342. According to Mr Davies, the suggestion that any individuals affiliated with the IAAF leaked details about the identity of athletes being investigated in relation to gender/hyperandrogenism issues is "completely untrue". On the contrary, he says that the IAAF had done its best to protect their confidentiality and privacy at all times.
- 343. In his statement, Mr Davies explained the background and circumstances of Ms Semenya's case. He stated that while she was being investigated for possible hyperandrogenism, stories had begun to circulate in the media that the IAAF had asked Athletics South Africa (ASA) to carry out tests to verify Ms Semenya's sex. The IAAF was not the source of those stories; however Mr Davies began to receive questions from journalists seeking confirmation whether they were true. After initially refraining from making any comment, Mr Davies eventually confirmed that an investigation was being carried out into Ms Semenya's eligibility to compete in women's competitions. He did this, he explained, in order to prevent further damaging and inaccurate speculation about Ms Semenya. He explained that he had been careful to emphasise that Ms Semenya was not accused of cheating; that she had been allowed to compete because there was no evidence that she was ineligible; and that Ms Semenya's privacy should be respected while this complex medical issue was resolved.
- 344. Mr Davies said that the IAAF subsequently worked with Ms Semenya and her advisers to resolve the matter. Throughout that period they carried out the investigation in strict confidence. In July 2010, the IAAF announced that a panel of medical experts had concluded that she could compete with immediate effect and that the medical details of the case would remain confidential.

- 345. Mr Davies ended his statement by stating that he was not aware of any other case where it had been alleged that the IAAF leaked the name of an athlete being investigated. Since April 2011, the IAAF has dealt with cases under the Hyperandrogenism Regulations. None of the athletes involved has ever been named in the press as the subject of an investigation under those Regulations. Even Mr Davies does not know the names of those involved. As far as he is aware, the only people who do know the identities of the athletes are Dr Pierre-Yes Garnier (the IAAF Medical Manager); Dr Stéphane Bermon (a member of the IAAF's Medical & Anti-Doping Commission); and possibly Dr Juan Manuel Alonso (Chair of the IAAF's Medical & Anti-Doping Commission).
- 346. In his oral testimony Mr Davies expanded upon his account of his public statements concerning Ms Semenya in 2009. He described the "unpleasant tabloid-style reporting" which involved speculation about Ms Semenya's anatomy and whether she had male levels of hormones. The level of media attention and speculation ultimately reached such a level that the IAAF took the view that "enough was enough". They therefore publicly confirmed that Ms Semenya was undergoing tests, but emphasised that she was free to compete and that her privacy should be respected while the process unfolded.
- 347. The Athlete's counsel referred Mr Davies to press reports containing quotes from the IAAF's General Secretary, who had told the media that Ms Semenya was undergoing tests at hospitals in Berlin and South Africa. Mr Davies said that he did not believe that the disclosure of this information constituted a breach of confidentiality, as the IAAF official was merely explaining the testing procedure. Mr Davies confirmed that in response to journalists' questions he had referred to "suspicions of gender issues" following a "bombshell result" at an athletics competition earlier in the year. Mr Davies went on to say that, as a result of the sustained media attention on Ms Semenya, the IAAF was presented with a choice between lying or confirming that she was undergoing testing.
- 348. Mr Davies said that he believed his answers to journalists' questions were "perfectly acceptable". However he candidly acknowledged that he would not take the same approach today, adding that the Hyperandrogenism Regulations are "very clear and different" to the regime that was in force when Ms Semenya was investigated in 2009.

Madeleine Pape (witness who gave evidence for the Athlete)

- 349. Madeleine Pape submitted a witness statement dated 25 February 2015. Ms Pape is a former Olympic athlete who represented Australia in the 800 metres sprint event. She is currently undertaking a Ph.D. at the University of Wisconsin and describes herself as "a passionate advocate of gender equality in sport".
- 350. In her statement, Ms Pape described her experience of competing alongside Caster Semenya at the World Athletics Championships in Berlin in 2009. She described how, having heard reports that Ms Semenya's sex was being investigated by the IAAF, she had felt angry when Ms Semenya appeared to win the race so convincingly. She suspected that Ms Semenya had a competitive advantage over other female athletes as a result of possessing certain biological traits associated with male bodies (including male levels of endogenous testosterone). Her feelings were reinforced by the comments of her fellow athletes (both male and female) who described Ms Semenya as a man.
- 351. Ms Pape's statement went on to describe how her views had evolved very significantly as a result of her educational studies and her engagement with social scientific critiques of gender relations and sexuality. In particular, her appreciation of the complex and non-binary nature of sex has resulted in a substantial revision from her previous views, which were founded on a deep conviction that the division of athletes into discrete male and female categories is straightforward and underpinned by uncontroversial scientific knowledge.
- 352. Ms Pape expressed the view that despite their express disavowal of "gender verification", the Hyperandrogenism Regulations do amount to sex testing and are perceived as such by the athletics community. In her view, this is because "the act of drawing a line between the endogenous testosterone levels of male and female athletes, in combination with scrutinising other bodily and behavioural characteristics of women, is unmistakably an attempt to define those who are not women for the purposes of athletic completion, even if they are not explicitly being defined as men". She added that, "the use of the term 'masculine' in place of 'male' is a semantic strategy that in no way absolves the Regulations of their sex test function".

- 353. Ms Pape took issue with Paula Radcliffe's reliance on the notion of "a fair and level playing field". According to Ms Pape, this position is problematic for two reasons. First, sport is inherently unfair and there are innumerable randomly distributed factors that affect athletic performance and which preclude the possibility of a level playing field. She cited the examples of variations in: (i) height; (ii) vision; (iii) aerobic capacity and endurance; (iv) muscle growth; (v) access to state-of-the-art training facilities and methods; (vi) access to superior coaching; (vii) access to sports-psychology services and sports-science services; and (viii) access to nutritious food and health supplements. Second, Ms Pape suggested that Ms Radcliffe's reliance on the IAAF's position regarding the scientific effects of endogenous testosterone fails to acknowledge the complexity of the scientific evidence or the extent of divergent views amongst the experts themselves.
- 354. Towards the end of her statement, Ms Pape stated that in light of the performance gap between men and women in many sports, she supported the ongoing separation of the sexes where appropriate. However, she opposes "resorting to flawed scientific perspectives to police that separation" and "targeting of women whose self-presentation is inconsistent with dominant gender stereotypes". She added that there was no sign that the IAAF had engaged with a diverse group of female stakeholders in the process of adopting the Hyperandrogenism Regulations. Ms Pape strongly rejected the suggestion in Dr Murray's witness statement that the Hyperandrogenism Regulations received support from the majority of the community of female athletes.
- 355. Ms Pape exhibited to her statement a letter to the IAAF Council signed by a number of elite-level athletes, medical professionals and human rights activists. The letter, which was dated 3 December 2014, expressed strong opposition to the Athlete's suspension. The letter attacked the scientific basis of the Hyperandrogenism Regulations and argued that the policy exacerbates the unfair scrutiny and discrimination of women in sport who are perceived as deviating from gender norms. It added that the Hyperandrogenism Regulations place a disproportionate burden on women from developing countries and women who earn low incomes, adding that the policy "fundamentally undermines the spirit of sport".

356. During her oral testimony, Ms Pape repeated that there is a diversity of ways in which an athlete may enjoy a competitive advantage over other athletes. Women in developed countries, for example, enjoy certain advantages as a result of their location. In her opinion, by focusing on a single biological trait the Hyperandrogenism Regulations exhibit a profound failure to appreciate the many different ways in which the sport of track and field is inherently un-level. She added that there is a complex and dynamic interaction between human biology and the social context and structures within which humans operate. She believed that it is necessary to move beyond a binary opposition between nature and nurture and to explore the complexity of that interaction. In effect, her view is that the IAAF's narrow focus on endogenous testosterone fails to grapple with that multi-faceted complexity.

Issue 4: Impermissible doping sanction

The Athlete's submissions

- 357. The Athlete's fourth ground of challenge contends that the Hyperandrogenism Regulations have the practical effect of imposing a doping sanction on female athletes who fall foul of the endogenous testosterone limit. That sanction is not authorised under the WADA Code and is therefore unlawful.
- 358. The Athlete submits that the Hyperandrogenism Regulations operate as "disguised doping rules" because they establish, under the guise of ensuring a level playing field, a testosterone threshold above which a female athlete is automatically banned from competing. The Athlete's Appeal Brief described the Hyperandrogenism Regulations as having "the feel and effect of a ban on 'endogenous doping'". Because they share the same rationales and consequences as the rules on exogenous testosterone doping, the Hyperandrogenism Regulations are, she contends, effectively an attempt by the IAAF to add natural testosterone production to the WADA Prohibited List. This would be contrary to Article 4.3.3 of the WADA Code, which provides that WADA's list of prohibited substances is final, and Article 23.2.2, which requires all WADA signatories to implement Article 4.3.3 of the Code without any substantive changes.
- 359. In addition, the Athlete submits that the Hyperandrogenism Regulations have the effect of establishing a sanction that is not authorised by Article 10 of the WADA Code, which

contains an exhaustive list of permissible anti-doping sanctions. An athlete who chooses not to undergo the medical interventions necessary to resume competing effectively faces a lifetime ban from all athletic competition. This is the most severe possible sanction in professional sport. The Athlete says that the Hyperandrogenism Regulations therefore have the effect of imposing – and are perceived by athletes as imposing – an additional sanction beyond those permitted under the WADA Code.

- 360. In support of this argument, the Athlete relies on the decision of the CAS Panel in <u>United States Olympic Committee v International Olympic Committee</u>, CAS 2011/O/2422. In that case, the IOC had established a rule that any person who had been sanctioned by an anti-doping organisation with a suspension longer than six months was automatically prevented from participating in the next Summer Olympics or Winter Olympics. The CAS Panel declared the rule invalid because it contravened Article 23.2.2 of the WADA Code, which requires signatories to implement particular Articles of the WADA Code "without substantive change" and without adopting "additional rules...which change the effect of" those Articles.
- 361. The Athlete also relied on the decision of the CAS Panel in <u>British Olympic Association v WADA</u>, CAS 2011/A/2658, which concerned a bylaw that declared that any individual who had committed an anti-doping rule violation would be ineligible for selection to the Great Britain Olympic Team. The CAS Panel did not accept that the bylaw was a selection policy and not an extra doping sanction. The Athlete submits that the CAS Panel placed particular weight on the effect of the bylaw, noting that it imposed the same sanction as under the WADA Code, namely "ineligibility".
- 362. Accordingly, the Athlete submitted that even if the Hyperandrogenism Regulations have elements of both an eligibility rule and a sanction, the consequences of their application and athletes' general perception of the Hyperandrogenism Regulations mean that they should be treated as a disciplinary sanction. This view is reinforced by the fact that the consequence of exceeding the 10 nmol/L testosterone threshold a lifetime prohibition on competing is more severe than the available sanction for a first doping offence under the WADA Code. It follows, the Athlete submits, that the Hyperandrogenism Regulations should be declared invalid because they violate the WADA Code.

363. During his closing submissions, the Athlete's counsel candidly conceded that this ground of attack is the weakest limb of the Athlete's challenge to the Hyperandrogenism Regulations, and that it would likely stand or fall with the Athlete's other grounds of challenge.

The IAAF's submissions

- 364. The IAAF rejects the Athlete's argument that the Hyperandrogenism Regulations constitute a form of impermissible anti-doping control.
- 365. The IAAF submits that the two CAS cases relied on by the Athlete concerned rules that were clearly doping-related. In both cases, the rules sought to remedy what was perceived to be an excessively lenient approach under the WADA Code by establishing an additional sanction for athletes who commit anti-doping violations. The IAAF submits that the Hyperandrogenism Regulations are entirely different in character and that the Regulations do not add a further punishment on top of the prescribed WADA Code sanctions for an anti-doping violation; nor do they create a new anti-doping rule violation in addition to the ten species of violations set out in the Code. Instead, the IAAF says that they establish an eligibility condition equivalent in character to a boxing weight-limit. Exceeding the specified level of testosterone is not treated as doping or any other form of misconduct. On the contrary, as soon as an athlete meets the eligibility criteria she is permitted to compete.
- 366. The IAAF points out that WADA has never suggested that the Hyperandrogenism Regulations breach the WADA Code. On the contrary, the IAAF produced a letter from WADA's General Counsel and Chief Operating Officer, Mr Oliver Niggli, which expressly confirmed that WADA does not consider the Hyperandrogenism Regulations to infringe the WADA Code. Mr Niggli's letter confirmed that:

It is not an anti-doping rule violation under Code Article 2 for an athlete to have present in his or her system testosterone that is endogenous (i.e., that has been produced naturally by the body), irrespective of the concentration of that endogenous testosterone in the athlete's body. Such naturally produced substances simply are not prohibited and do not constitute doping.

367. Mr Niggli's letter added that, based on what the IAAF had told him about the Hyperandrogenism Regulations (which was consistent with WADA's own

understanding of those Regulations) "it is clear that they condition eligibility on a matter (having serum levels of endogenous testosterone below 10 nmol/L) that is not an anti-doping rule violation, and indeed has nothing to do with doping. For that reason, I can confirm that WADA does not consider the IAAF's Hyperandrogenism Regulations to infringe Code Article 23.2.2."

368. The Athlete did not seek to cross-examine Mr Niggli at the hearing. However, the Athlete's counsel made it clear that the Athlete did not thereby accept the content of his statement, which the Athlete submitted was inadmissible opinion evidence on issues of law rather than issues of fact.

The circumstances of the Athlete's suspension

- 369. The Athlete's Appeal Brief invited the CAS to quash the AFI's decision, recorded in the Decision Letter, to suspend the Athlete from competing.
- 370. For the reasons outlined above at paragraph 105, it is unnecessary for the Panel to make any order in respect of the AFI's Decision Letter. Nevertheless, the circumstances in which the Athlete was suspended from competing are important background to the Athlete's case and cast relevant light on the manner in which national federations investigate and test athletes with suspected hyperandrogenism. The Panel received detailed written and oral evidence from a number of witnesses about this issue. Accordingly, the Panel considers it appropriate to summarise that evidence and its findings in relation to some of the disputed issues in this Award.

Dutee Chand (The Athlete)

371. The Athlete submitted a short witness statement dated 14 November 2014. In her statement, the Athlete described her personal background and her route to national-level junior athletics from her family home in a small rural village in Odisha, India. The Athlete explained the rigour of her training regime, her passion for athletic competition and summarised her athletic achievements during her short career to date. The Athlete emphasised that she was born and raised as a woman; is legally recognised as a woman under Indian law; and has always considered herself to be a woman in every respect.

- 372. The Athlete's statement set out her account of what occurred during the medical examinations that she underwent in June and July 2014. The Athlete described how, having been asked by Mr Dogra to meet him in Delhi, on 27 June 2014 she attended a clinic in Delhi with Dr Mendiratta. According to the Athlete, Dr Mendiratta told her that in order to create a "high performance profile", she would need to undergo a test to check if she had any diseases. Dr Mendiratta said that since no nurses were available to take a blood test, she would need to undergo an ultrasound scan instead. The Athlete duly underwent an ultrasound examination. The Athlete said that she never received any prescription or report from the doctor who carried out that examination.
- 373. Several days later, the Athlete underwent further medical examinations by SAI doctors in Bangalore. The Athlete described how she was subjected to a "humiliating" examination by a male doctor, who asked intrusive questions about her body hair, menstrual cycle, surgical history and her hobbies. Several doctors carried out physical examinations of the Athlete body, including on her genital area. The Athlete said she felt vulnerable and did not feel that she had any choice in relation to the testing.
- On 13 July 2014, a SAI medic, Dr Sarala, told the Athlete that she would not be allowed to compete in the World Junior Championships and would not be considered for selection to the Commonwealth Games. The Athlete described her shock and devastation upon being informed that she could no longer compete. She described the severe distress she experienced as a result of the ensuing media speculation about her gender, which humiliated and "shamed" the Athlete and her family. The Athlete said that she felt abandoned, insecure and helpless. She was subjected to cruel questions from reporters and felt like a student who had failed her exams. Even in the Athlete's rural village, she and her parents could not escape the intense and invasive media attention.
- 375. Following a meeting with officials from the SAI and AFI on 14 August 2014, the Athlete attended the Railway Athletic Meet in Chennai on 31 August 2014. At that event, Mr Valson handed the Athlete the Decision Letter, which notified her that she was ineligible to compete in any athletics events with immediate effect. Although she knew the decision was coming, she was very upset at being prevented from competing.

- 376. The Athlete concluded her witness statement by explaining that while she desires more than anything to return to competitive athletics, she does not want to change who she in order to conform to the eligibility conditions imposed by the Respondent.
- 377. During her oral evidence, the Athlete repeated that she had never complained of abdominal pains before the ultrasound examination. She said she had asked Dr Mendiratta why she had to undergo an ultrasound examination and not a blood test. Dr Mendiratta replied that an ultrasound was necessary in order to compile a "high performance profile" for the Athlete.
- 378. In response to a question by the IAAF's counsel, the Athlete confirmed that Dr Mitra had discussed the various options open to her, but had not mentioned the fact that it might be possible for the Athlete to continue competing without having to undergo any medical treatment and/or challenge the Hyperandrogenism Regulations.
- 379. At the conclusion of the hearing, the Athlete delivered a short statement to the Panel with the assistance of an interpreter. She stated that while people would recognise her as a woman if her appeal succeeds, she is deeply concerned they may not do so if her appeal is dismissed. She described how a young female friend had been forced to leave her village after people refused to accept her as a girl because of her physical appearance. The Athlete went on to describe how she had already developed a good reputation her country. She fears that if she loses her appeal, she will have to leave her village.

Dr Payoshni Mitra (witness of fact who gave evidence for the Athlete)

- 380. Dr Payoshni Mitra prepared a witness statement dated 14 November 2014. Dr Mitra describes herself as "a researcher and activist in the area of gender and sports". She holds a PhD on gender and sport issues and has worked with a number of international women's sports organisations. She expressly provided her statement to the CAS "in support of" the Athlete's appeal.
- 381. In her statement, Dr Mitra described how she has spent five years working with athletes affected by gender verification tests and policies on hyperandrogenism. Through this experience she has observed "the misuse of these tests and policies due to a lack of clear understanding".

- 382. In Dr Mitra's opinion, the Hyperandrogenism Regulations are "unethical, unfair and prejudicial rules that have caused substantial harm to a number of women". In this regard, she cited examples of athletes being forced to undergo surgery without clear information about what the treatment involved.
- 383. Dr Mitra was involved in the creation of the Indian Ministry's Standard Operative Procedure. According to Dr Mitra, her recommendations to the Ministry were "ignored" and she was "not satisfied" with the final version of the document.
- 384. Dr Mitra said that she became involved with the Athlete's appeal after she learned about the case from a member of the Indian media on 17 July 2014 (Dr Mitra later clarified that the date was erroneous, and that she had in fact been informed about the case on 15 July). Dr Mitra made contact with the Athlete and offered her assistance. On 21 July 2014, Dr Mitra met with the Athlete and her sister at their home in Odisha. According to Dr Mitra, the Athlete was extremely upset about her treatment by the SAI and AFI. During the meeting, it became clear to Dr Mitra that the Athlete had not understood the medical testing and had not provided her informed written consent to the medical examination.
- 385. According to Dr Mitra's statement, at the Athlete's request she held discussions with senior staff at the SAI in Delhi during the following days. Dr Mitra told the Director General of the SAI that the Athlete had not been treated in accordance with the Hyperandrogenism Regulations; that the Regulations were flawed and discriminatory; and that the SAI should support the Athlete in pursuing any appeal against the decision to prevent her from competing. During the meeting, Mr Thomson appointed Dr Mitra to act as a mediator and advisor on behalf of the Athlete.
- 386. On 13 August 2014, Dr Mitra attended a meeting in Delhi with the Athlete and senior officials from the AFI and SAI. According to Dr Mitra, at that meeting the AFI stated that it would formally notify the Athlete that she had been declared ineligible under the Hyperandrogenism Regulations. After the Athlete received the AFI's Decision Letter, Dr Mitra worked with the Athlete and the SAI to challenge the decision under the Hyperandrogenism Regulations.

- 387. Dr Mitra's statement sought to explain the effect of the Athlete's suspension in light of the prevailing social climate in India, which includes high levels of misogyny and violence against women. According to Dr Mitra, Indian culture places a high value on fertility and sexual purity. Against that backdrop, the repeated public references to the Athlete's "gender" and the presence of "male hormone" in her body have made life extremely difficult for the Athlete. The Athlete often breaks down because of the way her sexual identity, honesty and ability to procreate have been questioned in the media. While the Athlete has responded with remarkable resilience to the invasive and deeply personal coverage, her life is unlikely ever to be what it would have been had she not been exposed to such intense public scrutiny and questioning about her gender.
- 388. During her oral evidence, Dr Mitra confirmed her account of her involvement in events in June and July 2014. In response to a question by counsel for the IAAF, Dr Mitra confirmed that she had not advised the Athlete that if she was androgen insensitive she would be eligible to resume competing without undergoing any medical treatment. Dr Mitra added that she had assumed that the issue of androgen insensitivity had already been addressed and that was why the Athlete had been disqualified from further competition.
- 389. Dr Mitra confirmed that she was not an employee of the SAI. She explained that she had previously acted as a consultant to the SAI on hyperandrogenism; however the consultancy was now finished. Dr Mitra stated that she had expressed numerous concerns to the SAI about the SOP which, according to Dr Mitra, was subsequently withdrawn on 20 February 2015.

Dr Arun Kumar Mendiratta (Chairman of the AFI Medical Committee)

- 390. Dr Mendiratta produced a witness statement dated 16 January 2015. Dr Mendiratta is a medical doctor and is the chairman of the AFI's Medical Committee.
- 391. In his statement, Dr Mendiratta explained how the AFI is required to comply with the regulatory requirements imposed by the Ministry, including the Standard Operative Procedure. Under the Standard Operative Procedure, cases of suspected hyperandrogenism must be referred to the "nodal officer" of the national sports federation or SAI, who must then arrange for a female doctor to conduct a physical

examination of the athlete. If that examination raises questions, a test is undertaken to determine the level of testosterone in the athlete's serum. If the concentration exceeds 6.9 nmol/L, a medical panel selected by the SAI will conduct a detailed medical evaluation that includes determining the level of certain hormones, chromosomal analysis and may also include an MRI scan of the pelvis and a psychological evaluation. On the basis of those tests, the panel will then make a recommendation to the SAI as to whether the athlete should be allowed to compete in the female category.

- 392. In his statement, Dr Mendiratta described how, following the National Inter-State Athletics Championships in June 2014, the President of the AFI told Dr Mendiratta that during a recent visit to a SAI training camp, "several female athletes had expressed concern to him that the Athlete appeared to be very masculine in her physique, and queried whether she should be allowed to compete in the female category". Subsequently, during the Junior Athletics Championships in Taipei between 12 15 June 2014, officials from the Asian Athletics Federation and some national coaches "informally observed about the Athlete's stride and musculature" and questioned her right to participate in female events.
- 393. According to Dr Mendiratta, in late June 2014 Mr Dogra informed him that the Athlete and another female athlete had complained of repeated stomach problems. Mr Dogra therefore advised Dr Mendiratta to conduct an ultrasound examination to investigate the cause of the problems. In addition, he asked Dr Mendiratta to arrange for blood and urine samples to be tested for anti-doping and health monitoring purposes. Dr Mendiratta expressly denied that any of these tests were connected with gender testing or testing for hyperandrogenism.
- 394. Dr Mendiratta stated that the two athletes subsequently attended his clinic in Delhi in late June 2014. Dr Mendiratta said that he explained the purpose of the blood and urine samples to the athletes. They then attended a nearby private clinic where a different doctor carried out the ultrasound examinations. Dr Mendiratta stated that he told the doctor that the two women required ultrasound examinations to determine the cause of unexplained abdominal pains. He insisted that he did not ask the doctor to look for anything else, and did not participate in the ultrasound examination himself.

395.	According to Dr Mendiratta, after examining the Athlete, the doctor explained that he
	had been unable to determine the cause of her abdominal pain.
	In his witness statement, Dr Mendiratta cited a desire
	to protect the Athlete's medical confidentiality as a reason for not describing exactly
	what the doctor said to him.

- 396. Following the ultrasound examination, Dr Mendiratta informed the athletes that the blood testing had to be conducted at a NABL-accredited laboratory, while the urine sample had to be conducted by the national anti-doping agency. Both of these venues were at least a 60-90 minute journey away. According to Dr Mendiratta, the athletes' representative said that they did not have enough time because they had to fly to Bangalore that afternoon. Dr Mendiratta therefore told them to get the blood and urine testing done at the training camp in Bangalore. In his statement, Dr Mendiratta expressly denied that he had told the Athlete that no nurses were available to do a blood test and that an ultrasound examination would therefore have to be undertaken instead. He denied telling the Athlete that the AFI was creating a high performance profile for her and did not recall the Athlete being "edgy", as she had described in her witness statement.
- 397. According to Dr Mendiratta, after the ultrasound examination in Delhi he told Mr Valson

 Dr Mendiratta said there was now

He noted that the Hyperandrogenism Regulations contained a procedure that served as a guide at national level, whereas the Standard Operative Procedure is mandatory. He therefore told Mr Valson that the AFI needed to follow the Standard Operative Procedure to obtain a proper diagnosis. However, since the AFI had not found a suitable female to appoint as "nodal officer" to investigate such cases (as was required under the Standard Operative Procedure) he said the AFI would need to refer the case to the SAI.

- 398. From 15 July 2014 onwards, reports began to be published in the Indian media suggesting that the Athlete was undergoing gender tests. The AFI was not given any advance warning of the SAI's press release dated 16 July 2014.
- 399. Dr Mendiratta stated that on 17 July 2014, the IAAF Medical Director, Dr Gabriel Dollé, contacted him to say that he had read media reports and was concerned that he had not heard anything from the AFI about the case. Mr Valson subsequently told Dr Mendiratta that he could tell Dr Dollé that the Athlete would not be competing in the forthcoming World Junior Championships. On 19 July 2014, the SAI sent Mr Valson an email stating that the Athlete "may not participate in the World Junior Championships in the female category". According to Dr Mendiratta, the SAI then cancelled the Athlete's travel arrangements to the Championships and withdrew her from the team.
- 400. On 14 August 2014, Dr Mendiratta attended a meeting with the Athlete, Mr Valson, Mr Thomson and Dr Mitra. Dr Mendiratta denied that at this meeting the AFI had agreed to send a letter to the Athlete informing her that she had been deemed ineligible under Hyperandrogenism Regulations. According to Dr Mendiratta, Mr Thomson opened the meeting by saying that the AFI should formally notify the Athlete that she was disqualified under the Hyperandrogenism Regulations. Dr Mendiratta replied that the AFI could not inform her of anything, since it had not received the medical reports from the SAI, and therefore could not determine whether the Athlete was ineligible to compete.
- 401. Later in the meeting, Dr Mitra said that if the AFI concluded that the Athlete was not eligible to compete, then the Hyperandrogenism Regulations were unethical and unlawful. Mr Thomson said that the SAI agreed with this position and would support the Athlete if she chose to appeal. Dr Mendiratta said that he was surprised about the SAI's stance, since up to that point he had understood that the SAI had concluded that the Athlete was ineligible to compete under the Standard Operative Procedure.
- 402. On the evening of 14 August 2014, the SAI gave Dr Mendiratta a copy of the Athlete's medical reports. Dr Mendiratta subsequently chaired a meeting of the AFI Medical Committee to discuss the case. The Committee reviewed the results of the Athlete's

tests. According to Dr Mendiratta, the AFI Committee saw "no reason to question" the SAI's diagnosis of hyperandrogenism. The AFI Committee therefore "concluded unanimously, based on the [Hyperandrogenism Regulations], that the Athlete should be removed from competition immediately, but only on a provisional basis, with the opportunity then to pursue the option set out in the [Hyperandrogenism Regulations] of having an Expert Medical Panel recommend a treatment protocol that she could undertake (should she and her medical advisors think fit) in order to establish her eligibility to compete". On the basis of that recommendation, Mr Valson wrote to the Athlete on 29 August 2014 stating that she was provisionally stopped from competing and that in order to be eligible to compete she should follow the Hyperandrogenism Regulations.

- 403. According to Dr Mendiratta, the Athlete never asked to be referred to an Expert Medical Panel under the Hyperandrogenism Regulations. Instead, she requested the AFI either to reconsider its decision or to support her appeal to the CAS against the Regulations.
- 404. Dr Mendiratta ended his witness statement by emphasising that the Athlete's examination and diagnosis was conducted by the SAI in accordance with the Ministry's Standard Operative Procedure. It was not undertaken by the AFI under the Hyperandrogenism Regulations. Dr Mendiratta did not know what the SAI doctors had told the Athlete about the investigation because neither he nor anyone else at the AFI was involved in the investigation at all. Dr Mendiratta was therefore unable to confirm whether the SAI doctors had complied with the Standard Operative Procedure. However, he did confirm that the AFI had received the results of the SAI's medical analysis and had relied on those reports in deciding that the Athlete should be excluded from competition under the Hyperandrogenism Regulations.
- 405. During Dr Mendiratta's oral evidence, he repeated that the AFI had not conducted any medical investigation of the Athlete. Instead, it had contacted the SAI after "doubts" were expressed regarding the Athlete's potential hyperandrogenism. He added that the AFI had not leaked any information about the Athlete's medical tests to the media.
- 406. Dr Mendiratta stated that several female athletes had expressed concerns to the President of the AFI that the Athlete appeared to be masculine in her physique. When

pressed during cross-examination, Dr Mendiratta said he did not know the names of the athletes, and had only learned of this through a conversation with the President of the AFI. Dr Mendiratta also said that at the Junior Asian Athletics Championships in Taipei he had overheard several coaches and officials express "concerns" about the Athlete's "very masculine" appearance. However he could not say which countries the coaches and officials were from.

- 407. During his oral testimony, Dr Mendiratta was asked questions about the medical examination that took place in June 2014. Dr Mendiratta stated that on 27 June 2014 the Athlete and two other women had attended his clinic in Delhi. The two athletes had been "repeatedly complaining" about abdominal problems. According to Dr Mendiratta, his standard advice in such cases is to undertake an ultrasound examination in order to make a provisional diagnosis. During cross-examination, Dr Mendiratta was asked whether he had asked the Athlete any questions before proceedings to conduct an ultrasound examination. Dr Mendiratta did not answer this question directly, however it was clear from his response that he did not ask the Athlete any questions about her condition before the ultrasound was conducted.
- 408. According to Dr Mendiratta, the woman who accompanied the Athlete had discussed the Athlete's problem with Dr Mendiratta, although she "did not elaborate" on the nature of the problem. Dr Mendiratta stated there was "not enough time" for him to undertake a clinical examination before conducting the ultrasound, and in any event he was not allowed to conduct an external physical examination of a female patient without a female attendant being present. Since there is no female attendant at his clinic, he was therefore unable to conduct a physical examination before the Athlete underwent the ultrasound at the nearby laboratory. Dr Mendiratta added that the woman who accompanied the Athlete had requested him to undertake an ultrasound examination.
- 409. Dr Mendiratta confirmed that there were no notes or medical records concerning the ultrasound examination. He denied that he had told the Athlete that the examination was part of a high performance profile being created for the Athlete. He also denied telling the Athlete that the purpose of the ultrasound was to investigate abdominal pain. In response to a question by the Athlete's counsel, Dr Mendiratta confirmed that he was aware that he was not permitted to undertake "gender verification" testing. He added

- that, had the AFI been seeking to verify the Athlete's gender, they could have referred her for blood tests and/or an MRI examination.
- 410. During cross-examination Dr Mendiratta acknowledged that he had informed Mr Valson about "possible doubts" about the Athlete's gender, but stated that he had not mentioned her "diagnosis" to him. Dr Mendiratta insisted that he had not disclosed any of the medical information that was communicated to him by the doctor who conducted the ultrasound examination and that he had therefore preserved the Athlete's medical confidentiality. Dr Mendiratta sought to distance himself from the content of the letter sent by Mr Valson three days later on 30 June 2014 (entitled "Gender Verification issue"). He again insisted that the ultrasound had nothing to do with seeking to verify the Athlete's gender.

Natasha Singh (witness of fact who gave evidence for the Athlete)

- 411. Natasha Singh provided a two-page witness statement dated 17 Marcy 2015. Ms Singh is the Marketing Manager for the Athlete's commercial sponsor, the Anglian Medal Hunt Company. Ms Singh's statement provided her account of the medical examination that the Athlete underwent in late June 2014. Although Ms Singh's statement was filed a substantial time after all of the Athlete's other witness statements (and after the IAAF had filed its witness statements), the Panel permitted the statement to be admitted in evidence on the basis that it responded to points made in the IAAF's witness evidence and, if not admitted, the Panel would be left with an incomplete factual picture of the relevant events.
- 412. According to Ms Singh, the Athlete travelled to New Delhi at the end of June 2014 and asked Ms Singh to accompany her to the AFI's office. Upon arrival, AFI officials informed the Athlete that she had to undergo a routine doping test. Ms Singh stated that Dr Mendiratta informed the Athlete that the test was a "High Performance Profile test" to assess the Athlete's performance level and to gauge what steps could be done to enhance it.
- 413. Ms Singh stated that she had never heard anyone mention the Athlete having stomach pains. Ms Singh was never told that the Athlete's tests would involve an ultrasound

examination and she only learned about this after the Athlete returned from the ultrasound examination. Ms Singh stated that after the ultrasound, Dr Mendiratta informed the Athlete that further tests would be carried out at another laboratory, since the necessary kit and staff were not presently at that site. Ms Singh told Dr Mendiratta that the Athlete had to catch a flight to Bangalore and there would not be time to travel to the other lab. In reply, Dr Mendiratta stated that the further tests could be carried out at Bangalore.

414. During her oral evidence, Ms Singh explained that she was first put in touch with the Athlete through the Athlete's sister. She repeated that the AFI had said that the Athlete must undergo a routine anti-doping test and that Dr Mendiratta had told her the Athlete was undergoing a high performance profile test. Ms Singh maintained that she had not discussed the Athlete's ultrasound examination with Dr Mendiratta or made any reference to the Athlete suffering abdominal pains at any point.

VI. ADMISSIBILITY

415. Article R49 of the Code provides as follows:

In the absence of a time limit set in the statutes or regulations of the federation, association or sports-related body concerned, or of a previous agreement, the time limit for appeal shall be twenty-one days from the receipt of the decision appealed against. After having consulted the parties, the Division President may refuse to entertain an appeal if it is manifestly late.

416. Rule 60.23 of the IAAF Competition Rules 2014-2015 provides as follows:

Unless the Council determines otherwise, the appellant shall have thirty (30) days in which to file his statement of appeal with CAS starting from the date of communication of the written reasons of the decision to be appealed (in English or French where the IAAF is the prospective appellant) or from the last day on which the decision could have been appealed to the national level appeal body in accordance with Rule 6.15. Where the appellant is not the IAAF, at the same time as filing his statement of appeal with CAS, the appellant shall send a copy of the statement of appeal to the IAAF. Within fifteen (15) days of the deadline for filing the statement of appeal, the appellant shall file his appeal brief with CAS and, within thirty (30) days of receipt of the appeal brief, the respondent shall file his answer with CAS.

- 417. The AFI's written reasons for declaring the Athlete ineligible to continue to compete were communicated to the Athlete by letter on 31 August 2014. The Athlete filed her Statement of Appeal 26 days later on 26 September 2014. Having been granted two extensions of time by the CAS, the Athlete filed her Appeal Brief on 17 November 2014.
- 418. The AFI has not filed any objection to the admissibility of the arbitration. The IAAF has expressly stated that the arbitration is admissible. It follows, therefore, that the arbitration is admissible.

VII. JURISDICTION

419. Article R39 of the Code provides as follows:

[...] The Panel shall rule on its own jurisdiction, irrespective of any legal action already pending before a State court or another arbitral tribunal relating to the same object between the same parties, unless substantive grounds require a suspension of the proceedings.

When an objection to CAS jurisdiction is raised, the CAS Court Office or the Panel, if already constituted, shall invite the opposing party (parties) to file written submissions on jurisdiction. The Panel may rule on its jurisdiction either in a preliminary decision or in an award on the merits. [...]

The IAAF

420. Article 7.2 of the Hyperandrogenism Regulations provides:

The decision of the IAAF regarding the athlete's eligibility shall be notified to the athlete and her designated physician and, where necessary, to her National Federation. The IAAF decision may be appealed exclusively to CAS in accordance with the provisions of IAAF Rule 60.23 and following.

421. The Appeal Brief submitted that the Athlete is an "International-Level Athlete", having competed at the Asian Junior Athletics Championships in June 2014. She is therefore entitled to appeal to the CAS under Rule 60.14 of the IAAF Competition Rules, which states:

In any case involving International-Level athletes (or their athlete support personnel), the following parties shall have the right to appeal a decision to CAS:

a. the athlete or other person who is the subject of the decision being appealed;

[...]

- 422. In its Answer Brief, the IAAF stated that the IAAF's statutes and regulations IAAF do not provide for a right of appeal to the CAS in the present case. The decision under challenge is a decision of the AFI at national level, not a decision of the IAAF. According to the IAAF, the Athlete does not fall within the definition of an International Athlete, namely an athlete "who is in the Registered Training Pool...or who is competing in an International Competition under Rule 35.7".
- 423. Consequently, the IAAF submits that the Athlete's right of appeal against the AFI's decision should have been exercised before a national-level body in India. In this regard, Rule 16.15 of the IAAF Competition Rules provides:

In any case which does not involve International-Level athletes (or their athlete support personnel), the parties having the right to appeal a decision to the national level appeal body shall be as provided for in the rules of the Member, but shall include at a minimum:

(a) the athlete or other person the subject of the decision being appealed;

[...]

424. Notwithstanding this position, the IAAF stated that it wished to ensure that the Athlete received a fair hearing and that it wanted the validity of the Hyperandrogenism Regulations to be determined by an independent tribunal with the necessary sport-specific expertise. It therefore agreed to the *ad hoc* submission of the dispute to the jurisdiction of the CAS. The IAAF confirmed the jurisdiction of the CAS by signing the Order of Procedure. The IAAF's counsel repeated that agreement orally at the hearing. Accordingly, it follows that the CAS has jurisdiction to hear the Athlete's challenge to the Hyperandrogenism Regulations.

The AFI

425. Article I of the AFI Rules and Regulations provides:

The Athletics Federation of India recognises, accepts, applies, observes and abide by the current Constitution, Rule and Regulations of the IAAF and the

Asian Athletics Association, as well as any future amendments. This applies especially to the Anti-Doping Rules, the handling of disputes, and relations with Athlete Representatives.

426. Article XXXII of the AFI Rules and Regulations provides:

JURISDICTION OF THE FEDERATION

Delhi Courts will have exclusive jurisdiction in all matters pertaining to the AFI, its activities and members.

- 427. In her Appeal Brief, the Athlete submitted that the AFI has "adopted, and incorporated by reference, all of the Rules and Regulations of the IAAF. This includes the Hyperandrogenism Regulation" (Appeal Brief, para 12). Having done so, the Athlete submits that the AFI is bound by all of the terms of the Hyperandrogenism Regulations, including the unqualified right of appeal to the CAS under Article 7.2.
- 428. The Panel notes that even if the Athlete's argument is correct, Article 7.2 of the Hyperandrogenism Regulations only gives a right of appeal in respect of "the IAAF decision". The Regulations do not create a right of appeal to the CAS in respect of a decision by a national-level body such as the AFI. In addition, the point made by the IAAF that the Athlete is not an international-level athlete for the purposes of the IAAF competition rules would prevent the Athlete from establishing a right to appeal to the CAS under the IAAF Competition Rules,
- 429. Notwithstanding those points, the Panel must consider the possibility that the AFI has nevertheless voluntarily submitted to the *ad hoc* jurisdiction of the CAS to determine this matter, either by the doctrine of unconditional appearance or by an implied agreement to submit to submit to *ad hoc* arbitration before the CAS.
- 430. The AFI has not expressly consented to or objected to the jurisdiction of the CAS in relation to this matter. It did not file any written submissions in the proceedings, nor was it represented at the hearing. However, it did engage with the CAS in the following respects:
 - By a letter dated 21 October 2014, Mr Taylor submitted "The Respondents' joint nomination" of Dr Hans Nater as an arbitrator. The letter was copied to Dr

Mendiratta "as confirmation of the joint nature of this nomination". The letter was headed "without prejudice as to jurisdiction".

- On 26 November 2014, the AFI wrote directly to the CAS Finance Director noting its request that the IAAF pay its share of the advance costs.
- By a letter dated 3 December 2014, Mr Taylor stated that the IAAF did not object
 to the Athlete participating in national competitions pending the determination
 of the proceedings. The AFI was copied to the letter and it was indicated that
 the AFI had informed the IAAF that it would not object to the Athlete's
 participation in those events.
- By an email to Mr Taylor dated 31 January 2015 (which was forwarded to the CAS by Mr Taylor), the AFI stated that it did not object to the IAAF's request for an extension of time to file its answer.
- 431. In addition to that correspondence, the Chairperson of the AFI Medical Commission, Dr Mendiratta, gave oral evidence as a witness of fact at the hearing. Dr Mendiratta was not asked any questions about whether the AFI had submitted to the jurisdiction of the CAS.
- 432. Under Swiss federal law an unconditional appearance by a party at an arbitration constitutes a waiver of the plea of lack of jurisdiction. Under the circumstances, and on the basis of the above actions, the Panel is not satisfied that the CAS has jurisdiction over the AFI in respect of this matter under the principle of unconditional appearance. In these circumstances, the CAS Panel must examine of its own initiative whether there is a valid arbitration agreement which is binding on the AFI.
- 433. Article 178(2) of the Swiss Federal Code on International Private Law provides that an arbitration agreement is valid if it conforms to the law chosen by the parties, or to the law governing the subject matter of the dispute, or to Swiss law. For these purposes, the Swiss Federal Tribunal has held that a contract must be interpreted by reference to the parties' unanimous actual intention. If the common and true intention of the parties can be ascertained then the arbitral tribunal is bound by it. Accordingly, if an objective appraisal of all the facts establishes a mutual intention to subscribe to arbitration by the

CAS in this case, then the Panel has jurisdiction to determine the case for the purposes of Swiss Federal law.

- 434. In <u>WADA v Cheah & Ng & Masitah</u>, CAS 2007/A/1395, the Panel stated that the delivery of pleadings (especially pleadings containing an allegation of the Panel's jurisdiction to hear the case) was capable of constituting an offer to arbitrate, even where the party delivering the pleadings had not specifically pleaded the existence of an arbitration agreement in those pleadings. In the present case, the Athlete delivered pleadings that positively asserted the existence of the CAS's jurisdiction over the AFI. The Panel concludes that the Athlete's actions constituted an implicit offer to arbitrate before the CAS.
- 435. Having established the existence of an offer to arbitrate, the Panel must determine whether the actions of the AFI demonstrated an acceptance of that offer. In this regard, it is notable that while the AFI took a largely passive stance in the proceedings, it did engage with the CAS on a number of procedural issues that indicated an implicit acceptance of the CAS's power to determine the Athlete's appeal (albeit falling short of an "unconditional appearance" before the CAS). In particular, the AFI requested the IAAF to pay its share of the advance costs and expressly confirmed that it did not object to an extension of time for the IAAF to file its Answer Brief. Neither of those steps was consistent with a refusal of the Athlete's offer to arbitrate. On the contrary, the AFI's voluntary engagement on these procedural matters impliedly recognised the validity of the arbitration proceedings. The position is reinforced by the AFI's participation in the process of nominating an arbitrator for the hearing. Although the letter communicating the joint nomination was headed "Without Prejudice As To Jurisdiction", that heading was a common feature of several pieces of correspondence from the IAAF (most of which were sent exclusively on behalf of the IAAF) and there is nothing to suggest the disclaimer was included at the request of the AFI. In any event, the joint nomination of an arbitrator casts light on the AFI's general attitude towards the proceedings and its receptiveness to the Athlete's offer to arbitrate.
- 436. In all the circumstances of this case, the CAS Panel is satisfied that the AFI's actions in engaging with the CAS without raising any jurisdictional objection established an

implicit acceptance of the Athlete's offer submit to the *ad hoc* jurisdiction of the CAS. The Panel is therefore satisfied that it has jurisdiction over the AFI.

VIII. APPLICABLE LAW

437. Article R58 of the Code provides as follows:

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

438. Rule 60.25 of the IAAF Competition Rules states:

In all CAS appeals involving the IAAF, CAS and the CAS Panel shall be bound by the IAAF Constitution, Rules and Regulations. In the case of any conflict between the CAS rules currently in force and the IAAF Constitution, Rules and Regulations, the IAAF Constitution, Rules and Regulations shall take precedence.

439. Rule 60.26 states:

In all CAS appeals involving the IAAF, the governing law shall be Monegasque law and the arbitration shall be conducted in English, unless the parties agree otherwise.

440. Accordingly, in deciding this appeal, the Panel will apply the IAAF's Constitution and Rules and, subsidiarily, Monegasque law.

IX. MERITS

A. Burden and standard of proof

441. During the course of the hearing, the Panel requested the parties to set out their position concerning the burden and standard of proof. The parties agreed that the Athlete bore the burden of proving that the Hyperandrogenism Regulations are invalid. The parties also agreed that, once a *prima facie* case of discrimination is established, the burden shifts to the party responsible for the discriminating measure to justify the discriminatory effect.

- 442. In the Athlete's Appeal Brief it was suggested that IAAF bore the burden of establishing the scientific basis of the Hyperandrogenism Regulations to the comfortable satisfaction of the Panel. The Athlete appeared to resile from that position during the hearing by expressly accepting that Athlete bears the burden of proof on the issue of scientific basis and that the standard of proof is the balance of probabilities.
- 443. The Panel concludes that the Athlete bears the burden of proving that the Hyperandrogenism Regulations are invalid. If the Athlete establishes that the Hyperandrogenism Regulations are *prima facie* discriminatory by reference to a higher ranking rule or otherwise, on the balance of probabilities, the burden shifts to the IAAF to establish that they are justifiable as reasonable and proportionate, that is, to justify the discrimination. The requisite standard to justify discrimination of a fundamental right, which includes the right to compete as recognised in the Hyperandrogenism Regulations, should be to a level higher than that of the balance of probabilities.
- 444. It is a relevant matter to take into account that the Hyperandrogenism Regulations have been established (as explained in the Regulations) by a sports governing body pursuant to its stated objectives. This alone does not support a justification of discrimination.
- 445. If the IAAF establishes justification, the burden shifts back to the Athlete to disprove the bases of that justification.
- 446. The Panel notes in this regard that in <u>Pistorius v IAAF</u>, CAS 2008/A/1480, the Panel there noted that the standard of proof is clearly not the "beyond reasonable doubt" standard applicable in criminal cases in most jurisdictions. Nor could it, in that Panel's view, be any of the possible intermediate standards that are discussed from time to time in connection with, for example, the disciplinary processes of professional or regulatory bodies. In <u>Pistorius</u> the standard applied was the balance of probabilities. By contrast, the Panel in <u>Veerpalu v International Ski Federation</u>, CAS 2011/A/2566 applied the standard of comfortable satisfaction to invalidate a regulation for a human growth hormone testing procedure for doping cases.
- 447. The standard of proof for each issue is the balance of probabilities. The Panel does not accept that the IAAF must establish justification to the comfortable satisfaction of the Panel. However, the Panel accepts that the requisite standard to justify discrimination

of a fundamental right, including the right to compete that is recognised in the Hyperandrogenism Regulations themselves, requires the IAAF to overcome positively the onus to establish that justification.

B. Issue 1: Discrimination

- 448. The Hyperandrogenism Regulations only apply to female athletes. It is not in dispute that it is *prima facie* discriminatory to require female athletes to undergo testing for levels of endogenous testosterone when male athletes do not. In addition, it is not in dispute that the Hyperandrogenism Regulations place restrictions on the eligibility of certain female athletes to compete on the basis of a natural physical characteristic (namely the amount of testosterone that their bodies produce naturally) and are therefore *prima facie* discriminatory on that basis too.
- 449. The Athlete contended, and the IAAF did not submit to the contrary, that the IOC Charter, the IAAF Constitution and the laws of Monaco all provide that there shall not be discrimination and that these provisions are higher-ranking rules that prevail. Accordingly, unless the Hyperandrogenism Regulations are necessary, reasonable and proportionate, they will be invalid as inconsistent with the IOC Charter, the IAAF Constitution and the laws of Monaco.
- 450. The Panel concludes that, on their face, the Hyperandrogenism Regulations are discriminatory. It follows that the onus shifts to the IAAF to establish that the Hyperandrogenism Regulations are necessary, reasonable and proportionate for the purposes of establishing a level playing field for female athletes. Such an approach is consistent with the countervailing requirements for sport and is recognised in a wide range of domestic and international laws, including laws directed to the prohibition of discrimination generally. The Panel will address the question of justification below under Issue 3: Proportionality.

C. Issue 2: Scientific basis for the Hyperandrogenism Regulations

The expert witnesses

451. In support of her challenge to the scientific validity of the Hyperandrogenism Regulations, the Athlete relied primarily on the testimony of three expert witnesses:

- Professor Holt, Dr van Anders, and Dr Karkazis (see paragraphs 135, 159 and 172 above for a summary of their experience and qualifications).
- 452. The IAAF relied primarily on the evidence of Professors Hirschberg and Ritzen and Dr Bermon. All three were involved in drafting and administering the Hyperandrogenism Regulations currently at issue. That fact does give rise to the question of independence and impartiality. However, the Panel observed them giving evidence and formed the view that they are acting as independent professional experts and that they gave evidence and opinions accordingly. It was those opinions that undoubtedly provided the scientific basis for the Hyperandrogenism Regulations, which each of them expressly supported.
- 453. In addition, some of Professor Ljungqvist's evidence touched on the scientific relationship between testosterone and athletic performance. Professor Ljungqvist was similarly involved in the process that led to the adoption of the Hyperandrogenism Regulations. Professor Ljungqvist expressly deferred to the expertise of Professors Hirschberg and Ritzen in relation to the disputed scientific issues in this case (although he agreed that testosterone is a significant factor in elite female athletic performance). The Panel is satisfied that Professor Ljungqvist's evidence represented his honest and independently held expert opinion and appropriately reflected the extent and limits of his scientific expertise.

Relationship between testosterone and athletic performance

- 454. Both parties agree that LBM contributes to strength and ultimately to sports performance. However they do not agree on the effect of testosterone in generating LBM. This gives rise to two questions: First, does testosterone have this effect? Second, is there a difference between exogenous and endogenous testosterone?
- 455. Based on the Healy study's finding that testosterone, of all the demographic and hormone variables measured, had the fewest correlations to other factors of LBM, Professor Holt concluded in his oral testimony that the Healy study demonstrated that there is no correlation between testosterone and LBM. However, many studies have arrived at the opposite conclusion: that there is such a correlation.

- 456. Professors Hirschberg and Ritzen and Dr Bermon co-authored a letter to the editor of *Clinical Endocrinology* taking issue with the Healy study. They contended that the study faced severe methodological limitations, such as not using state of the art methods for testosterone measurements. Moreover, the researchers collected the athletes' blood samples during a time period when testosterone levels in men are likely to be decreased and when testosterone levels in women tend to remain unchanged or moderately increased. Professors Hirschberg and Ritzen and Dr Bermon noted that the Healy paper lacks discussion on the underlying reasoning supporting the authors' conclusion. Further, Healy *et al* did not discuss what *is* the best predictor of LBM.
- The issues that the IAAF's experts raised with the Healy *et al* study are persuasive. The timing of the blood samples, taken post competition, limits the study's applicability to this appeal. At issue here is determining the normal difference between men and women's testosterone. The timing of sampling could be a confounding factor and a reason for the lack of correlation between testosterone and LBM for reasons given by the IAAF witnesses. Further, the study's lack of discussion on the relationship between LBM and testosterone is problematic. This relationship is the subject of many related studies. Healy *et al* explicitly used the contention that LBM fully accounts for the gender difference in sports performance to negate the IAAF's justification for the Hyperandrogenism Regulations at issue in this application. They do so without accounting for the possible confounding factor or providing a reasoned basis for rejecting the correlation with testosterone, or suggesting an alternative cause.
- 458. It is problematic that the relationship between LBM and testosterone is not addressed in detail in the study as the authors boldly refute this claim. The Athlete's reliance on the Healy study as if it were definitive is, in the Panel's view, misplaced. Further, the Athlete's evidence did not sufficiently address the relationship between testosterone (exogenous and endogenous) and LBM.
- 459. The IAAF's experts specifically addressed the relationship between testosterone and LBM. Professors Hirschberg and Ritzen explained their view that LBM is a key determinant of strength, and that it is clear that LBM is in turn heavily influenced by testosterone levels. Prior to puberty, there is no significant gender difference in body composition between males and females. However, throughout puberty, boys gain

significantly more LBM than girls. This correlation, in their view, is explained by the rise in testosterone levels during male puberty. Moreover, Professors Hirschberg and Ritzen point out that Veldhuis (2005) found that physiological amounts of testosterone stimulate lean tissue accrual and augment total muscle volume. Therefore, Professors Hirschberg and Ritzen inferred, in their professional opinion, that since testosterone is a significant factor of LBM, which in turn determines strength, this hormone is "the best discriminating factor" between male and female athletic performance.

- 460. Professor Holt agreed that boys and girls demonstrate a difference in LBM ratios post-puberty, but asserted that this phenomenon is not directly attributable to testosterone and that growth hormone (for which he is a renowned specialist) is also very influential on LBM. While he did not support his statements by scientific studies, his statement has credibility, given his work with his partner Professor Peter Sonksen on the development of the test to detect athletes' misuse of growth hormone, which has attracted the attention of WADA. However, this rejection of a correlation between LBM and testosterone represents a hypothesis, and Professor Holt's professional experience and hypothesis do not outweigh the scientific evidence.
- 461. In oral concurrent expert evidence, in which Professors Holt, Ritzen and Hirschberg and Dr van Anders participated, the following points and views emerged:
 - There is an overlap in testosterone ranges in elite male and female athletes. One question that arises is whether there is an overlap in "normal situations" of healthy men and women. There can be very low testosterone in men who have over-trained or if testosterone is measured directly after competition.
 - Professors Ritzen and Hirschberg said that there is no woman with normal ovaries and normal adrenal glands with testosterone at 10 nmol/L.
 - There was also controversy about the Healy article, for example that samples were not taken for medical purposes and there was no clinical information.
 - Professor Holt asked whether outliers should be included in defining normal reference ranges and said that in his view, they should not. This view was, he said, accepted by the CAS, namely that they should not be excluded in the consideration of growth hormone. He added that all Olympic athletes could

be said to be outliers. He accepted that in clinical practice outliers are excluded, but said that the purpose of a reference range in the spectrum of sport is different.

- As to the reasons for high levels of testosterone, Dr van Anders pointed out that women with DSDs can be considered within the normal, healthy range and do not necessarily connote disorders that require clinical attention. The discussion then turned to the causes of high endogenous levels of testosterone, such as functioning testes, a tumour, or adrenal disorders. Professor Holt pointed out that there are not enough samples to determine whether there is a relevant disorder, as the samples taken are insufficient in circumstances where, generally, testosterone levels are not measured in healthy people.
- As to the Daegu results, Professor Holt said that not all women with levels over 10 nmol/L had a clinical diagnosis or were shown to be doping.
 Professors Ritzen and Hirschberg said that those above 10 nmol/L either had a DSD or there was a strong suspicion of doping.
- Professor Holt accepted that it is likely that women with high testosterone
 levels and functioning androgen receptors will present with features of
 virilism but he says that there are not enough data to say that this is always
 the case. He pointed out that women with a DSD but without symptoms may
 not present themselves to an endocrinologist.
- The experts also discussed the assumption that testosterone explains the difference between men and women. Professor Hirschberg pointed to the fact that the sex difference in physical performance that occurs at puberty is at least related to differences in testosterone levels. Professor Ritzen pointed to evidence that a change of sex from male to female results in a decrease in muscle volume within a year.
- Professor Holt expressed the view that there are many reasons why men and women perform differently – some biological and some sociological. He accepted that it is a reasonable hypothesis to suggest that testosterone is one reason for the differences between men and women in terms of performance

- and LBM in boys but said that the evidence is not there to test it and that other factors may also be important, such as growth hormone.
- The experts were asked to address directly the question whether there are differences to the body's reaction to exogenous and endogenous testosterone. Dr van Anders said that studies have shown that exogenous administration of testosterone does increase sexual desire, but not endogenous testosterone. Further, she stated that various exogenous androgens do not work the same way as do endogenous androgens. She said that exogenous testosterone bypasses the body's system of integration, that is, an exogenous dose does not mimic the whole system. As to athletic performance, Professor Holt accepted that athletes who have doped with testosterone have had performance benefits. However, he pointed to the Healy study where there was no correlation in either men or women between serum testosterone and LBM. That is, he said that there was no established link between endogenous testosterone and LBM. He said that testosterone is just one aspect of an extraordinarily complex system and when one changes testosterone, other aspects are also changed. Professor Holt did not accept that one can choose one marker to distinguish males and females; if asked, he would choose a panel of markers.
- Professor Hirschberg responded. She agreed that there are other factors that distinguish physical performance but she said that testosterone is the best factor for that purpose. She said that the body cannot distinguish the origin of testosterone. She also pointed to the difficulties of testing. For example, in circulation, testosterone is bound to a protein and, in that form, is inactive. In that way, the protein regulates the testosterone and in the cases of DSD, the protein is not decreased. Time and rate of exposure are also relevant. For a proper study, these factors would need to be controlled for. She drew a distinction between a hypothesis and evidence or proof. She expressed the opinion that the best analysis is the clinical response, which is the same for exogenous and endogenous testosterone, namely virilisation. There are also studies that show that testosterone can increase body mass and performance. Professor Hirschberg pointed out that the IAAF Regulations do not use one

marker but look to testosterone levels in combination with androgen resistance.

- The experts elaborated on the causative relationship. There is a shortage of data but there are some studies. Professor Hirschberg pointed to randomised studies with post-menopausal women that demonstrated a correlation between testosterone and muscle mass and muscle performance, a result similar to that obtained for men with more data. She accepted that this did not prove a causal relationship between endogenous testosterone in female and male athletes. However, she maintained that testosterone is the most important factor explaining performance differences between men and women.
- Professor Ritzen provided a persuasive explanation, concerning a standard dose response curve, plotting the concentration of exogenous testosterone against the response in terms of increased muscle mass. The relationship is not linear. At the lower and upper levels, it is difficult to prove a relationship between exogenous testosterone and muscle mass. However, if the increase is from 3 to 5 or 10 nmol/L, it is high on the responsive S-shaped curve such that the difference in muscle mass between the average woman and those on 10 nmol/L will be great. Professor Ritzen, when asked, said that he would expect the same dose response curve for endogenous testosterone but he does not have the data. He said that, in his opinion, there is not a difference between exogenous and endogenous testosterone. For someone with complete androgen insensitivity, the "curve" would be a flat line. Androgen sensitivity is not either present or not present: there is a gradation of response. The shape and height of the curve would vary with the individual, as pointed out by Professor Holt. Professor Ritzen's curve represented mean levels.
- Professor Holt pointed out that within the normal female range there is a 30-fold difference in testosterone levels, and it is not the case that women whose testosterone level is 3 nmol/L have a 30-fold advantage compared to women with 0.1 nmol/L. He said that there is variability in terms of response to

testosterone. Professor Ritzen did not dispute a wide variation but said that this affects standard deviations of the mean.

- There was some discussion about the choice of 10 nmol/L as the appropriate level and the available evidence at the time that it was chosen. Professor Hirschberg said that no woman with normal ovaries and normal adrenal function could have that level. In response to Professor Holt's comment that lower male levels were, in available data, within the "female range", she pointed out that there is no need to discuss a lower limit. Professor Holt commented that if a significant number of men have a level lower than 10nmol/L, it tends to destroy the argument for using that lower level as the male range. He did concede that the choice of 10 nmol/L, being five standard deviations above the normal range for females, means that the likelihood of a female athlete having that level is very small.
- Professor Holt explained why, in his view, 10 nmol/L cannot be used as the lower limit when looking at the lower end of male athletes but, as Professor Hirschberg pointed out, this is a non-issue.
- their view on whether there was an exogenous/endogenous divide but it was clear that no single study has established, to an appropriate level of certainty a scientific basis to come to a conclusion one way or the other. Such papers that were cited by Professor Holt and Dr van Anders drew criticism from Professors Ritzen and Hirschberg. Professor Holt agreed that the chief study on which he relied, Sader, provides some evidence but that there are some "limitations" in drawing a conclusion of a different effect. However, the experts agreed that exogenous testosterone and endogenous testosterone can be metabolised differently in different individuals and Professor Hirschberg said that there could be genetic differences and a difference between ethnic groups. However, there is also some published evidence that once in the bloodstream, it has the same mechanism of action.
- That leaves, as Professor Hirschberg pointed out, the clinical effects, with which she is so familiar. She said that the clinical response is the same and

- there is no evidence that an excess of endogenous testosterone, of 10nmol/L and above, does not cause the same symptoms as exogenous testosterone.
- Professor Holt summed up his approach on the evidence by saying that with growth hormone, there was a long period to develop scientific proof. He described the evidence as to testosterone as being "rudimentary" and based on hypothesis. Professors Ritzen and Hirschberg do not agree and explained in some detail the logic behind the formulation of the Hyperandrogenism Regulations (see above at paragraphs 179 203).
- 462. While the Harper study is, as Ms Harper acknowledges, of small size, it provides support for the conclusion that testosterone is an appropriate differentiating factor between male and female athletes and a conclusion that a lowering of endogenous testosterone reduces athletic ability, as does the lowering of exogenous testosterone.
- 463. The Athlete relied on an article by Dr Karkazis *et al* in The American Journal of Bioethics. This article noted, *inter alia*, that a 10-fold difference in male and female endogenous testosterone levels is not reproduced as a 10-fold gap in athletic performance. The Panel does not give great weight to this article for the purposes of this case. The article is primarily an argument against the Hyperandrogenism Regulations. The argument contained in the article represents a sociological opinion, which does not equate to scientific and clinical knowledge and evidence. It is based on observations of overlap in race times between men and women's competitions and is unsupported by scientific study or analysis. It does, however, raise a question as to direct correlation between testosterone levels and the quantum of athletic performance.
- 464. The Athlete rebuts the IAAF's deference to testosterone as the best predictor of sports performance by emphasising observed anomalies in testosterone's physiological effects to deny a straightforward relationship between testosterone and sport performance. Professor Holt spoke of the phenomenon of elite female athletes with complete AIS. These women cannot derive any benefit from their testosterone, as their faulty androgen receptors prevent the testosterone from exerting its normal biological action. However, Dr Bermon, who has served as a member of the IAAF Medical and Anti-Doping Commission since 2006, has only seen one case where a female athlete was completely

- androgen insensitive. In any event, the second stage of the IAAF testing, the physical examination, allows for androgen insensitivity.
- 465. Professor Holt also raised the example of male athletes with low levels of testosterone. If testosterone were the most important predictor of athletic performance, he said that it should follow that men with low levels of testosterone should not demonstrate athletic performance and success in sport. This represents a hypothesis but is not based on scientific evidence. It does not assist the Panel in coming to a conclusion, now, on the basis of evidence and supported opinion.
- 466. Further, Dr Bermon advanced a responsive hypothesis. He said that low levels of testosterone could be explained by a depressed gonadic axis or overtraining without adequate recovery, which may provide a partial explanation as to why there are elite male athletes with low levels of testosterone and elite female athletes with complete AIS. However, this does not fully address the anomalies presented by the Athlete.
- 467. The Athlete also sought to utilise evidence from the Daegu and Moscow studies to further the proposition that when properly considering all of the subject athletes, including the outliers, it is evident that testosterone levels should not be used as the criterion for eligibility to compete in the female category. Dr van Anders and Professor Holt claimed that the Daegu and Moscow data demonstrated that there is an overlap in the testosterone ranges of elite male athletes and elite female athletes. In juxtaposition, Professor Hirschberg and Professor Ritzen claimed that the Daegu and Moscow data confirmed that there is no overlap in testosterone levels between men and women.
- 468. This discrepancy stems from the way in which the experts treated the "outliers" from the study. Professors Hirschberg and Ritzen take the position that only the data from testing the "healthy" women (i.e. subjects who have normal gonadal and adrenal function) should be used. This is because they believe that in defining the normal range of any laboratory parameter, it is important to make sure that only individuals without known abnormalities or diseases are included in the data. On the other hand, Professor Holt and Dr van Anders take the position that data from all non-doped women, including outliers, should be included in the study. Professor Holt expressed the view that since Olympic athletes represent such a minuscule percentage of the human population, they

are in fact outliers. Furthermore, Professor Holt argues that outliers should only be excluded for good reason from the reference range and that to exclude outliers because they seem "too high" when describing a population has no basis in science.

- 469. The IAAF's experts acknowledged that there may be other contributing factors to the difference in athletic performance between men and women. However, Professors Hirschberg and Ritzen strongly maintained that as "no other known factors show such a clear-cut difference between women and men", testosterone remains the most suitable differentiating factor between male and female sports performance. Dr Bermon was adamant that testosterone is the best available parameter to explain performance differences between men and women, together with a clinical examination to take account of biology, phenotype and virilisation.
- 470. It is important to note that the Hyperandrogenism Regulations provide for that clinical examination. It is not only the level of testosterone that results in a decision but also that examination. In other words, matters such as androgen insensitivity and individual levels of reaction to high levels of testosterone are accounted for in coming to a conclusion as to whether an athlete may compete in the female category.
- 471. The Panel notes that both the Daegu and Moscow studies are significant, in that both provided large-scale samples, whereas other studies directed to the issue were typically comprised of much smaller samples. A large sample would be relevant when considering the reliability and consistency of a study and, in the case at hand, whether there is an overlap of testosterone levels between men and women. However, the Athlete has not demonstrated the relevance of the overlap to the issue in question. The Hyperandrogenism Regulations are about females with testosterone levels well outside the normal female range and into the male range and the effect of such levels in athletic competition. The issue of the overlap of testosterone levels does not address the arguments in the present case, particularly those of the IAAF, based on a principle of ensuring fairness in competition.
- 472. Ultimately, the anomalies pointed to by the Athlete are not sufficiently explained by the scientific evidence adduced. In the absence of evidence explaining these anomalies one way or the other, the Panel can only deal with the evidence before it. Nonetheless, the

significance of these anomalies must be seen in context. Importantly, where the evidence is not available, the onus of proof remains. The Athlete has not established that there is no relationship between testosterone and athletic performance.

The differences between exogenous and endogenous testosterone

- 473. The remaining scientific issue pertinent to this appeal is whether endogenous and exogenous testosterone impact LBM, and by extension sports performance, in the same way. On this issue, the Athlete has the onus to establish, on a balance of probabilities, that there is a difference in the effects of exogenous and endogenous testosterone. The IAAF seeks to establish on the balance of probabilities that the effects of testosterone are the same regardless of source.
- 474. The expert witnesses each relied on different published papers to support his or her view on whether there was an exogenous/endogenous divide. However, it was clear to the Panel that no single study has established, to an appropriate level of certainty, a scientific basis to come to a definitive conclusion one way or the other.
- 475. Dr van Anders claimed that the 2005 Sader study showed that the effects of exogenous testosterone are sometimes opposite to effects of endogenous testosterone. Specifically, she claimed that endogenous testosterone increases the binding sensitivity of androgen receptors, whereas exogenous testosterone decreases it. The study found that on average androgen receptor expression was consistently higher in young healthy males than in young healthy females. Dr van Anders concluded from the study that the effects of endogenous and exogenous testosterone can be opposite. Notably, Dr van Anders is not an expert in clinical medicine or endocrinology, and this is her interpretation of a medical study.
- 476. Professor Ritzen stated in his oral testimony that, as an editor of a scientific journal, he would not accept the Sader paper due to its severe methodological issues. Specifically, he pointed out that the Sader study did not sufficiently control for testosterone variation in its subjects, as it did not specify whether the subjects were normal or hyperandrogenic. Professor Holt supported the credibility of the paper by noting that it was in fact published by a peer-reviewed, journal (*Clinical Endocrinology*). However, Professor Holt conceded in his oral testimony that the while the Sader paper provides

- some evidence that there is a difference in the way exogenous and endogenous testosterone effect the body, the study is subject to limitations.
- 477. The Sader study is not convincing evidence that there is a difference between the effects of exogenous and endogenous testosterone on sports performance. First, Professor Ritzen pointed out that the study measures the level of leucocyte androgen receptors, which is relevant to cardiovascular disease. Any observed effects cannot automatically be generalised to the effects that exogenous and endogenous hormones have on muscles or the brain. Secondly, the methodological limitations raised by Professor Ritzen and conceded by Professor Holt raise doubts as to the validity of Dr van Anders' conclusion. Dr van Anders then extrapolates from the findings of the Sader study, in effect to hypothesise a generalised conclusion.
- 478. Dr van Anders also cited a 2011 study by Crewthler *et al* for the proposition that endogenous increases in testosterone do not lead to the same enhancement of muscle growth as do increases in exogenous testosterone. Professors Hirschberg and Ritzen stated their belief that Dr van Anders misrepresented Crewthler *et al* (2011). They explained that Crewthler *et al* (2011) were examining the short-term effects of exogenous and endogenous testosterone on the neuromuscular system, and concluded that "the exact contribution of" endogenous testosterone to resistance training remains unclear. In weighing the evidence as to the conclusions that can properly be drawn from Crewther *et al* as a matter of science and clinical medicine, the Panel gives more weight to Professors Ritzen and Hirschberg, as their opinion comes more directly from their fields of expertise. Accordingly, the Panel does not accept that the Crewther *et al* study establishes that endogenous increases in testosterone have a different effect on muscle growth than do exogenous increases in testosterone. Dr van Anders' view remains a hypothesis that has not been established.
- 479. The expert testimony reveals that the question of whether there is a difference in the way the body processes exogenous and endogenous testosterone has not received sufficient attention. This was evidenced in Professor Ritzen's oral testimony. When he was asked to predict the dose line of endogenous testosterone, he admitted to having insufficient data to predict or construct the curve associated with endogenous testosterone levels.

- 480. The IAAF cited Cardinale & Stone (2006) as a study which solidified a proven correlation between endogenous testosterone levels and performance. The study examined testosterone levels and jumping ability in female sprinters and volleyball players. The study specifically found that the positive relationship identified between testosterone levels and vertical jumping indicated that this hormone plays a crucial role in neuromuscular function. Therefore, Professors Hirschberg and Ritzen contended that this study demonstrated a positive correlation between testosterone concentration in blood and explosive strength of both female and male athletes.
- 481. The Athlete's expert Professor Holt agreed that this study established a correlation between endogenous testosterone levels and performance, but he noted that correlation does not establish causation. Furthermore, Professor Holt took issue with the finding that sprinters have higher testosterone levels than do the volleyball players. He focused on this finding to suggest that any difference between sprinters and volleyball players may be caused by other discrepancies between the sporting disciplines and that any differences in testosterone may be coincidental. If this were the case, Professor Holt claimed, testosterone may have no impact on jumping ability. However, this assertion that other differences may account for the difference in jumping abilities between the sprinters and the volleyball players was merely speculative and unsupported by evidence, as is the suggestion that differences in testosterone levels may be coincidental. The Panel cannot accept unsupported speculation and hypothesis to overcome established data and expert conclusions drawn from those data.
- 482. Dr Bermon stated in his report that there was "good evidence that high levels of endogenous testosterone in elite female athletes who are androgen-sensitive are performance enhancing." However, in his oral testimony, Dr Bermon admitted this evidence was indirect and was a reference to the observed recruitment bias of XY women competing in the athletics discipline in sport. Dr Bermon's clinical observations of an apparent "recruitment bias" or overrepresentation of a trait are not scientific evidence establishing his stated proposition. This is at best indirect evidence.
- 483. In her oral evidence, Dr van Anders noted that endogenous and exogenous testosterone are released at different parts of the body's metabolic pathways, such that exogenous testosterone bypasses a pathway that acts in response to, and mimics, neural activity,

whereas endogenous testosterone does not. This means that endogenous testosterone is affected by an axis, the "HPG axis", which acts in response to and integrates neural activity. This seems to be accepted. This means, she says, that the response from administering a large solitary dose of testosterone, similar to exogenous treatments, will not mimic the functioning of the entire system and can be expected to be different to the effects of endogenous testosterone. However, this conclusion does not necessarily follow and represents an unproven hypothesis.

- 484. Professor Hirschberg argued that a cell in the body cannot distinguish whether the origin of the testosterone is the body or an external source, as the same molecule binds with the androgen receptor. However, Professor Hirschberg acknowledged that it is very difficult to compare exogenous and endogenous testosterone, as that total testosterone level is not an accurate assessment because of the different effects exogenous and endogenous testosterone have on protein. Furthermore, it is difficult to control the duration of exposure to testosterone.
- 485. Professor Hirschberg stated that the most accurate comparison between endogenous and exogenous testosterone is to evaluate their clinical responses. As both lead to virilisation, she believes that ultimately there is no difference.
- of hyperandrogenic females with whom the IAAF has dealt under the Hyperandrogenism Regulations. In his expert report, he noted that of the stabletes found to have functional testosterone levels over 10 nmol/L who underwent treatment to bring those levels below 10 nmol/L, all experienced a decrease in athletic performance. These IAAF cases may provide some indirect recognition but do not establish that there is a difference in the effects of exogenous and endogenous testosterone on sports performance. This evidence does not constitute a scientifically based study or a clinical trial from which conclusions can soundly be drawn.
- 487. Further, when asked to estimate the difference in athletic performance based on the amount of testosterone, Dr Bermon stated, based on his experience, that for a difference between 1.5 nmol/L and 15 nmol/L, he estimated a 3% improvement in athletic performance. These nmol/L figures coincide with expected figures of a female with an

average testosterone level and of a female with hyperandrogenism. However, again, Dr Bermon's estimate is from his own experience and cannot be accepted as evidence arising from a scientific study or clinical trial.

488. The evidence as to whether endogenous and exogenous testosterone have the same or different effects on the body did not enable the Panel to draw a conclusion one way or the other. There was competing evidence and competing hypotheses but there is an absence of acceptable data properly to validate either hypothesis. This issue then falls to be determined on the basis of the onus of proof. The Hyperandrogenism Regulations are reasonably based on such scientific and medical data and opinion as were available to the IAAF. The onus is on the Athlete to demonstrate that the Hyperandrogenism Regulations are unsupported by, or not based on, scientific data and that a difference does exist between the effects of endogenous and exogenous testosterone. She has failed to meet that onus.

Conclusion

- 489. The first issue raised by the Athlete was that the science does not demonstrate that testosterone is a material factor in determining athletic performance. The Athlete suggested that LBM or human growth hormone could account for the observed difference in male and female athletic performance. The Athlete's suggestion of LBM was incomplete as it did not address testosterone's underlying relationship to LBM. The Athlete's suggestion that human growth hormone could alone, or without testosterone, account for the observed difference was not supported by scientific evidence, but represented a mere hypothesis. The Athlete raised the examples of AIS women and low testosterone men as anomalies of the physiological impact of testosterone. The IAAF was unable to explain the existence of these outliers sufficiently. However, this point was not sufficient to "tip the scales". On a balance of probabilities, the Athlete did not establish that testosterone is not a material factor in determining athletic performance.
- 490. The second issue that the Athlete bore the onus of proving was that there is a difference in the physiological effects of endogenous and exogenous testosterone. This was important because the Athlete (and her expert witnesses) accepted that exogenous testosterone has performance enhancing affects on the athletic performance of male and female athletes. The Athlete relied on the evidence of Dr van Anders. The IAAF

answered her assertions largely by pointing out that she was not the relevant expert to interpret and draw conclusions from published medical and clinical data. The IAAF also presented countervailing evidence and opinion to support the conclusion that endogenous and exogenous testosterone have identical physiological effects. This evidence was not supported by scientific data from a properly conducted study and was comprised mainly of experts' opinions based on clinical observations. There is no suggestion that there is any chemical difference between exogenous and endogenous testosterone. However, the onus was not on the IAAF to establish that there is not a difference between exogenous and endogenous testosterone, but on the Athlete to establish there is such a difference. The Athlete was unable to discharge her onus on a balance of probabilities.

- 491. Nevertheless and notably, while the IAAF was able to refute the Athlete's argument that testosterone is not a material factor in determining athletic performance, this was largely based on data concerning exogenous testosterone. Although the IAAF did not bear the onus to establish that the effects of endogenous and exogenous testosterone were the same, the IAAF was unable to demonstrate with scientific certainty that there is no difference between the effects of endogenous and exogenous testosterone on athletic performance.
- 492. The Panel notes that the evidence presented by the IAAF in support of the Hyperandrogenism Regulations indicates that this remains an unresolved issue that would benefit from further exploration.
- 493. The question with respect to this issue is whether there is a scientific basis for the Regulations. That is, is there a scientific basis for using testosterone as a marker for the difference between males and females? If this question is answered affirmatively, then a second, related sub-issue must be considered: is there a difference in the body's physiological response to endogenous (naturally produced) testosterone, and exogenous (artificially introduced) testosterone?
- 494. The evidence establishes that, apart from some "outliers", there is a significant difference in the testosterone levels of normal populations of males and females. When these outliers are included, there is a significant overlap in the testosterone levels

between males and females. However, the experts who gave evidence for the IAAF have provided an explanation why those outliers should be disregarded for the purposes of this conclusion. The Panel accepts this explanation. The Panel is satisfied that that there is such a difference in average testosterone levels and that this marker can be relied on for the purposes of differentiating male and female populations. That is, the Panel is satisfied, on the balance of probabilities, that the IAAF is reasonably entitled to rely on testosterone for this purpose.

- 495. The Athlete has questioned whether testosterone represents a differentiating factor but has not presented a positive case to contradict the conclusions of the IAAF's witnesses. The Athlete relied on the Daegu and Moscow data to demonstrate there is an overlap in the testosterone levels of males and females. However, as stated, the apparent overlap, and the reason to disregard it for these purposes, was explained by the IAAF. The Athlete has not met the onus of demonstrating that the IAAF was not entitled to rely on testosterone as a differentiating factor.
- 496. Both parties and the experts accept that LBM provides the key difference between males and females for the purposes of athletic ability. The question is whether testosterone is a cause of that difference.
- 497. It is fair to say that the scientific and medical basis for the difference in LBM has not been established and that more work would need to be done fully to understand how the metabolism of males and females post puberty results in differences in LBM. The IAAF has, however, provided evidence that refutes the Athlete's argument that testosterone is not a material factor in causing that difference. The Athlete's case is essentially that testosterone alone does not cause differences in LBM. She has suggested other possible causes, both medical and sociological. However, those suggestions are based on hypotheses and sociological explanation and deductions by the Athlete's experts, not scientific or clinical data sufficient to establish them. On the other hand, the IAAF has provided such data and evidence to support its case on this issue.
- 498. The Athlete has not met her onus, on the balance of probabilities, to establish that testosterone is not a material causative factor in athletic ability or sports performance, whether or not LBM can fully account for the observed difference. Nor has the Athlete

- met her onus, on the balance of probabilities, of establishing that exogenous testosterone has a different effect on athletic performance than endogenous testosterone.
- 499. The Panel is satisfied, to the requisite standard of proof, that there is a scientific basis in the use of testosterone as a marker for the purposes of the Hyperandrogenism Regulations.
- D. Issue 3: Whether the Hyperandrogenism Regulations are justified as a necessary and proportionate means of attaining a legitimate sporting objective

Overview of the issue

- 500. The Panel accepts the Athlete's submission that the Hyperandrogenism Regulations discriminate against women and discriminate based on a natural physical trait. Such discrimination is, unless justified, contrary to the Olympic Charter, the IAAF Constitution and the laws of Monaco. Accordingly, if the Hyperandrogenism Regulations cannot be justified, specifically as a reasonable and necessary response to a legitimate need, then they should be declared invalid.
- 501. The IAAF bears the burden of establishing on the balance of probabilities that the Hyperandrogenism Regulations are a proportionate means of achieving the legitimate objective of ensuring fairness in athletics competition.
- The IAAF relies primarily on two contentions. The first is that the essence of sport is a level playing field and that this necessitates some categorisation in the interests of achieving fair competition. Further, it says, the "community" of female athletes demands a level playing field in the female category vis-à-vis the male category. This means, among other things, excluding female athletes from competing against other females where they enjoy the alleged performance advantages associated with "male" levels of hormones. Secondly, it says that testosterone provides the best criterion by which to ensure two things: (a) a means of preserving the rationale underpinning the accepted categories of male and female athletes; and (b) ensuring a level playing field within the female category with respect to a characteristic, LBM, that provides a competitive advantage for male athletes over female athletes.

503. The Athlete submits that the Hyperandrogenism Regulations cannot be justified and that they should therefore be declared invalid. The Athlete accepts that fair sport is a legitimate objective but says that the Regulations are not necessary to achieve that objective. Moreover, she says, the concept of the need to preserve a "level playing field", as relied upon by the IAAF, is illusory.

The position of the IAAF

- 504. As the body responsible for regulating the sport of athletics, the IAAF is in the invidious position of having to reconcile the existence of a binary male/female system of athletics categorisation with the biological reality that sex in humans is a continuum with no clear or singular boundary between men and women. Devising eligibility rules that respect both of these contrasting realities while ensuring fairness to individual athletes is difficult and presents unique scientific, ethical and legal issues. The Panel is conscious of the significant challenges that the IAAF faces in establishing a regulatory framework that achieves the IAAF's goals in this sensitive and complex area.
- 505. The IAAF has invested considerable time, resources and expertise in attempting to develop a solution that protects fairness in sport while respecting the rights of all individual athletes. The good faith of the IAAF and its scientific experts was reflected in the material that was presented to the Panel and in the testimony of the IAAF's witnesses. The Panel is fully satisfied that the IAAF has diligently sought to create a system of rules that are fair, objective and founded on the best available science. There is no doubt that the IAAF has consistently acted in pursuit of its understanding of the best interests of the sport of athletics. The level of care the IAAF displayed while consulting and drawing up the Hyperandrogenism Regulations is a testament to the seriousness with which the IAAF takes its responsibilities as the global regulator of the sport.
- 506. The bona fides and competence of the IAAF are therefore not in question. The IAAF recognised that previous rules were flawed and based on poor science. The IAAF consulted widely with respect to this issue in order to create a new set of rules that reflect the state of the available science and avoid the shortcomings inherent in the old gender verification policy. While it is apparent to the Panel that there is a range of views within

the body of female athletes on this subject, the representatives of those athletes to the IAAF were supportive of the present Regulations. Indeed, their urging was, apparently, a motivating factor in the adoption of a regulation that recognised the need to separate males and females on the basis of a criterion that reflected the significant performance advantage of male athletes over female athletes.

- 507. In relation to the practical application of the Hyperandrogenism Regulations, the Panel accepts that the Regulations are administered in confidence and with care and compassion. Athletes are given the benefit of the doubt (although this is not expressly reflected in the text of the Regulations). In some cases the testing reveals a medical condition that requires treatment, which the IAAF then provides, to the benefit of the athlete concerned. The Panel also acknowledges the IAAF's openness to the possibility of making further improvements to the Hyperandrogenism Regulations, to ensure that they remain up-to-date and to protect the rights of athletes who are subject to their provisions.
- 508. The IAAF has introduced the Hyperandrogenism Regulations to provide for fair competition and a level playing field within the female category. The Panel accepts that the Hyperandrogenism Regulations are therefore intended to pursue a legitimate objective. However, in the circumstances just outlined, the Panel also needs to be satisfied that the Hyperandrogenism Regulations are an effective and proportionate means of achieving that purpose. The need to establish the connection between the restriction imposed and the facilitation of fair competition arises: (a) because of the significant detrimental consequences for hyperandrogenic athletes affected by the Hyperandrogenism Regulations; and (b) because it is accepted that the Hyperandrogenism Regulations are discriminatory, not only because they only apply to females and not to males, but also because they discriminate between females based on a naturally occurring characteristic.

The starting point for the Panel's analysis

509. The question before the Panel does not lend itself easily to an answer. Clearly, the IAAF has over time grappled with these difficult issues. The Panel, however, is dealing with the matter from a legal perspective and in the context of accepted facts. It is worth

reiterating some of those facts and some of the evidentiary matters that have and have not been established.

510. First, the parties agree that it is reasonable and proportionate to divide athletes into male and female categories. Secondly, there should be an objective criterion or criteria to police this divide. Thirdly, gender testing is not an appropriate criterion. Fourthly, athletes may be female while still possessing high levels of testosterone, and thereby increased LBM, which creates a competitive advantage. Fifthly, whether a person is a female is a matter of law. Sixthly, there is no evidence before the Panel that legal recognition as a female varies in most countries other than reference by the parties to the fact that there are a small number of countries where a person's status as a male or female is determined exclusively by a process of self-identification. Seventhly, the level of endogenous testosterone and sensitivity to testosterone may provide an appropriate criterion to divide normal male and female populations. However, eighthly, there are females such as those with DSDs who have high levels of endogenous testosterone relative to other females and are sensitive to testosterone and remain females. There is no separate category in which those athletes may compete (for example, an "intersex" category). Ninthly, the Hyperandrogenism Regulations only apply to females. Tenthly, if the Regulations apply to a female to preclude her competing as a female, she may not compete as a male. That is, the Regulations do not police the male/female divide but establish a female/female divide within the female category. Eleventhly, the criteria of a level of endogenous testosterone of 10 nmol/L with a degree of virilisation as an indicator of 'masculine traits', are based on the best available science concerning the typical ranges of testosterone in males and females and physical indications of androgen sensitivity.

Justification for a rule that excludes some females from competing in the female category on the basis of a natural physical characteristic

511. The distinction between male and female is a matter of legal recognition. Nevertheless, as explained above, the Panel is of the view that levels of endogenous testosterone are a key biological indicator of the difference between males and females. However, that is not the use to which endogenous testosterone is being put under the Hyperandrogenism Regulations. It is not being used to determine whether an athlete

should compete either as a male or as a female. Instead, it is being used to introduce a new category of ineligible female athletes within the female category. The necessity and proportionality of that restriction therefore requires particularly careful analysis.

- As noted above, there are only two categories of competition: male and female. These categories are together intended to cover *all* athletes who wish to participate in competitive athletics. Female athletes who exhibit high levels of endogenous testosterone may include females with intersex characteristics. As an intersex population exists, and is represented in female athletics, it must be accepted that these athletes may exhibit characteristics across a range, from those within the normal female range to those within the normal male range. Where an athlete is female, and thereby only eligible to compete as a female, is it reasonable and proportionate to impose a test that excludes her from the female athlete category for the purposes of competition, when she exhibits, naturally, the characteristic most closely associated with male competitive advantage? The Panel need to be satisfied on a balance of probabilities that it is.
- 513. The Panel considers that every athlete must in principle be afforded the opportunity to compete in one of the two categories and should not be prevented from competing in any category as a consequence of the natural and unaltered state of their body. A rule that prevents some women from competing at all as a result of the natural and unmodified state of their body is antithetical to the fundamental principle of Olympism that "Every individual must have the possibility of practising sport, without discrimination of any kind". So too is a rule that permits an athlete to compete on condition that they undergo a performance-inhibiting medical intervention that negates or reduces the effect of a particular naturally occurring genetic feature. Excluding athletes from competing at all on the basis of a natural genetic advantage, or conditioning their right to compete on undergoing medical intervention which reduces their athletic performance, imposes a significant detriment on the athletes concerned, and is therefore only valid if it is clearly established to be a necessary and proportionate means of achieving fair competition.
- 514. It is not in dispute that it is appropriate to segregate athletic competition into male and female categories. It is clear that this may require policing and give rise to difficult decisions when nature does not divide into these categories so simply.

- S15. It is apparent from Professor Ljungqvist's evidence that the Hyperandrogenism Regulations were designed to protect the majority of female athletes by ensuring that a person with a condition (for example a DSD) that confers a competitive advantage by reason of the presence of a very high level of testosterone compared to other females (which is a key reason for and measure of male athletic advantage) does not compete in the female category. However, it was also recognised that not only complete androgen insensitivity but also partial androgen insensitivity may mean that the advantage of high testosterone levels is only of "minor importance" for competitive advantage.
- 516. Professor Ljungqvist's evidence indicates that the Hyperandrogenism Regulations are intended to protect female athletes from having to compete against other athletes who enjoy a competitive advantage similar to the competitive advantage that males have by reason of higher levels of testosterone and the resulting higher LBM.
- The premise underpinning the Hyperandrogenism Regulations is therefore that some members of the female class have a competitive advantage over other members of the female class that is similar to the performance advantage enjoyed by male athletes. In other words, the Hyperandrogenism Regulations are based on an implicit assumption that hyperandrogenic females enjoy a *significant performance advantage* over their non-hyperandrogenic peers, which outranks the influence of any other single genetic or biological factor, and which is of comparable significance (if not identical magnitude) to the performance advantage that males typically enjoy over females. That is, it is the *degree* of competitive advantage that is said to make for unfair competition and absence of a level playing field.
- This underlying premise is reflected in the Preface to the Hyperandrogenism Regulations, which makes reference to the strict division between male and female categories and states that "[t]he difference in athletic performance between males and females is known to be predominantly due to higher levels of androgenic hormones in males", before explaining that the Regulations are designed to address the fact that hyperandrogenic females "often ... have an uncommon athletic capacity in relation to their fellow female competitors".

- 519. Once an athlete is legally recognised as female, the Panel considers that an athlete must be permitted to compete in the female category unless her naturally high androgen levels confer a significant performance advantage over other female competitors, comparable to the performance advantage that male athletes enjoy over female athletes. Has the IAAF established that women with levels of endogenous testosterone of at least 10 nmol/L and who are androgen-sensitive have a sufficiently clear and significant competitive advantage over other females such that there may be a fairness-based reason why they should be precluded from competing as females, or at all?
- 520. This raises the question whether the IAAF can demonstrate a correlation between this level of testosterone in females and a real competitive advantage that interferes with fair competition within the female category. This question cannot simply be answered by noting that male athletes have a particular advantage over female athletes. This is because the Hyperandrogenism Regulations are not concerned with upholding a male/female divide and because other factors besides testosterone that may also contribute to the significant male athletic advantage over females have not been evaluated and discounted.
- 521. There is a class of female athletes who, by reason of DSDs, have high levels of endogenous testosterone. These athletes are female but have a medical or genetic condition that is believed to give them an athletic advantage. On the evidence, this advantage does not arise directly from the level of endogenous testosterone but rather arises from the effect of testosterone on the body, specifically an increase in LBM. However, importantly, there is no evidence before the Panel and it is understood that there is presently no available evidence as to the quantitative effect on female athletic performance of levels of endogenous testosterone above 10 nmol/L.
- 522. In other words, there is presently insufficient evidence about the *degree* of the advantage that androgen-sensitive hyperandrogenic females enjoy over non-hyperandrogenic females. In the Panel's opinion this is significant. It is not self-evident that a female athlete with a level of testosterone above 10 nmol/L would enjoy the competitive advantage of a male athlete, which performance advantage would be, on the IAAF's evidence, in the order of 10 12% (the approximate difference, on the evidence of the IAAF, between men and women and, therefore, an unfair advantage), rather than, say,

1% (a relatively marginal advantage, having regard to the many other variables that contribute to athletic performance).

- 523. The Panel notes that in 2014 Professor Ritzen, Professor Hirschberg and Dr Bermon coauthored an article (together with several other authors) entitled Serum Androgen Levels in Elite Female Athletes, which was published in the Journal of Clinical Endocrinology and Metabolism. The article, which examined the ranges of male and female testosterone revealed by the Daegu data, described the absence of positive evidence concerning the magnitude of the performance advantage that hyperandrogenic females enjoy as a result of their enhanced androgen levels. The article stated that: "The lack of definitive research linking female hyperandrogenism and sporting performance is problematic and represents another central point of the controversy. With the exception of data extracted from doping programs in female athletes in the former German Democratic Republic, there is no clear scientific evidence proving that a high level of [testosterone] is a significant determinant of performance in female sports." The article explained, however, that the significant over-representation of hyperandrogenic females in the population of elite female athletes provided "indirect evidence for performanceenhancing effects of hyperandrogenic DSD conditions and their associated high [testosterone] concentration in female athletes".
- 524. While the over-representation of hyperandrogenic females in elite female population does indeed provide indirect evidence that high levels of endogenous testosterone improve athletic performance, the article confirms the lack of clear data concerning the degree of the performance advantage that hyperandrogenic females enjoy over their non-hyperandrogenic peers.
- 525. During the course of his oral evidence before the Panel, Dr Bermon noted the significant over-representation of DSD individuals in the population of elite female athletes. Dr Bermon suggested that a female athlete with functioning androgen receptors and 15 nmol/L endogenous testosterone would experience a performance advantage of approximately 3% over a female athlete with 1.5 nmol/L endogenous testosterone. This figure was based on his experience and his unpublished data. In response to a further question by the Panel, Dr Bermon also confirmed that the IAAF had not analysed the Daegu data to look for any correlation between testosterone levels and athletes' rankings

in particular events. Dr Bermon stated that he had been asked by Professor Ritzen to undertake such an analysis, but he had not yet done so as he was unsure what the results could establish. He noted that in order to examine any possible correlation, it would be necessary to collate a wide range of data within narrow limits and on an event-by-event basis. He acknowledged that the IAAF had not done this and noted that correlation does not mean a causal effect.

- 526. The Panel notes, in this regard, that the performance advantage of approximately 3% suggested by Dr Bermon is significantly smaller than the 10% 12% difference between elite male and elite female athletic performance referred to by the IAAF in its appeal brief, the 10% difference in male/female performance referred to by Professor Ritzen and Professor Hirschberg in their joint expert report, and the 12.64% difference in male/female performance referred to in Dr Bermon's report. The Panel does not place great weight on the 3% figure referred to by Dr Bermon; however, it does demonstrate that the IAAF recognises that the performance advantage that hyperandrogenic females enjoy over normal females may be of a different order to the performance advantage that males enjoy over females.
- 527. The Panel considers the lack of evidence regarding the quantitative relationship between enhanced levels of endogenous testosterone and enhanced athletic performance to be an important issue. While a 10% difference in athletic performance certainly justifies having separate male and female categories, a 1% difference may not justify a separation between athletes in the female category, given the many other relevant variables that also legitimately affect athletic performance. The numbers therefore matter.
- 528. The Panel accepts that exogenous testosterone improves athletic performance in male and female athletes. The Panel has also concluded that the Athlete has failed to establish on the balance of probabilities that exogenous and endogenous testosterone have different effects on the body. However, in order to justify excluding an individual from competing in a particular category on the basis of a naturally occurring characteristic such as endogenous testosterone, it is not enough simply to establish that the characteristic has some performance enhancing effect. Instead, the IAAF needs to establish that the characteristic in question confers such a significant performance advantage over other members of the category that allowing individuals with that

characteristic to compete would subvert the very basis for having the separate category and thereby prevent a level playing field. The degree or magnitude of the advantage is therefore critical.

- 529. In this connection, the fact that female athletes are banned from using exogenous testosterone because of its performance enhancing effects does not prove that high levels of endogenous testosterone confer such a significant advantage that they destroy fair competition within the female category. There are many features of human biology which have no effect on an athlete's eligibility to compete when they occur naturally, but whose artificial induction is prohibited because of their performance enhancing qualities. Two examples include human growth hormone and adrenaline, which both exist naturally in varying levels in all athletes without having any effect on athletes' eligibility to compete, but whose exogenous administration is prohibited under the WADA Code.
- The determinative factor adopted by the IAAF in the Hyperandrogenism Regulations is not only a high level of testosterone in the male range but also a medical examination intended to give an assessment of the likely effect of the testosterone on the athlete's body. However, the examination involves what may be termed a qualitative assessment about the extent of the athletic performance advantage that the athlete derives from their high androgen levels. In light of the paucity of data concerning the magnitude of the performance advantage that hyperandrogenic females typically derive from enhanced androgen levels, the IAAF has not established that the medical examination does enable a reliable conclusion to be reached as to the degree of competitive advantage that results from a level of endogenous testosterone over 10nmol/L in an athlete. In this regard, the Panel agrees with Dr Bermon, Professor Hirschberg and Professor Ritzen that "[t]he lack of definitive research linking female hyperandrogenism and sporting performance is problematic".
- 531. It follows that the Panel is unable to conclude that the Hyperandrogenism Regulations fulfil their stated purpose. This may be because available data are not yet available. The evidence is that there are inadequate data to establish or refute hypotheses in this area. In the context of this issue, the onus lies on the IAAF. The IAAF has not established, on the balance of probabilities that the Hyperandrogenism Regulations

- apply only to exclude female athletes that are shown to have a competitive advantage of the same order as that of a male athlete.
- 532. On the basis of the evidence currently before the Panel, the Panel is unable to conclude on the balance of probabilities that androgen-sensitive hyperandrogenic female athletes enjoy such a substantial performance advantage over non-hyperandrogenic female athletes that excluding them from competing in the female category, and thereby excluding them from competing at all unless they take medication or undergo treatment, is a necessary and proportionate means of preserving fairness in athletics competition and/or policing the binary male/female classification. In particular, while the evidence indicates that higher levels of naturally occurring testosterone may increase athletic performance, the Panel is not satisfied that the degree of that advantage is more significant than the advantage derived from the numerous other variables which the parties acknowledge also affect female athletic performance: for example, nutrition, access to specialist training facilities and coaching, and other genetic and biological variations. Further evidence as to the quantitative relationship between androgen levels in hyperandrogenic females and increased athletic performance is therefore required before the IAAF can discharge its onus of establishing that the Hyperandrogenism Regulations are a necessary and proportionate means of achieving the IAAF's stated objective.

Conclusion

533. The Panel has accepted that testosterone is a key causative factor in the increased LBM in males. The Panel accepts that increased LBM confers a competitive advantage. The Panel accepts the evidence that male athletes have a competitive advantage over female athletes of the order of 10 - 12%; that LBM is of key importance in conferring this advantage; and that separation between male and female athletes is therefore justifiable in the interests of fair competition. There is, however, an assumption involved in the Hyperandrogenism Regulations as a proportionate justification for discriminating between females. The assumption is that an endogenous testosterone level within the male range + virilisation (indicating sensitivity to the high level of testosterone) = a degree of competitive advantage over non-hyperandrogenic females of commensurate significance to the competitive advantage that male athletes enjoy over female athletes.

- 534. This assumption may well be proved valid but, on the present evidence, the Panel cannot be satisfied on the balance of probabilities that this is so. The Panel has accepted that testosterone is the best indicator of performance difference between male and female athletes. However, the evidence does not go so far as to equate, or correlate, the level of testosterone in females with a percentage increase in competitive advantage. The evidence does not, for example, establish an advantage of the order of 12% rather than, say 1% or 3%. Once the degree of competitive advantage is established, the IAAF would then need to consider, if the degree of advantage were well below 12%, whether that justified excluding women with that advantage from the female category.
- 535. As the Panel stated above, where the evidence is unavailable, the onus of proof remains. The onus is on the IAAF to establish that the degree of competitive advantage conferred by a testosterone level above 10 nmol/L accords with the degree of competitive advantage that justifies the male/female divide such that it is reasonable and proportionate to render females with, and sensitive to, that level of testosterone ineligible to compete as female athletes. The evidence before the Panel has not enabled the IAAF to fulfil that onus.
- 536. For these reasons, the Panel finds that the IAAF has not discharged its burden of establishing that the criteria in the Hyperandrogenism Regulations are necessary and proportionate to pursue the legitimate objective of regulating eligibility to compete in female athletics to ensure fairness in athletic competition.
- 537. In reaching this conclusion, the Panel wishes to reiterate that its conclusion does not reflect any bad faith or incompetence on the part of the IAAF. On the contrary, the IAAF has acted with conspicuous diligence and good faith throughout the process of consulting, drafting and implementing the Hyperandrogenism Regulations. The Panel accepts that the IAAF, which represents the interests of athletes, including female athletes, has decided that it is in the interest of fair competition in the female category to exclude athletes who, naturally, have characteristics that give them a similar competitive advantage to that enjoyed by male athletes. The evidence before the Panel was that the IAAF considers this to be necessary and proportionate. For the reasons explained above, the Panel has reached a different conclusion. The Panel's view is that the evidence has not established that competition against hyperandrogenic females to

- whom the existing Regulations apply is unfair due to superior sport performance caused by high levels of testosterone.
- 538. It may be that evolving scientific evidence or the compilation of existing evidence and data will reach a sufficient level of proof of unacceptable competitive advantage to enable a specific standard to be reached, either by reference to testosterone or by reference to, for example, LBM or otherwise. In this regard, the Panel notes Dr Bermon's evidence concerning the possibility of reanalysing the Daegu data to investigate whether there is evidence of a correlation between testosterone levels and relative rankings in competitive athletics events.

E. Issue 4: Impermissible doping sanction

- 539. The Athlete contends that the Hyperandrogenism Regulations constitute an impermissible ban on "endogenous doping" since they effectively seek to add naturally occurring testosterone to the WADA Prohibited List of banned substances. The IAAF strongly disputed this characterisation of the Regulations. The IAAF submitted that the Hyperandrogenism Regulations are an eligibility rule, not a doping sanction, and there is no question of hyperandrogenic female athletes being subjected to any punishment or censure as a result of the natural state of their bodies.
- 540. The Athlete's fourth ground of challenge was addressed only briefly during the course of the hearing. As noted above, in his closing submissions the Athlete's counsel conceded that this ground was the weakest aspect of the Athlete's case.
- 541. The Athlete bears the burden of establishing, on a balance of probabilities, that the Hyperandrogenism Regulations are a disguised doping sanction that is incompatible with the provisions of the WADA Code. The Panel does not accept the Athlete's arguments on this issue. In the Panel's view, the Athlete's case does not accurately reflect the nature of the Hyperandrogenism Regulations, which have nothing to do with doping and do not impose any punishment or penalty on female athletes who fall within their terms.
- 542. The Athlete's submissions confound eligibility rules and anti-doping sanctions. Eligibility rules establish objective conditions that regulate the ability of individual athletes to participate in particular categories of athletics competition. Those rules may

operate to prevent a particular individual from competing in a particular category (or, in some cases, in any category). However they do not involve any element of punishment or censure; they are not framed in terms of "violations" of prohibited conduct; and they do not serve any retributive or deterrent purpose.

- 543. By contrast, anti-doping sanctions seek to punish and deter certain prohibited conduct, namely the deliberate or inadvertent ingestion of performance enhancing substances. In particular, anti-doping rules are concerned with limiting the distorting effect of *external* substances that give athletes advantages over other competitors who have not received the same *extrinsic* performance aid. The concept of "*endogenous doping*" is therefore a contradiction in terms.
- 544. The Hyperandrogenism Regulations are an eligibility rule. They are not framed in terms of prohibited conduct and sanctions for corresponding "violations". They do not impose penalties on athletes who have particular levels of naturally occurring testosterone. Nor do they involve any reprimand or censure (indeed, the Regulations stress the importance of keeping the outcomes of examinations confidential). While female athletes who have endogenous testosterone above 10 nmol/L and who are not androgen resistant will be prevented from competing, those individuals can immediately resume competing as soon they meet the eligibility criteria (for example, by taking pharmacological steps to reduce their testosterone levels beyond 10 nmol/L). All of these factors indicate that the Hyperandrogenism Regulations are not a form of anti-doping control.
- 545. The WADA Prohibited List contains restrictions concerning the use of non-approved pharmacological substances; anabolic agents; peptide hormones, growth factors, related substances and mimetics; beta-2 agonists; hormone and metabolic modulators; diuretics and masking agents; stimulants; narcotics; glucocorticoids; alcohol and beta-blockers. It also contains prohibited methods including manipulation of blood, chemical and physical manipulation (e.g. urine substitution or intravenous infusions outside the context of legitimate surgical treatment) and gene doping. The Hyperandrogenism Regulations do not purport to modify, supplement or expand that list in any way.
- 546. For all these reasons, the Panel rejects the Athlete's fourth ground of challenge. In reaching this conclusion, the Panel notes the statement from Mr Niggli, WADA's

General Counsel and Chief Operating Officer, who explained that rules restricting eligibility to compete based on levels of naturally occurring testosterone are not anti-doping rules. The Panel accepts the Athlete's submission that Mr Niggli's personal opinion cannot determine the legal character of the Hyperandrogenism Regulations, which is exclusively a matter for the Panel to decide. Nevertheless, the Panel notes that the conclusion it has reached on this issue is entirely consistent with the stance taken by the organisation responsible for promulgating and enforcing the Code which the Athlete claims has been breached.

F. Conclusion and next steps

- 547. For the reasons explained above, the Panel concludes that the IAAF has not discharged its onus of establishing that the Hyperandrogenism Regulations are necessary and proportionate to pursue the legitimate objective of organising competitive female athletics to ensure fairness in athletic competition. Specifically, the IAAF has not provided sufficient scientific evidence about the quantitative relationship between enhanced testosterone levels and improved athletic performance in hyperandrogenic athletes. In the absence of such evidence, the Panel is unable to conclude that hyperandrogenic female athletes may enjoy such a significant performance advantage that it is necessary to exclude them from competing in the female category.
- 548. In these circumstances, the Panel is unable to uphold the validity of the Regulations. The Panel therefore suspends the Hyperandrogenism Regulations for a period of two years, subject to the following provisos. At any time during that two-year period, the IAAF may submit further written evidence to the CAS concerning the magnitude of the performance advantage that hyperandrogenic females enjoy over other females as a result of their abnormally high androgen levels. In the event that the IAAF submits such evidence, the Panel will issue further directions enabling the Athlete to respond to that evidence and listing the matter for a further hearing for the Panel to consider whether that evidence is sufficient to establish the validity of the Regulations. In the event that the IAAF does not file any evidence within that two-year window (or if it notifies the CAS in writing that it does not intend to file such evidence) then the Hyperandrogenism Regulations shall be declared void.

X. Costs

549. (...).

ON THESE GROUNDS

The Court of Arbitration for Sport rules that:

- 1. The appeal filed by Ms Dutee Chand on 26 September 2014 against the Athletics Federation of India's letter of 29 August 2014 declaring Ms Chand ineligible to compete under the IAAF Regulation Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition (the "Hyperandrogenism Regulations") is partially upheld.
- 2. The Hyperandrogenism Regulations are suspended for a period of no longer than two years from the date of this Interim Award. In the interim, Ms Dutee Chand is permitted to compete in both national and international-level athletics events.
- 3. The International Association of Athletics Federations may, at any time within two years of the date of this Interim Award, submit further written evidence and expert reports to this Panel addressing the Panel's concerns concerning the Hyperandrogenism Regulations as set forth in this Interim Award and, in particular, the actual degree of athletic performance advantage sustained by hyperandrogenic female athletes as compared to non-hyperandrogenic female athletes by reason of their high levels of testosterone.
- 4. To the extent the International Association of Athletics Federations submits further written evidence and expert reports in accordance with paragraph 3 above, the Panel shall issue further procedural instructions to the parties, including the opportunity for Ms Chand to file written evidence and submissions in response to the submissions filed by the International Association of Athletics Federations, prior to determining whether the new evidence establishes the validity of the Hyperandrogenism Regulations. The Panel will then decide whether any further oral hearing shall take place and notify the parties accordingly.
- 5. In the event that no evidence is filed in accordance with paragraph 3 above, or in the event that the International Association of Athletics Federations confirms in writing to the CAS Court Office that it does not intend to file any such evidence, the Hyperandrogenism Regulations shall be declared void.
- 6. (...).
- 7. (...).
- 8. All other motions or prayers for relief are dismissed.

Seat of arbitration: Lausanne, Switzerland

Date: 24 July 2015

THE COURT OF ARBITRATION FOR SPORT

The Hon. Justice Annabelle Claire Bennett AO President of the Panel

Professor Richard H. McLaren Arbitrator Dr Hans Nater Arbitrator

Edward Craven Ad hoc Clerk