CAS 2018/O/5794 Mokgadi Caster Semenya v. International Association of Athletics Federations
CAS 2018/O/5798 Athletics South Africa v. International Association of Athletics Federations

ARBITRAL AWARD

Delivered by the

COURT OF ARBITRATION FOR SPORT

sitting in the following composition:

President:	The Hon. Dr. Annabelle Bennett AO SC, Retired Judge, Sydney, Australia
Arbitrators:	The Hon. Hugh L. Fraser, Judge, Ottawa, Ontario, Canada
	Dr. Hans Nater, Attorney-at-Law, Zurich, Switzerland
Ad hoc Clerk:	Mr. Edward Craven, Barrister, London, England

in the arbitration between

Mokgadi Caster Semenya, South Africa

Represented by Mr. James Bunting and Mr. Carlos Sayao, Attorneys-at-Law with Davies Ward Phillips & Vineberg LLP in Toronto, Ontario, Canada, and Mr. Gregory Nott, Mr. Patrick Bracher, and Ms. Sandra Sithole, Attorneys-at-Law with Norton Rose Fulbright South Africa, Inc. in Sandton, Gauteng, South Africa

First Claimant

Athletics South Africa, South Africa

Represented by Mr. Norman Arendse SC, Ms. Ncumisa Mayosi, of Counsel and Mr. Dev Maharaj and Ms. Jean Kelly, Attorneys-at-Law with Dev Maharaj and Associates, Inc. in Bryanston, Gauteng, South Africa

Second Claimant

and

International Association of Athletics Federations, Monaco

Represented by Mr. Jonathan Taylor QC and Mr. Chris Lavey, Attorneys-at-Law with Bird & Bird in London, England, and Ms. Elizabeth Riley, Attorney-at-Law in Bonn, Germany

I. OVERVIEW OF THE CASE

1. This dispute arises under the Constitution of the International Association of Athletics Federations (the "IAAF"), in force as from 1 November 2017, following the IAAF's decision to enact the Eligibility Regulations for the Female Classification (Athletes with Differences of Sex Development) (the "DSD Regulations").

2. Ms. Mokgadi Caster Semenya ("Ms. Semenya" or the "Athlete") and Athletics South Africa ("ASA") (collectively, the "Claimants") assert *inter alia* that the DSD Regulations unfairly discriminate against athletes on the basis of sex and/or gender because they only apply (i) to female athletes; and (ii) to female athletes having certain physiological traits. They contend that the DSD Regulations lack a sound scientific basis; are unnecessary to ensure fair competition within the female classification; and are likely to cause grave, unjustified and irreparable harm to affected female athletes. Accordingly, the Claimants seek a judgment from the CAS declaring the DSD Regulations unlawful and preventing them from being brought into force on the basis that they are unfairly discriminatory, arbitrary and disproportionate and therefore violate the IAAF Constitution, the Olympic Charter, the laws of Monaco, the laws of jurisdictions in which international athletics competitions are held, as well as universally recognised fundamental human rights.

II. PARTIES

3. Ms. Semenya is a female athlete of South African nationality. She specialises in middle distance races and has achieved outstanding success at the elite international level. In the 800m event she finished in first place at the 2009, 2011 and 2017 IAAF World Championships and the 2012 and 2016 Olympic Games.

4. ASA is the national governing body for the sport of athletics in South Africa. Its seat and headquarters are located in Johannesburg, South Africa.

5. 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 ASA as its member federation for South Africa.

III. FACTUAL BACKGROUND

6. The parties adduced extensive evidence and submissions. Below is a summary of the relevant facts and allegations based on the parties' written submissions, pleadings and evidence adduced at the hearing before the Panel on 18 to 22 February 2019. 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. Similarly, the Panel has referred to the expertise of the expert witnesses called by the parties by broad description. In each case, details of relevant expertise were provided in the evidence.

7. In September 2014, Dutee Chand, a female athlete of Indian nationality, brought proceedings before the CAS against the IAAF and the Athletics Federation of India

("AFI") appealing against the AFI's declaration that she was ineligible to compete under the IAAF Regulations Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition (the "Hyperandrogenism Regulations").

8. On 24 July 2015, the CAS delivered an Interim Award partially upholding Ms. Chand's appeal and suspending the Hyperandrogenism Regulations for a period of up to two years (CAS 2014/A/3759 *Dutee Chand v AFI & IAAF*). The Interim Award stipulated that at any time during that period the IAAF could submit further written evidence and expert reports addressing the Panel's concerns set out in the Interim Award (in particular regarding 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).

9. Following a short extension of the two-year deadline, on 29 September 2017 the IAAF filed expert evidence and legal submissions seeking to support the Hyperandrogenism Regulations. The CAS subsequently made an order by consent of the parties suspending the proceedings in *Chand* for a further six months, during which time the Hyperandrogenism Regulations remained suspended.

10. On 9 March 2018, the IAAF informed the CAS Panel that it intended to withdraw the Hyperandrogenism Regulations and to replace them with new Regulations, which would take effect on 1 November 2018. In light of that development, and the fact that the Hyperandrogenism Regulations as sought to be supported did not apply to Ms. Chand, the proceedings in *Chand* were terminated.

11. On 5 and 6 March 2018, a meeting of the IAAF Council took place in Birmingham, United Kingdom. During the course of that meeting, the IAAF Council approved the enactment of the DSD Regulations. On 23 April 2018, the DSD Regulations were sent to the IAAF's member federations together with accompanying Explanatory Notes.

12. The relevant provisions of the DSD Regulations are set out below. In summary, the DSD Regulations establish new mandatory requirements governing the eligibility of women with certain differences of sex development ("DSD") and levels of endogenous testosterone above 5 nmol/L to participate in the female classification in eight events (the "Restricted Events") at international athletics competitions ("International Competitions"). Athletes who fall within the ambit of the Regulations are defined as "Relevant Athletes". The Restricted Events include 400m, 800m and 1500m races – events in which Ms. Semenya regularly participates at International Competitions. The text of the relevant provisions of the DSD Regulations is set out below.

13. The DSD Regulations came into force on 1 November 2018. Prior to that date, however, Ms. Semenya and ASA each initiated proceedings before the CAS challenging the validity of the DSD Regulations. The history of these proceedings before the CAS, which were formally consolidated as ordinary arbitration proceedings on 29 June 2018, is summarised immediately below.

IV. PROCEEDINGS BEFORE THE COURT OF ARBITRATION FOR SPORT

14. On 18 June 2018, Ms. Semenya filed her request for arbitration with the CAS against the IAAF requesting *inter alia* that the DSD Regulations be declared unlawful in accordance with Article R38 of the Code of Sports-related Arbitration (the "CAS Code"). In her request for arbitration, Ms. Semenya nominated the Hon. Hugh L. Fraser as arbitrator.

15. On 25 June 2018, ASA filed a statement of appeal against the IAAF similarly seeking a declaration that the DSD Regulations be declared unlawful in accordance with Article R47 *et seq.* of the CAS Code. In its statement of appeal, ASA nominated Ms. Susan Ahern as arbitrator.

16. On 26 June 2018, following email communication between the CAS Court Office and ASA, the CAS Court Office confirmed that ASA's statement of appeal would be converted to a request for arbitration and its procedure referred to the CAS Ordinary Arbitration Division.

17. On 27 June 2018, the IAAF appointed Dr. Hans Nater as arbitrator in both procedures and, with the agreement of Ms. Semenya, suggested that the Hon. Dr. Annabelle Bennett be appointed Chair of the Panel presiding over this procedure. Both Dr Nater and Dr Bennett sat on the *Chand* Panel.

18. On 28 June 2018, ASA objected to the appointment in this procedure of any members of the *Chand* Panel. At the same time, ASA withdrew its nomination of Ms. Ahern and joined in a joint nomination of Hon. Hugh Fraser with Ms. Semenya.

19. On 29 June 2018, the CAS Court Office, on behalf of the President of the Ordinary Arbitration Division, and following the agreement of all parties, confirmed the consolidation of both procedures in accordance with Article R39 of the CAS Code.

20. On 23 July 2018, the CAS Court Office, on behalf of the President of the Ordinary Arbitration Division, confirmed the constitution of the Panel as follows:

President: The Hon. Dr Annabelle Bennett AO SC, Retired Judge, Sydney, Australia

Arbitrators: The Hon. Hugh L. Fraser, Judge, Ottawa, Ontario, Canada

Dr. Hans Nater, Attorney-at-Law, Zurich, Switzerland

21. On 30 July 2018, ASA filed a petition to challenge the appointment of both the Hon. Dr. Annabelle Bennett and Dr. Nater to the Panel. The petition was objected to by Ms. Semenya and the IAAF.

22. On 6 August 2018, the IAAF filed a consolidated answer to the consolidated requests for arbitration in accordance with Article R39 of the CAS Code.

23. On 20 September 2018, the Board of the International Council of Arbitration for Sport issued its decision on ASA's petition for challenge. ASA's petition was denied and the Panel confirmed as constituted.

24. On 9 October 2018, Mr. Edward Craven, Barrister, London United Kingdom, was appointed *ad hoc* clerk in these procedures.

25. On 10 October 2018, a telephone hearing took place before the President of the Panel for the purpose of making case management directions in the proceeding.

26. On 31 October 2018, the CAS Court Office, on behalf of the Panel and after obtaining the positions of the parties, confirmed the request of the United Nations, Office of High Commissioner for Human Rights, to file an amicus curiae submission in accordance with Article R41.4 of the CAS Code.

27. On 16 and 19 November 2018, the Claimants filed their "evidence brief/documentation" and statements of claim, respectively, in accordance with Article R44.1 of the CAS Code.

28. On 19 December 2018, the United Nations, Office of High Commissioner for Human Rights, filed its amicus curiae submission. On behalf of the Panel, the CAS Court Office invited the parties to file a response thereto, if necessary, within ten (10) days prior to the hearing.

29. On 9 February 2019, the IAAF filed its answer to the Claimants' statements of claim in accordance with Article R44.1 of the CAS Code.

30. On 1 February 2019, Ms. Semenya and ASA each filed a Reply to the IAAF's Answer.

31. Also on 1 February 2019, ASA filed a request for an order compelling the IAAF to produce certain documents in its custody or under its control pursuant to Article R44.3 of the CAS Code. Specifically, ASA sought production of the athletes' files regarding all cases that were dealt with by the IAAF pursuant to the Hyperandrogenism Regulations. ASA submitted that production of this evidence was critical to enable the Claimants to test the evidence put forward by the IAAF in defence of the DSD Regulations. ASA also sought copies of all consent forms signed by athletes whose data were used in the study relied on by the IAAF in support of the DSD Regulations. ASA also sought an order that the proceedings before the CAS be stayed until the IAAF had provided the information and data requested.

32. On 4 February 2019, Ms. Semenya wrote to the CAS stating that she supported ASA's request insofar as it related to the case files of the athletes who had been dealt with by the IAAF under the former Hyperandrogenism Regulations. Ms. Semenya did not, however, support the request for a stay of the proceedings. Instead, she sought a direction that in the event the IAAF failed to produce those files (a) the IAAF should be prevented from relying on the data withheld and any information, evidence or opinions based upon those data; and (b) certain passages of the IAAF's witness and expert evidence should be struck from the record.

33. On 7 February 2019, the IAAF filed a response to the Claimants' disclosure requests. The IAAF stated that in the 18 weeks since the IAAF had provided disclosure of relevant documents to the Claimants on 3 October 2018, neither Ms. Semenya nor ASA had raised any issues concerning the adequacy of that disclosure. Nor had they pressed this issue during the telephone hearing on 10 October 2018. Since it would take the IAAF

significant time to locate, collate, redact and produce those documents, the delay is itself a basis to refuse the application. In addition, the IAAF submitted that (a) in respect of the request for disclosure of case files relating to DSD athletes, it had already produced all of the data sought in respect of changes in performance following testosterone suppression, and the other documents and data sought were clearly not disclosable; and (b) there was no good basis for the request for disclosure of consent forms signed by athletes whose data were used in the IAAF study. Accordingly, the IAAF submitted that the request for disclosure orders and the request for a stay of the proceedings should be refused.

34. On 8 February 2019, the IAAF and ASA each filed a response to the amicus curiae brief submitted on behalf of the United Nations on 19 December 2018.

35. On 10 and 11 February 2019, ASA and Ms. Semenya, respectively, filed a reply to the IAAF's submission dated 7 February.

36. On 12 February 2019, the CAS wrote to the parties explaining that it was clear from the nature of ASA's request and the submissions of the IAAF that the further production sought would result in significant delay to the proceedings. The letter stated that the Panel was not prepared to make a decision prior to the hearing on the application for production and/or a stay. Accordingly, the parties were notified that (a) ASA's request for a stay was denied without prejudice to any application for a stay to be made at the hearing; and (b) ASA was permitted to file a further reply to the IAAF's submissions by 15 February 2019 if it wished to do so.

37. On 14 February 2019, ASA filed a further reply to the IAAF's submission.

38. On 12 and 19 February and 13 March 2019, ASA, Ms. Semenya, and the IAAF, respectively, signed and returned the order of procedure in this matter.

39. Between 18-22 February 2019, a hearing was held in Lausanne, Switzerland. The Panel was assisted by Mr. Brent J. Nowicki, Managing Counsel, and Mr. Edward Craven, *ad hoc* clerk, and joined by the following legal counsel or party representatives:

For Ms. Semenya:

- Caster Semenya
- James Bunting
- Carlos Sayao
- Patrick Bracher
- Gregory Nott

For ASA:

- Norman Arendse
- Jean Kelly
- Devendranath Maharaj
- Shikar Maharaj
- Ncumisa Thoko Mayosi
- Aleck Skhosana

For the IAAF:

- Lord Sebastian Coe
- Chris Lavey
- Elizabeth Riley
- Jonathan Taylor

40. At the outset of the hearing, each of the parties confirmed that they had no objection to the Panel and specifically, that they had no objection to the Panel proceeding to decide this dispute.

41. Also at the outset of the hearing, the Panel was invited by the Claimants to make an order compelling the IAAF to disclose case files relating to the athletes who were dealt with under the Hyperandrogenism Regulations. After a short adjournment to deliberate on the application, the Panel informed the parties that it had decided to refuse the request but that this refusal did not prevent the Claimants from inviting the Panel to draw adverse inferences against the IAAF based on the absence of such material. The Panel explained that the reasons for the refusal of the application would be provided in the reasoned Award. Those reasons may be summarised as follows. First, the Panel considered that the delay in making the application for a production order had not been properly explained by the Claimants. Second, from a practical perspective, if the Panel were to make the order sought then it is inevitable that the relevant evidence could not all be put before the Panel before the end of the hearing. It would not be appropriate to permit evidence to be filed after the conclusion of the hearing, however, because it is likely that such evidence would give rise to questions which could then not be properly addressed through written submissions alone. Third, although none of the parties were seeking a delay to the proceedings, such a delay would inevitably result if the Panel were to issue a production order against the IAAF. This would jeopardise the Panel's ability to deliver its reasoned award in accordance with the expedited timetable agreed by the parties. That expedited timetable was on the basis of the agreed necessity for the hearing to conclude no later than the hearing dates allocated. Accordingly, for these reasons the Claimants' application was refused.

42. At the conclusion of the hearing, each of the parties confirmed that their right to be heard had been fully and fairly respected.

43. Following the conclusion of the hearing, on 26 February 2019 the CAS wrote to the parties inviting them to provide any specific references to evidence relating to the use of oral contraceptives and fluctuations in testosterone concentration. The following day, the CAS wrote to the parties clarifying that to the extent that the evidence they rely on in relation to this point was given by an expert in oral evidence, the parties may refer the Panel to that portion of the witness's oral testimony.

44. On 5 March 2019, the IAAF wrote to the parties identifying portions of the oral evidence concerning the effectiveness of oral contraceptives to reduce and maintain testosterone levels below 5 nmol/L. In the same letter, the IAAF stated that while it "*remains firmly of the view that compliant use of oral contraceptives is effective to reduce testosterone levels and to maintain them reliably below 5 nmol/L, it accepts that the subject pool to date is limited in number*". Accordingly, the IAAF had "*decided to add a new clause 3.15 to the DSD Regulations that allows the IAAF to waive disqualification of results*

and suspension of eligibility where a Relevant Athlete's testosterone levels go above 5 nmol/L, if it is satisfied that that increase was temporary and inadvertent and is unlikely to have conferred any material advantage on the athlete." The IAAF stated that the revised version of the DSD Regulations would be presented to the IAAF Council for approval and, if approved, would come into effect on 27 March 2019.

45. On 7 March 2019, Ms. Semenya wrote to the CAS in response to the IAAF's proposed post-hearing amendment of the DSD Regulations. She submitted that it was entirely improper for the IAAF to attempt to submit a new and material amendment to the DSD Regulations following the close of the hearing. She stated that the IAAF had "*unfairly shift[ed] the goal posts in this arbitration*" and highlighted that she had had no opportunity to adduce expert evidence in relation to the amended clause or to cross-examine the IAAF's witnesses about it. Accordingly, she submitted, allowing the IAAF to rely on this proposed post-hearing amendment would seriously violate her right to procedural and substantive fairness. In addition to those submissions, Ms. Semenya also highlighted various passages of the written and oral evidence concerning the use of oral contraceptives and fluctuations in testosterone concentrations.

46. On 12 March 2019, the CAS wrote to the parties explaining that the Panel did not understand the relevance of the IAAF's proposed amendment to the DSD Regulations and expressing concern that the Claimants should have a full opportunity to respond to this. The Panel sought clarification as to whether the Claimants consented to the amended DSD Regulations being put before the Panel and asked what the parties proposed should be done with respect to allowing the IAAF to provide a further explanation of the DSD Regulations and a right to respond to that explanation. The Panel also sought clarification regarding the parties' positions concerning the timing for the delivery of the Award in light of this post-hearing development.

47. On 15 March 2019, the IAAF notified the CAS that on 11 March 2019 the IAAF Council had approved the incorporation of a new clause 3.15 as foreshadowed in the IAAF's earlier post-hearing correspondence. The IAAF submitted that there was nothing improper about the post-hearing amendment, which was simply the result of the IAAF complying with its duty to address reasonable concerns about the operation of its regulations promptly. The letter went on to clarify that the IAAF consented to the Panel proceeding *ex aequo et bono* in accordance with Article R45 of the Code to the extent that this give the Panel "*the ability to consider any refinements to the way the DSD Regulations operate in practice, in order to guarantee that they will operate in a fair and proportionate manner*".

48. On 19 March 2019, Ms. Semenya notified the CAS that she did not consent to the Panel considering the post-hearing amendment to the DSD Regulations. She highlighted that the amendments approved by the IAAF Council were materially different to the proposed amendments put forward by the IAAF in its correspondence on 5 March 2019. She objected to the Panel's consideration of any of these amendments on the basis that the proceedings are "*not an ongoing, iterative, "trial and error" process, whereby the IAAF has carte blanche to put before the Panel amended Regulations whenever it chooses*". She further stated that she did not consent to the IAAF's proposal that the Panel should have only partial discretion to make use of the additional flexibility conferred by Article R45 of the CAS Code. She stated that if the Panel is to be permitted

to make use of that provision, then it cannot be limited to exercise its discretion with partial flexibility. Ms Semenya further stated that in the circumstances she would not oppose an extension of the 21 March 2019 deadline for delivery of the Panel's Award. She also stated that there was no need for any further evidence to be put before the Panel with respect to the unamended DSD Regulations.

49. ASA also filed a submission on 19 March 2019. ASA stated that the Panel should disregard the post-hearing amendments to the DSD Regulations, which should be excluded from the record. ASA also stated that it did not authorise the Panel to exercise a power under Article R45 of the CAS Code in the manner invited by the IAAF. ASA added that if the Panel did intend to consider the post-hearing amendments, then ASA would insist upon a full hearing involving supplementary expert reports and oral evidence. ASA confirmed that it had no objection to an extension of the 21 March 2019 deadline for the Award.

V. SUBMISSIONS AND EVIDENCE AS PRESENTED BY THE PARTIES

A. Ms. Semenya

50. Ms. Semenya's submissions, in essence, may be summarised as follows.

51. The DSD Regulations are discriminatory:

- First, the DSD Regulations discriminate on the basis of birth or natural, physical, genetic or biological traits. The Regulations restrict the ability of some female athletes to compete based solely on a natural or genetic trait which they have possessed since birth and over which they have no control.

- Second, the DSD Regulations discriminate against female athletes on the basis of sex. The Regulations impose thresholds and burdens (such as screening for high testosterone, invasive medical examinations, and eligibility restrictions) on female athletes, while no equivalent requirements are applied to male athletes. Further, the IAAF's position (advanced for the first time during these proceedings) that women with 46 XY DSDs are "*biological males*" is itself a form of discrimination based upon a sex characteristic. In this regard, the prohibition on discrimination is "*a broad prohibition on discrimination on the basis of any sex/gender characteristic, both within and between sexes/genders*".

- Third, the DSD Regulations discriminate on the basis of gender, as a social term, by classifying "Relevant Athletes" (as defined by Regulation 2.2) as "intersex" or as having a male "sport sex" regardless of how the athlete self-identifies and irrespective of how they were born and raised.

- Fourth, the DSD Regulations discriminate on the basis of physical appearance since the testing of female athletes is based on a subjective assessment of their phenotype and their virilisation characteristics. The Regulations deliberately seek out women with a stereotypically male phenotype, while not targeting women who possess a stereotypically female appearance.

- Fifth, the DSD Regulations discriminate against female athletes who compete in specific events (namely 400m to 1 mile), while female athletes who compete in shorter or longer events are not subjected to scrutiny under the Regulations.

52. The DSD Regulations are not necessary. Ms. Semenya submits, first, that it is not necessary to discriminate based on DSD in order to preserve fair competition within the female category. Success in elite competitive sport is the product of both genetic and environmental factors. There are numerous genetic variations and mutations associated with physical performance. Indeed, the significant role that genetics plays in determining sporting performance means that sport is inherently not fair. The world celebrates the genetic differences that make athletes such as Usain Bolt, Michael Phelps and Serena Williams great. DSD are a form of genetic difference that should be celebrated in the same way.

53. Ms. Semenya contends that from a scientific perspective there is no sensible basis for distinguishing between DSD and other genetic variations and mutations that improve athletic performance. To the extent that athletes with DSD enjoy any performance advantage by virtue of their elevated testosterone levels, there is no qualitative difference between DSD and other genetic variations that make athletes particularly tall or strong, or which provide unusual haemoglobin concentration, unusually large skeletal muscles etc. It is illogical and unnecessary to regulate one genetic trait while celebrating all the others.

54. Second, Ms. Semenya submits that the studies relied on by the IAAF in support of the DSD Regulations are flawed and unreliable. In this respect:

- The IAAF's studies were produced by individuals with conflicts of interest and bias (conscious or subconscious) against women who do not conform to a particular socio-cultural view of femininity. This is demonstrated by the assumption of the IAAF researchers that women with DSD are biological men. This assumption is wrong in fact and shows that the IAAF's approach to the DSD Regulations is driven by a cultural and social construct, rather than science.

- As Prof. Richard Holt observes in his evidence, the IAAF's studies are rudimentary and lack rigour. Similarly, as Prof. Roger Pielke observes, the IAAF has deviated from commonly recognised best practices, leading to unreliable results that are an inadequate basis for regulation.

- In particular, Prof. Pielke's analysis of the IAAF's data identified various significant errors in those data. Those errors vitiate the reliability of those data and the IAAF's analysis based upon them.

55. Third, even if the IAAF's studies are accepted, they do not establish necessity. In particular:

- The empirical data contained in Bermon & Garnier[1] (2017) ("BG17") and the letter published by Dr. Stéphane Bermon and his colleagues in the British Journal of Sports Medicine in July 2018[2] ("BHKE18") do not show a significant degree of testosterone-related athletic performance advantage to demonstrate the necessity of the DSD Regulations.

- Professor Dankmar Böhning has undertaken a regression analysis on the IAAF's data underlying BHKE18. That analysis, which is more statistically robust and meaningful than the tertile analysis conducted by Dr. Bermon and his colleagues found that there is no evidence of a statistically significant relationship between testosterone and athletic performance at either the Daegu or Moscow World Championships in respect of either male or female athletes.

- BG17 and BHKE18 contend that elevated testosterone confers a performance advantage between 0% and 3% depending on the event. The magnitude of that advantage is in the range of (if not higher than) the magnitude of Ms. Semenya's margin of victory in her best event (the 800m race).

- The alleged advantage of 0% to 3% falls well short of the degree of advantage that male athletes enjoy over female athletes. The alleged advantage does not support the IAAF's metaphor of an adult beating a child, or a heavyweight boxer beating a flyweight boxer.

- The paper authored by David Handelsman, Angelica Hirschberg and Dr. Bermon [3] (the "Handelsman Paper") does not establish the degree of performance advantage that females with DSD have over females without DSD. The paper is a literature review that does not provide any empirical data.

- Further, Prof. Handelsman expressly acknowledged that there is a "*lack of substantial direct evidence of the effects of a high (male) level of serum testosterone on elite female athletic performance*" – a fact that constitutes "*a severe limitation*" and necessitates reliance on "*surrogate evidence*". However, surrogate or proxy evidence is insufficient to establish that the DSD Regulations are necessary. There are many confounding factors that make it inappropriate to extrapolate directly the effect of testosterone on muscle, bone or haemoglobin to changes to athletic performance. In addition, there are differences in how testosterone acts in the bodies of females with DSD compared with males and women without DSD.

- The IAAF's empirical data show larger testosterone-based performance differences in several events that are *not* covered by the DSD Regulations than the testosterone-based performance differences for events that are covered by

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[1] Bermon and Garnier, *Serum androgen levels and their relation to performance in track and field: mass spectrometry results from 2127 observations in male and female athletes*, Br J Sports Med 2017;0:1-7.

[2] Bermon, S., Hirschberg, A. L., Kowalski, J. *et al. Serum androgen levels are positively correlated with athletic performance and competition results in elite female athletes.* Br J Sports Med 2018;52:1531-1532.

[3] Handelsman DJ *et al* (2018) *Circulating Testosterone as the Hormonal Basis of Sex Differences in Athletic Performance*, Endocrine Reviews Vol. 39, Issue 5, 1 October 2018, 803-829.

the DSD Regulations. Moreover, in some instances, athletes with lower testosterone concentrations significantly outperformed athletes with higher testosterone levels. In addition, the fact that in 10 of 22 events males with high testosterone outperformed males with low testosterone undermines the IAAF's position that male athletic performance does not correlate with significantly higher endogenous testosterone.

- The Handelsman Paper does not seek to account for female athletes with either partial androgen insensitivity syndrome ("PAIS") or complete androgen insensitivity syndrome ("CAIS") at the highest level of elite international athletics. This is important since the testosterone in these women's bodies has no or very limited effect and, therefore, it follows that their success at the elite level of the sport must mean that testosterone has either no or a very limited performance enhancing effect.

56. Fourth, Ms. Semenya submits that the fact that she and two other female athletes experienced poorer athletic performance while their natural testosterone levels were medically suppressed does not support the IAAF's case concerning the performance enhancing effects of high levels of endogenous testosterone. In particular:

- This evidence is anecdotal and the sample size of three people is insufficient to form the basis for valid scientific conclusions.

- There is an array of confounding factors that could have caused the decline in performance. This is supported by Ms. Semenya's own evidence, which describes how she experienced weight gain, constant nausea and impaired mental focus as a result of the medication that she was required to take, and also suffered a serious knee injury that affected her ability to train and compete for a substantial period.

- Even if the decrease in performance could be attributed exclusively to lower testosterone, it does not follow that the reverse is true. And even if the reverse was true, it would not follow that the *magnitude* of the advantage derived from high levels of natural testosterone is the same as the magnitude of the deterioration in performance caused by the artificial suppression of that natural testosterone.

57. If (contrary to the submissions summarised above) the DSD Regulations are necessary, the IAAF must also establish that they are reasonable in that they are rationally connected to the objective of ensuring fair competition in the female category. Ms. Semenya submits the IAAF is unable to do this.

58. First, Ms. Semenya contends that it is arbitrary and irrational to limit the application of the DSD Regulations to a handful of selected events in circumstances where BG17 found that similar or greater testosterone-based performance differences existed for other events (including pole vault and shot put). Of the 21 events considered by BG17, the four individual Restricted Events showed only the second, fifth, sixth and tenth largest correlations between athletic performance and testosterone.

59. Second, the threshold of 5 nmol/L is arbitrary since there is no empirical data suggesting that women with testosterone over this threshold have any greater advantage than women with testosterone under this threshold. There is no rational scientific basis for the threshold established under the DSD Regulations.

60. Third, the DSD Regulations are also arbitrary because women with conditions other than DSD (for example polycystic ovarian syndrome ("PCOS")) who may have testosterone over 5 nmol/L are not covered by the Regulations. This differential treatment of women with endogenous testosterone over 5 nmol/L is arbitrary, particularly if (as the IAAF contends) testosterone is purported to be the critical factor conferring a performance advantage.

61. Fourth, the DSD Regulations rely entirely on a subjective assessment of the androgenising effect of elevated testosterone in order to determine who constitutes a Relevant Athlete. The expert evidence demonstrates that it is not possible to correlate an individual's level of serum testosterone with the degree of effect that it has on their body. The process of attempting to assess androgenisation is highly subjective and is also influenced by ethnicity. It follows that the virilisation assessments to determine whether particular athletes must undergo treatment in order to be eligible to continue competing will almost inevitably produce uncertain, inconsistent and arbitrary outcomes.

62. Ms. Semenya submits that the right to appeal to the CAS against a determination by the IAAF under the DSD Regulations does not cure the inherently unreliable and arbitrary nature of this virilisation assessment. An appeal against such a finding would entail the CAS having to inspect the phenotypes of certain women with DSD for markers of androgenising effect (such as clitoris size) in a doomed attempt to determine the extent to which each athlete benefits from high testosterone. This is "*a fool's game*" which the CAS should not countenance approving.

63. Even if the IAAF is able to establish that the DSD Regulations are both necessary and reasonable, Ms. Semenya submits it must also establish that the DSD Regulations are also proportionate. This requires the IAAF to establish that achieving the policy objective is not outweighed by the significant interference with the rights of female athletes with DSD that the DSD Regulations entail.

64. In this regard, Ms. Semenya submits that the DSD Regulations will cause prolonged and severe harm to women. Among other things:

- The DSD Regulations will inevitably result in Relevant Athletes being excluded from competing in the female category in the Restricted Events. Those athletes are likely to be excluded from competing altogether. This exclusion is not ameliorated by the IAAF's suggestion that they could compete as men. Not only is it "*an insult*" to even suggest this, but women with DSD cannot compete against men because their athletic performance is inevitably significantly below that of men at the same level of competition. In any event, a female athlete competing in the male category would effectively be making a public declaration that she has a DSD, which will cause public scrutiny, loss of privacy and personal harm.

- The DSD Regulations provide for intrusive medical assessments that involve examination of female athletes' most intimate body parts (including measurement of the size of the clitoris). This is likely to cause feelings of shame and will undermine the affected athletes' dignity and self-esteem.

- Athletes who are subjected to the DSD Regulations will also suffer psychological harm caused by stigmatisation. Affected athletes will be labelled as intersex or sexually atypical. The associated stigma will pose a serious risk to their mental health.

- Since it is virtually certain that cases under the DSD Regulations will become publicly known, affected athletes will also be subject to public scrutiny, judgement, commentary and social stigmatisation.

- Lastly, the DSD Regulations will result in Relevant Athletes undergoing medical treatments with adverse health risks including venous thromboembolism ("VTE"), decreased bone mineral density, significant weight gain, hypotension, renal dysfunction, electrolyte abnormalities, cardiovascular disease and sterility. These physical side effects will have harmful knock-on effects on the mental health of those individuals. Moreover, it is unlikely that the decision to undergo the medical treatment will be the product of informed and voluntary consent.

65. Accordingly, Ms. Semenya submits that the DSD Regulations will cause harm and rights violations "*of a magnitude that is unprecedented in sport*". She rejects the IAAF's suggestion that the DSD Regulations are "*modest in nature*". Furthermore, in addition to the personal harms summarised above, Ms. Semenya submits that the Panel should also consider the wider implications of the DSD Regulations for the system of adjudicating sports disputes. In particular, the DSD Regulations will mean that the CAS is likely to be required to hear multiple appeals concerning whether a particular athlete has experienced a "*material androgenizing effect*" from their enhanced testosterone levels. This will mean among other things:

- Highly sensitive personal information concerning individual athletes' bodies will be placed before the CAS.

- In determining appeals against the IAAF's findings on androgenisation, CAS panels are likely to have to make findings in respect of sensitive biological issues such as the size of an athlete's breasts or the size of her clitoris.

- Women who undergo this process of scrutiny and judgment by the CAS will suffer "*terrible psychological harm*".

66. In considering the proportionality of the impugned Regulations, Ms. Semenya submits that the Panel should take note of the fact that women with DSD are a vulnerable and socially disadvantaged group. This increases the burden on the IAAF to demonstrate an extremely compelling justification for the DSD Regulations.

67. In light of the IAAF's Answer, Ms. Semenya submits that the IAAF has "*completely departed*" from its original position that the DSD Regulations are justified because high

testosterone levels confer an unfair athletic advantage on women with DSD. Instead, by asserting that the DSD Regulations govern the participation of "*biologically male athletes*" with female gender identities, the IAAF is attempting "*to convert the DSD Regulations into a shadow transgender rule*".

68. [...] she states that women with 5-ARD produce very little dihydrotestosterone ("DHT") compared to men. DHT is widely regarded as a powerful androgen and, indeed, is included in the WADA Prohibited List for this reason. The expert evidence establishes that DHT has an impact on athletic performance including by affecting muscle growth, red blood cell production, cardiac hypertrophy, body fat mass and maximal oxygen uptake. It is "*certain*" that the overall androgenic advantage that women with 5-ARD enjoy over other women is not the same as the advantage that men have over women. In this regard, the evidence shows that no woman with a DSD, including 5-ARD, has demonstrated athletic performances that come anywhere close to the performance of elite male athletes.

69. Ms. Semenya submits that the IAAF's characterisation of the DSD Regulations as "*progressive*" is false and misleading. The DSD Regulations introduce a regressive and "*egregious form of sex testing*". As a result, the IAAF "*has come full circle*" back to the gender verification and sex testing policies which it had previously publicly disavowed. Ms. Semenya contends that the IAAF's "*dramatic alteration*" of the proffered justification for the DSD Regulations is a response to its inability to establish that high testosterone gives female athletes a performance advantage that subverts fairness within the female category.

70. Ms. Semenya highlights the fact that while the IAAF seeks to justify the DSD Regulations by reference to the concept of "*biological females*" and "*biological males*", these expressions are not found anywhere in the regulations themselves. Nor are they referred to in the IAAF's answer. Further, a footnote in Dr. Bermon's witness statement dated 9 January 2019 states that two conditions listed in the DSD Regulations – namely CAH and CAH-variant 3-beta-hydroxysteroid dehydrogenase deficiency – will be removed from the scope of the DSD Regulations "*because...there is no evidence that 46 XX individuals with CAH or CAH variants benefit from any performance enhancement as a result of their condition*". According to Ms. Semenya, this demonstrates that the IAAF sought to amend the DSD Regulations to conform with its new rationale based on the notion of "*biological males*" and "*biological females*".

71. Accordingly, Ms. Semenya argues that the DSD Regulations that the IAAF invites the Panel to uphold are not the same regulations that were announced in April 2018. The IAAF's conduct in this respect is "*improper and unlawful*".

72. In support of her requests for relief, Ms. Semenya brought forward the following fact and expert witness statements and evidence:

a. Fact Witnesses

Ms. Mokgadi Caster Semenya

73. Ms. Semenya provided two witness statements in support of her challenge to the DSD Regulations. She began her first statement by explaining that "*it feels like this new rule was created because of me*". She described how her body "*has been scrutinized by the IAAF for almost ten years*" while also being widely discussed "*by other athletes, sports doctors, sports officials, and the public*". The "*scrutiny, judgment, speculation and medical intervention*" that Ms. Semenya has endured over the years has been an affront to her dignity and has caused her "*immense pain and suffering*". Ms. Semenya explained that she had decided to bring this challenge against the DSD Regulations in order to secure her right to compete as a woman, which is how she was born and how she has competed all her life. She explained that she simply wishes to be able to compete "*free of drugs, free of speculation and free of judgement*".

74. Ms. Semenya summarised her personal background, describing her journey from a small and impoverished village in the Limpopo Province of South Africa to elite level international athletics. She then proceeded to discuss the life-changing events that took place immediately before, during and after the IAAF World Championships in Berlin in August 2009. Shortly before those World Championships, ASA had sent a gynaecologist to conduct tests on Ms. Semenya, including a physical examination of her genitals and the collection of blood samples. Ms. Semenya was not told the purpose of this examination and it was only afterwards that she realised that she had been subject to "*a gender verification test*". Ms. Semenya subsequently won the gold medal in the 800m at the World Championships, attaining the fastest time of the year in the process (1:55.45). Prior to the race, however, a newspaper had published an article claiming that Ms. Semenya was not a woman and that she had female and male sex organs. Ms. Semenya described how following her victory in the 800m event, she was acutely conscious that many thousands of people in the stadium and millions of people around the world were scrutinising her body and judging her appearance – something she described as "*the most profound and humiliating experience of my life*".

75. After she won the 800m event at the 2009 World Championships, the IAAF conducted a further "*gender verification test*" on Ms. Semenya at a hospital in Germany. According to Ms. Semenya, the IAAF did not ask her whether she wanted to undergo the test; rather, "*It was an order by the IAAF which I had no choice but to comply with.*" After that gender test was conducted, several IAAF officials informed the media about the tests. A senior IAAF official was reported to have said that if the test established that Ms. Semenya was not a woman then her gold medal would be withdrawn and redistributed. The same official also reportedly said that, "*it is clear that [Ms. Semenya] is a woman but maybe not 100 per cent*".

76. Ms. Semenya went on to describe her deep shock and distress caused by the public discussion of her body and her private medical information by the IAAF and the international media. As an 18 year-old woman she could not comprehend what was happening and was profoundly confused that her gender was being questioned for the first time in her life. Ms. Semenya described how the "*atrocious and humiliating*" treatment she was subjected to "*continues to haunt me*". Ever since the 2009 World

Championship she has endured "*relentless public scrutiny*" and her love for the sport of athletics has been "*drained*".

77. Ms. Semenya went on to explain how the IAAF had subsequently informed her that if she wished to continue competing at international competitions then she would need to reduce her testosterone levels to below 10 nmol/L. Because Ms. Semenya wanted to keep competing in elite athletics, she agreed to take testosterone-suppressing medication to enable her to do so. The decision to undergo treatment, however, was not a meaningful choice since running was and is her life and her only means of making a living. The prospect of stopping competing was therefore never a viable option. Ms. Semenya also explained that the IAAF suspended Ms. Semenya from competing for a period of six months while she began taking the medication – something she experienced as a form of "*punishment*" for the natural state of her body.

78. Ms. Semenya described the negative effects that the testosterone-suppressing medication had on her mental and physical health. Her symptoms included becoming hot and sweating profusely each night and experiencing significant weight gain. She also felt sick constantly, suffered from regular fevers and had constant internal abdominal pain. These symptoms also had an "*enormous*" effect on her mental state, impeding her mental sharpness and undermining her self-confidence.

79. Ms. Semenya went on to discuss her athletic performance during the period while she was taking testosterone-suppressing medication. In summary:

- When Ms. Semenya resumed competing in 2010, her times were slower than they had been before she started taking testosterone-suppressing medication. She attributed the deterioration in performance to the weight gain, fevers, abdominal pain and constant nausea caused by the medication and the related impact of these physical symptoms on her mental state.

- In 2011, Ms. Semenya had her best international 800m performance at the World Championships in Daegu, South Korea. She achieved a winning time of 1:56.35 in the 800m event despite feeling sick as a result of the testosterone-suppressing medication.

- In 2012, Ms. Semenya won the silver medal in the 800m event at the Olympic Games in London, finishing in 1:57.23 despite the nausea caused by the medication. (Her silver medal was later upgraded to a gold medal following the disqualification of the first placed athlete for a doping violation.)

- In 2013 and 2014, Ms. Semenya had two years of poor performance, which she attributed to weight gain caused by the medication and a significant knee injury.

- In 2015, Ms. Semenya's best performance in the 800m was a time of 1:59.59, which she achieved at the IAAF World Championships.

80. Following the decision of the CAS in *Chand*, Ms. Semenya stopped taking the testosterone-suppressing medication. As a consequence, she stopped feeling sick and was once again able to sharpen her mental focus. In 2016, she became the first person to win the 400m, 800m and 1500m events at the South African National Championships

(although she pointed out that her time of 1:58.45 for the 800m was slower than the time she had run while taking testosterone suppressing medication at the 2011 World Championships). In August 2016, she won the Olympic gold medal in the 800m event at the Olympic Games in Rio de Janeiro, with a winning time of 1:55.28.

81. Ms. Semenya went on to explain why she takes issue with the IAAF's suggestion that her naturally high testosterone levels give her an unfair advantage over her female peers. Her witness statement provided a table showing her performances at major international events, which demonstrated that she had been in a number of close races and had also seen other athletes win races and outperform her by a significant margin. The statistics also compared her times with the significantly faster winning times for the same events in the male classification – a comparison which demonstrated that she could not compete against men.

82. Ms. Semenya ended her first statement by describing the pain she had experienced as a result of the treatment described above. She explained that it "*is deeply hurtful to be told that I should run with men. I am not a man, I am a woman.*" She is unable to express the depth of hurt and insult she feels as a result of the IAAF "*telling me that I am not a woman*". Ms. Semenya added that her case "*is not just about the right to participate in sport. It is about the right to be human.*"

83. In her statement in reply to the IAAF's evidence, Ms Semenya responded to the IAAF's suggestion that she had failed to comply with the medication protocol agreed with the IAAF for the purpose of controlling her testosterone levels. Ms Semenya stated that:

- As part of the agreement with the IAAF, she had agreed to undergo two sets of blood tests every month while she was taking the oral contraceptives.
- When she began taking the oral contraceptive medication in 2010 there was no information about how the medication would operate to reduce her levels of testosterone. She felt that the IAAF used her as a "*lab rat*" or "*guinea pig*" by "*experimenting*" with how the medication would affect her testosterone levels.
- The IAAF conducted random monthly blood tests. The IAAF did not, however, carry out any assessment or comparison to assess her testosterone levels during periods when she was training, and during periods when she was not training or was resting follow competitions.
- The fact that her testosterone levels varied and were sometimes high while she was taking testosterone-suppressing medication did not mean she had failed to take the medication properly.
- She was not concerned about the variation in her testosterone levels because she was taking the medication she had been instructed to take. She never ceased taking the medication on a daily basis until the Hyperandrogenism Regulations were suspended following *Chand.*

84. Ms. Semenya also responded to the suggestion that she had manipulated her testosterone levels in the period before she competed in certain events. She explained that the medication had the effect of reducing her testosterone levels to as low as 1 nmol/L,

which at times meant her testosterone was lower than that of other female athletes without DSD.

85. Ms Semenya rejected the suggestion by Dr. Bermon that she did not always run to her maximum ability in the 800m event. She explained that the 800m race is a tactical event and that she had been coached to moderate her pace during the first lap of the race in order to gauge the pace of the other athletes to determine the best point to pick up her pace and break from the pack. She also explained why she avoided running on the inside lane, citing the need to avoid being boxed in which can inhibit breaking and overtaking.

86. Ms. Semenya stated that she was distressed at the allegation that she had deliberately failed to take the medication she had agreed to take and was offended by the suggestion that she does not run to the full extent of her ability. She went on to explain that while she was greatly offended by the suggestion that she had not behaved honestly, this is nothing compared to her feelings of fury and profound sadness at being described as "*biologically male*" by the IAAF. She explained that the IAAF's stance "*hurts more than I can put in words*" and "*re-opens my wounds from 2009*". The IAAF's position regarding her biological sex is "*nonsense, fiction*". Ms. Semenya stressed that she is a woman, not a man, and that: "*The IAAF should know this by now.*"

87. Ms. Semenya gave evidence in person at the hearing. During cross-examination, she expanded upon the side effects of the testosterone-suppressing medication and insisted that she had never stopped taking that medication until the Hyperandrogenism Regulations were suspended following *Chand*. Ms. Semenya was questioned about the spikes in her endogenous testosterone levels immediately prior to certain major competitions including the 2012 Olympic Games. Ms. Semenya explained that her testosterone levels had increased significantly during periods of rest and decreased during periods of intense training. In the week before a major championship, she always reduced the intensity of her training and rested her body in preparation for racing. As a result of training less and resting more, her levels of testosterone naturally increased during those pre-competition periods.

Dutee Chand

88. Dutee Chand is an elite female sprint athlete from India. In 2015, Ms. Chand challenged the predecessor to the DSD Regulations, the Hyperandrogenism Regulations, before the CAS.

89. Ms. Chand provided a witness statement in support of Ms. Semenya's challenge to the DSD Regulations. She began by explaining that she felt that it was important for the Panel to understand the irreparable harm that she had personally suffered as a result of the Hyperandrogenism Regulations. After describing the events that culminated in her bringing a challenge to the Hyperandrogenism Regulations before the CAS, Ms. Chand went on to describe how her life was changed forever as a result of the Regulations. Although the decision of the CAS enabled her to resume competing, Ms. Chand has faced constant public speculation about her gender, bullying at national training camps and hostility from other competitors. The extent of the bullying and negativity is so severe that she no longer participates in national team training camps and instead trains independently at a badminton academy where she feels more comfortable.

90. Ms. Chand described how the public questioning of her gender had hurt her emotionally more than she was able to describe. She felt like she was not a human being and did not know how she could live with such humiliation. She described how her former partner had ended their relationship as a result of media speculation about her gender. As a result of the publicity and speculation about her body caused by the Hyperandrogenism Regulations, Ms. Chand now fears that she will be unable to find a life partner.

91. Ms. Chand ended her statement by questioning the need for any regulation that restricts her ability to compete in her natural state. She explained that she has never doped or cheated; nor has she ever experienced any health conditions associated with her elevated testosterone levels. She therefore cannot understand why she should be required to undergo treatment or change her body simply to compete as a woman. Ms. Chand believes that she should be permitted to compete against other women, many of her whom are taller than her or come from more privileged backgrounds – factors that certainly give them an advantage over her. In Ms. Chand's view, all female athletes "*should be allowed to run the way they are born, as they allow men*".

[...]

92. [...].

93. [...].

94. [...].

95. [...].

96. [...].

97. [...].

Dr. Greta Dreyer

98. Dr. Greta Dreyer is the Acting Head of the Department of Obstetrics & Gynaecology at the Steve Biko Academic Hospital. She is also the President of the South African Society of Obstetrics and Gynaecology and the President of the South African Society of Gynaecologic Oncology.

99. In her evidence Dr. Dreyer described how Ms. Semenya was referred to her for medical advice in 2009/10. In that advisory capacity, Dr. Dreyer led the South Africa medical team that was tasked with negotiating with the IAAF medical team following the 2009 World Championships. Pursuant to the protocol that Ms. Semenya subsequently agreed with the IAAF, Ms. Semenya agreed to take medication to suppress her testosterone levels and underwent monthly blood tests from 2010 until the decision in *Chand* in 2015. Those tests were conducted under Dr. Dreyer's supervision at the Lancet Laboratory. Dr. Dreyer was responsible for communicating the outcome of those tests to Dr. Bermon (with Ms. Semenya's consent).

100. Dr. Dreyer said that while she had not actually seen Ms. Semenya on a regular basis during that period, Ms. Semenya had consistently complained about the negative side

effects of the medication. Those side effects persisted throughout the whole period that Ms. Semenya took the medication. Dr. Dreyer stated that while Ms. Semenya had complained to her about side effects including sweating, weight gain and "*feeling horrible*", Dr. Dreyer had not regularly reported this to Dr. Bermon because it was not her role or obligation to do so, nor had the IAAF asked her to do this. She had, however, informed Dr. Bermon on 24 October 2011 that Ms. Semenya felt "*horrible*". Prior to that, Dr. Dreyer had informed Dr. Bermon of certain adverse effects in the context of a proposal to change Ms. Semenya's medication in order to assist with managing flushing.

101. Dr. Dreyer stated that during the initial discussions the IAAF had "*made it clear that their preferred treatment for an elite female athlete with evidence of natural hyperandrogenism is gonadectomy or castration*". Dr. Dreyer had objected to this recommendation in view of the extensive evidence that this would cause a "*dramatic physical and mental deterioration*". Instead, she insisted that if Ms. Semenya was to undergo any medical intervention, then she should undergo gonadal suppression. Dr. Dreyer went on to observe that Ms. Semenya's experience of ongoing negative side effects was consistent with medical science, which shows evidence of long term flushing and weight gain, changes in fat distribution, bone loss and muscle loss in post-menopausal women and following gonadectomy in men.

102. Dr. Dreyer concluded her statement by saying that after the initial induction period (when changes were made to Ms Semenya's treatment to improve compliance and side effects) she was not personally aware of any occasion when Ms. Semenya stopped taking the medication she had been directed to take. Ms. Semenya had "*certainly never*" told Dr. Dreyer she had done this, although she conceded that based on the variation in Ms. Semenya's testosterone levels it was "*possible*" that there were occasions when she had skipped a dose "*as is very common among young women taking the pill*".

103. Dr. Dreyer gave evidence in person at the hearing. During that testimony she expanded upon her clinical relationship with Ms. Semenya and answered questions concerning the medical treatment that Ms. Semenya underwent and the fluctuations in her levels of testosterone that occurred while undergoing that treatment.

Dr. Philda de Jager

104. Dr. Philda de Jager is a general practitioner with a specialty in sports medicine. She was part of the South African Olympic Committee Medical Team between 2000 and 2016. Between 2014 and 2016, she was one of Ms. Semenya's treating physicians.

105. In her witness statement in support of Ms. Semenya's case, Dr. de Jager stated that Ms. Semenya had experienced "*physiological and metabiological conditions related to her body's reaction to the testosterone suppression medication*". She had complained of feeling bad, having night sweats and experiencing significantly reduced performance as a result of the medication. In physiological terms, Ms Semenya's metabolism "*went haywire*" and she displayed symptoms similar to those experienced by menopausal women. As a result, she was more susceptible to injury and was unable to train or perform optimally as a result of the "*constant chemical imbalance*" in her body. In addition, she became significantly more susceptible to allergies, which prevented her

from being able to feed optimally for training, which in turn undermined her performance.

106. Dr. de Jager added that Ms. Semenya's inability to train optimally had a major impact on her psychological state, causing her to be clearly and visibly depressed. These negative effects subsided when she ceased taking the medication. From Dr. de Jager's perspective, Ms. Semenya was a "*completely different*" person in 2016 to the person she had been while taking medication in 2014.

Pierre-Jean Vazel

107. Pierre-Jean Vazel is an international athletics coach who has trained athletes from a number of countries at two Olympic Games and nine World Championships. He is also a member of the Association of Track & Field Statisticians. Mr. Vazel provided a witness statement in which he described a presentation by Dr. Bermon that he observed at a medical conference organised by the French Athletics Association on 14 October 2018.

108. Mr. Vazel stated that Dr. Bermon had begun his presentation by explaining that while he had an obvious conflict of interest because he is part of the IAAF which had commissioned two studies to prove the validity of the DSD Regulations, he had no interest in the on-going conflict regarding the Regulations, and simply wanted the issue to be resolved as soon as possible because he had grown tired of the debate.

109. Mr. Vazel went on to describe how Dr. Bermon had made certain comments about Ms. Semenya during his presentation. According to Mr. Vazel, Dr. Bermon said what had happened to Ms. Semenya at the World Championships in 2009 was a scandal and that the IAAF had to improve its regulations. Dr. Bermon stated that this was an "*issue of equity*" concerning whether "*those people*" should run with women. Dr. Bermon also made a comment about a Nike advertisement that featured Ms. Semenya, stating that he had assumed a man was narrating the video and that it was only at the end he had realised it was Ms. Semenya talking.

110. According to Mr. Vazel, Dr. Bermon's presentation included a slide which showed two images of women in underwear that depicted the perfect female body according to women and according to men (he then presented a similar slide in respect of the male body). Dr. Bermon proceeded to discuss the different phenotypes and athletic performances of men and women. Dr. Bermon stated that a woman's phenotype provides an indication of the degree to which androgen receptors are working. He said that while there is no reliable way to assess the efficiency of androgen receptors, the size of a woman's clitoris is an indication of the efficacy of androgen receptors; the longer the clitoris, the better the receptors are working. According to Mr. Vazel, Dr. Bermon then commented that, "*genetic mutations are often related to inbreeding in developing countries*".

111. Dr. Bermon also addressed the decision of the CAS in *Chand*. According to Mr. Vazel, Dr. Bermon said he disagreed with the decision and that the Panel did not understand that even a margin of 1% matters in elite competitive sport. Dr. Bermon speculated that the decision in *Chand* had been driven by a desire to create "*a live experimentation*" to

determine what happens when there is no regulation, adding that everyone saw what subsequently happened at the 800m final in the 2016 Olympic Games.

112. Dr. Bermon presented a table of hyperandrogenism cases with which the IAAF had dealt between 2011 and 2015. The table included [...] athletes in other events, including the 400m, 800m and 1500m. Dr. Bermon discussed the DSD Regulations. He explained that the hammer throw and pole vault were excluded since there was no confirmation that athletes with DSD were competing in those events. Dr. Bermon stated that the DSD Regulations were not targeted at Ms. Semenya.

113. According to Mr. Vazel, following the presentation he overheard a conversation between Dr. Bermon and another attendee during which Dr. Bermon stated that Ms. Semenya "*would run male times if her coach was better, if she was training harder and if she ran at full speed*" and that Ms. Semenya's coach was "*appalling*".

114. Mr. Vazel went on to describe how he has personally spoken out against the IAAF's efforts to regulate females with high natural testosterone. Mr. Vazel does not believe that there is clear scientific evidence establishing a performance advantage arising from elevated endogenous testosterone. Furthermore, even if there is an advantage, it is unclear why testosterone should be singled out for special treatment. Mr. Vazel was not aware of any female athlete during the past century who could have competed against elite male athletes in the same event. He observed that in the 2018 season Ms. Semenya's fastest time was 1:54.25, while 2,994 men ran faster than this. In South Africa alone, some 62 men had run faster than Ms. Semenya's season's best time.

Ashley LaBrie

115. Ashley LaBrie is the Executive Director of AthletesCAN, the independent association of Canada's national team athletes. Ms. LaBrie provided a witness statement which exhibited a letter signed by the members of the AthletesCAN board in support of Ms. Semenya's challenge to the DSD Regulations. The letter states among other things that:

- The DSD Regulations are discriminatory because they target specific individuals like Ms. Semenya, competing in only middle-distance track events, while the IAAF's evidence suggests that there is no performance advantage in her event (the 1500m). The IAAF has also failed to explain how athletes with DSD have an advantage that is different to other advantages such as height, long limbs or large feet, none of which are deemed to be unfair. Instead, the DSD Regulations are based on "*historical gender ideology that women should look and perform in a certain way*".

- The DSD Regulations are also arbitrary as they include some events but not others within their scope, with no reason for doing so. For example, the IAAF claims that its scientific evidence establishes that female athletes with naturally high testosterone enjoy the greatest advantage in the pole vault and hammer events, yet neither of these events falls within the scope of the DSD Regulations.

- The DSD Regulations violate athletes' basic human rights and have the potential to cause significant and long-term harm. This is borne out by what is now known

about how physically, emotionally and socially destructive the past practices of sex testing have been. The DSD Regulations will have long-term harmful consequences to the health and wellbeing of athletes.

- The DSD Regulations are premised on "*very rigid binary ideas about sex and gender*", while the rest of the world has gradually shifted to "*more nuanced recognition of gender: self-identification*".

b. Expert Witnesses

Professor Richard Holt

116. Professor Richard Holt is a Professor in Diabetes and Endocrinology at the Faculty of Medicine at the University of Southampton. He is a medical doctor, with particular expertise in general internal medicine, diabetes and endocrinology. Prof. Holt provided expert evidence on behalf of the claimant in *Chand*. In the present proceedings, he provided expert evidence concerning the scientific evidence relied on by the IAAF in support of the DSD Regulations.

117. In his expert report, Prof. Holt stated among other things that:

- The majority of the scientific evidence relied on by the IAAF in support of the DSD Regulations was published before *Chand*.

- The main scientific developments following *Chand* are BG17 and Eklund *et al*[4] (2017). These are the only articles that report on both data pertaining to elite athletes and data concerning actual athletic performance (as opposed to ergogenic proxies).

- Four comprehensive and relevant literature reviews have been conducted since *Chand*. Two of those reviews (BG17 and the Handelsman Paper) support the IAAF's position. Both reviews were authored by individuals who are affiliated with the IAAF and/or the IOC, who were consulted in respect of the drafting of the DSD Regulations and/or their predecessors, and who are involved in the implementation of the DSD Regulations. The other two reports (Huang & Basaria (2017) and Sönksen (2016)) were authored by individuals who are not affiliated with the IAAF have no involvement in the development or implementation of the DSD Regulations. Those reports do not support the IAAF's position.

118. Prof. Holt went on to critique the Handelsman Paper. He stated among other things that:

- The Handelsman Paper starts from the premise that women with DSD who have high testosterone are not "*healthy*" women. It endorses Coleman (2017), which

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[4] Eklund E, Berglund B, Labrie F, Carlstrom K, Ekstrom L, Hirschberg AL, *Serum androgen profile and physical performance in women Olympic athletes*, British Journal of Sports Medicine (2017) 51:1301-1308.

according to Prof. Holt "*very clearly and overtly classifies women with DSDs as men*".

- The authors of the Handelsman Paper apparently consider that women with DSD should be treated differently from other women. The article repeatedly refers to female athletes with DSD as "*genetic males*". This is inconsistent with the statement in the DSD Regulations that the Regulations are "*in no way... intended as any kind of judgment on or questioning of the sex or the gender identity of any athlete*".

- The Handelsman Paper states that it is "*necessary to make allowance for women with polycystic ovary syndrome (PCOS) and nonclassical adrenal hyperplasia*" even though these women also have elevated endogenous testosterone levels which according to the studies cited may provide them with a performance advantage. The Handelsman Paper's differential treatment of females with 46 XY DSD and females with PCOS "*suggests a predetermined ideological view*" that women with 46 XY DSD should be excluded from the female category because they are not truly "*biologically female*" but instead "*biologically male*". This, in turn, suggests that the article has been written with a view to justifying the DSD Regulations, rather than being an attempt to review the scientific literature from an unbiased scientific perspective.

119. Prof. Holt went on to note that the Handelsman Paper proposes testosterone reference ranges of 7.7 to 29.4 nmol/L for "*Healthy young men*" and 0 to 1.7 nmol/L for "*Healthy premenopausal/menstruating young women*". In Prof. Holt's view, however, these reference ranges may not be applicable to elite athletes, in part because the ranges are derived from data from both athletic and non-athletic populations. Prof. Holt noted that a more recent literature review by Clark *et al* identified reference ranges of 8.8 to 30.9 nmol/L (for males) and 0.4 to 2.0 nmol/L (for females). The difference between the two papers may partly reflect the different confidence limits used in each paper to define the ranges. The Handelsman Paper employed an upper and lower 95% confidence limit, while Clark *et al* used a confidence limit of 97.5%. This means that the Handelsman Paper excluded 10% of the population from which the reference ranges were derived, while Clark *et al* excluded 5% of the populations.)

120. Prof. Holt commented that although such confidence limits are useful for clinical purposes, "*a much more inclusive reference range is needed when considering what is normal in elite athletes*". In this regard:

- In the anti-doping context normal ranges include 99.99% of athletes and are calculated on the basis of mean ± 3.7 standard deviations. It is unclear why a different standard is being applied in the DSD elite sporting context.

- In both the Handelsman Paper and Clark *et al* women with DSD are specifically excluded, despite the fact that women with DSD such as complete androgen insensitivity syndrome are over-represented in elite athletics.

- Following CAS 2011/A/2566 *Andrus Veerpalu v. International Ski Federation*, WADA advised that all reference ranges should be determined using samples

greater than 500. However, only one of the female populations relied upon by the Handelsman Paper is larger than 500.

- In developing the reference range for men, the Handelsman Paper did not cite BG17 despite the fact that BG17 measured testosterone levels in 795 athletes, and despite the fact that the Handelsman Paper did use BG17 to determine reference ranges for women.

- The Handelsman Paper suggests a sigmoid curve for testosterone that appears inconsistent with the findings reported in BG17 (which found no correlation between testosterone and athletic performance in male athletes).

- The Handelsman Paper contends that a reduction in the athletic performance of a female 800m runner during the period when the Hyperandrogenism Regulations were in force provides further evidence that high testosterone confers a performance advantage. However, this is a single case and other factors (such as the side effect of any medicine used to lower the level of testosterone) could have caused the drop in performance. In this regard, the exogenous administration of testosterone or the suppression of endogenous testosterone result in wider effects on the endocrine system than are caused by natural fluctuations in endogenous testosterone.

- The Handelsman Paper cites studies of testosterone intervention in men and hypothesises that female athletes with high testosterone must experience the same degree of muscle increase as is experienced by men who have been administered exogenous testosterone after having it suppressed. In Prof. Holt's view, however, this involves an "*unwarranted*" degree of extrapolation in view of the "*numerous confounding factors potentially associated with testosterone suppression and restoration*" and the very different patterns of exposure.

- The Handelsman Paper omits the results from various studies regarding testosterone and physical performance in athletes. Some of those studies show no relationship or a negative correlation between these two factors.

121. Prof. Holt cited various examples of studies that showed either no or a negative correlation between testosterone and athletic performance:

- Izquierdo *et al* (2003) reported significant negative correlations in a group of weightlifters, cyclists and controls between cycling workload and serum total testosterone.

- Crewther *et al* (2016) found that elite athletes had lower overall concentrations of testosterone compared to non-elites; however they exhibited more physical power in the lower body than the non-elite athletes. The authors reported that in both groups hormonal measures were unrelated to individual changes in power and strength over time.

- Crewther *et al* (2018a) found no relationship between testosterone and performance in a group of Olympic male weightlifters.

- Crewther *et al* (2018b) measured pre-match salivary testosterone in a group of elite female field hockey players. The testosterone concentration of those players who were not using an oral contraceptive was on average 35% higher than those who were using an oral contraceptive. There was no difference, however, in any performance measure between those who were and were not taking oral contraceptives. The authors therefore concluded that, "*This suggests that the T differences had no impact on match performance.*"

122. In respect of BG17, Prof. Holt observed that:

- Although the DSD Regulations concern total endogenous blood testosterone, BG17 concentrated on the derived free testosterone (fT). It reported that in five of 21 events female athletes whose fT was in the highest tertile appeared to do better than those whose fT was in the lowest tertile. However, although not statistically significant, females with fT in the lowest tertile appeared to outperform those in the highest tertile in nine of 21 events (including the 100m and 100m hurdles). Moreover, in respect of total endogenous testosterone levels, only three running events showed significant performance differences between the high and low testosterone tertiles.

- The comparison between the tertile groups using unpaired testosterone test results was "*statistically inappropriate*". The absence of any adjustment for multiple comparisons was also "*a major flaw*" in the analysis. It would have been better if the authors had looked for a direct and statistically significant correlation between endogenous testosterone and performance.

- In the absence of a statistically significant correlation between androgens and performance, the evidence that either testosterone or free testosterone predicts athletic performance "*is not supported*".

- While BG17 provides "*useful information*" concerning the association between androgens and female athletic performance, it does not address the issue of causation. Nor can the findings be extrapolated to the very high but largely non-functional testosterone levels that are seen in women with androgen insensitivity syndrome.

123. Prof. Holt went on to identify various other possible alternative mechanisms that might explain the difference in athletic performance between males and females. In particular:

- There is cogent evidence that the Y chromosome plays an important role in determining performance.

- Growth hormone affects males and females differently. Moreover, during puberty it has a greater effect on linear growth than sex steroids.

124. Prof. Holt stated that he stood by the statement in his report in *Chand* that:

> *In order to establish a scientific causal relationship between endogenous testosterone levels in elite female athletes and enhanced athletic performance (i.e. one of the underlying assumptions in the Regulations), it would be*

> *necessary as a first step to show that testosterone levels in a large cohort of elite female athletes from a wide range of sports relates to performance. Even then, such evidence, if it existed, would not prove 'causation' but only association.*

125. Prof. Holt went on to say that the IAAF's further studies into the relationship between elevated endogenous testosterone and athletic performance "*are not robust*" and "*fall well short of the required analysis typically acceptable in the sports context to restrict athlete rights*". He added that there were "*no studies at all that prove causation*". Prof. Holt concluded by reaffirming the conclusion in his expert report in *Chand* that:

> *[The] assumption that elevated endogenous testosterone in female athletes confers a competitive advantage is scientifically flawed for two interrelated reasons: (i) endogenous testosterone does not explain the difference between male and female athletic performance; and (ii) there is no convincing evidence that endogenous testosterone enhances athletic performance in female athletes, including those with hyperandrogenism.*

126. In his supplementary expert report filed in response to the IAAF's evidence, Prof. Holt stated that that this conclusion was "*overstated*" when women with 5-ARD are included. This is because, in the specific case of women with 5-ARD, "*the combination of elevated endogenous testosterone levels and fully functional androgen receptors is likely to result in increased muscle mass and strength and haemoglobin concentrations*" which "*in turn is likely to be performance enhancing in certain athletics disciplines*".

127. Prof. Holt added, however, that from an endocrinological perspective he did not agree with the IAAF's proposition that women with 5-ARD are "*biologically indistinguishable*" from males. This is because women with 5-ARD cannot properly convert testosterone to DHT. Their DHT levels are therefore lower than men's DHT levels. DHT is a more potent androgen than testosterone, since it exerts a greater effect on the androgen receptor. Accordingly, women with 5-ARD will not experience the same androgenising effect of DHT as men. Prof. Holt stated that there is evidence to suggest that DHT levels can influenced athletic performance. In particular:

- The study by Eklund and Hirschberg reported "*clear positive correlations between the androgens DHEA and dihydrotestosterone (DHT) and physical performance*" in a group of female Olympic athletes. (Prof. Holt cautioned, however, that the cross-sectional design of the study only reveals information about correlation, not causation.)

- The WADA Prohibited List includes DHT as a banned substance.

128. Accordingly, in Prof Holt's opinion there is a difference between women with 5-ARD and men in terms of the overall physical effect exerted by the two principal bioactive androgens, including in terms of ergogenic effects that would be relevant for athletic performance. It is therefore wrong to suggest that women with 5-ARD are "biological males" or that they have the same exact athletic performance advantage that men have over women. [...].

Prof. Roger Pielke

129. Roger Pielke is a professor of environmental studies and the director of the Sports Governance Center at the University of Colorado. Prof. Pielke provided expert evidence concerning the appropriate use of science in regulatory decision making.

130. In his expert report, Prof. Pielke explained why, in his opinion, the IAAF had departed from commonly understood best practices in its use of science. In his view this departure had contributed to the production of, and the failure to correct, evidence that "*unambiguously contains fatal errors leading to unreliable results that do not provide a robust basis for regulation or rule making*".

131. Prof. Pielke described how upon learning that BG17 was the main empirical basis for the DSD Regulations, he and his colleagues, Ross Tucker and Erik Boye, had contacted Dr. Bermon to request the performance data used in the study. Dr. Bermon subsequently supplied 25% of the performance data that had been requested. In a covering email, Dr. Bermon explained that he had "*identified some errors; the most important in sprint performances. The file attached here contains these errors.*" Dr. Bermon did not provide any further information concerning the nature or significance of the errors.

132. Prof. Pielke and his colleagues subsequently analysed the data and identified a number of errors. According to Prof. Pielke:

- Prof. Pielke recreated the data for four events (*viz.* the women's 400m, 400m hurdles, 800m and 1,500m) by crosschecking times provided by Dr. Bermon with reported results from the 2011 and 2013 IAAF World Championships. This process identified "*significant anomalies and errors in the underlying data*".

- Dr. Bermon's data contained times for several athletes who had been disqualified for doping. In addition, the data contained "*Duplicated athletes*" (i.e. instances where more than one time was included for the same individual athlete); "*Duplicated times*" (i.e. instances where the same time was recorded more than once for an individual athlete); and "*Phantom times*" (i.e. times that did not correspond with any reported time for the event in question).

- Overall, the extent of the errors was significant. The proportion of erroneous data ranged from 17.2% (for the 800m event) to 32.8% (for the 400m event). The data errors were "*systemic and pervasive*".

- A comparison of BG17 and BHKE18 shows that BG17 overstated the purported relationship between testosterone and athletic performance in 73% of the running events compared to BHKE18.

- In respect of the four events covered by the DSD Regulations, the average difference in BG17 between the high testosterone tertile and the low testosterone tertile was 2.0%, whereas this reduced to 1.6% in BHKE18 – a reduction of one fifth. This is "*a large and consequential difference*".

- Further, even though BKHE18 acknowledged errors, based on Prof. Pielke's recreation of the data for four events, he does not believe that all errors have been identified.

133. Prof. Pielke said that in view of the "*systemic, pervasive and consequential errors in the underlying science put forward as the basis for*" the DSD Regulations, the IAAF should reconsider the DSD Regulations. He commented that while the fact that BG17 and BHKE18 were produced by researchers employed by or associated with the IAAF was not, in itself, a reason for rejecting the results of that research, the "*obvious conflicts of interest*" on the part of the researchers highlighted the importance of an independent review of such evidence. Prof. Pielke stated that he knew of no other regulatory context where the evidence base for regulation is provided primarily by the regulatory body itself.

134. In addition to the flaws in the data identified by Prof. Pielke and his colleagues, Prof. Pielke also identified other "*concern[s]*" about the evidence base for the DSD Regulations. In particular:

- Dr. Bermon and the IAAF had refused repeated requests to share the data underlying BG17 and BHKE18, "*contrary to typical scientific norms*".

- The journal that published BG17 and BHKE18 had refused to enforce those norms by either notifying readers of the errors, requiring disclosure of the underlying data, or retracting the flawed papers.

- In respect of the Handelsman Paper, the lead author is a paid consultant to the IAAF and is listed as a "*Medical Expert*" appointed by the IAAF to review cases arising under the DSD Regulations. The co-authors are Dr. Bermon – who is employed by the IAAF – and Prof. Angelica Linden Hirschberg, who is also listed as a "*Medical Expert*" appointed by the IAAF to review cases arising under the DSD Regulations. In addition, all three authors are members of either the IAAF and/or IOC working groups on hyperandrogenic female athletes, which were responsible for devising the DSD Regulations and their predecessors.

- In addition, an advance online version of the Handelsman paper included an acknowledgment (which was subsequently deleted in the final published version) that the authors of the report had received "*helpful insights and comments from Jonathan Taylor QC and Elizabeth Riley (Bird & Bird)*". Both of those individuals were counsel for the IAAF in *Chand*, while Mr. Taylor is the IAAF's lead legal counsel in the current proceedings.

- In light of these factors, Prof. Pielke opined that it was possible "*that the research was performed with the expectation of justifying or defending*" the DSD Regulations and therefore there was "*at least an appearance here that the research was conducted to support a pre-determined regulatory position*". In Prof. Pielke's opinion, the IAAF's reliance on research conducted by individuals with conflicts of interests is a "*significant departure*" from the proper role of evidence in policy making.

135. In conclusion, Prof. Pielke stated that:

- The IAAF has not differentiated between questions that involve scientific judgements and questions that involve judgements about ethics and other matters of policy.
- The studies used by the IAAF as the basis for its regulatory policy are not transparent in terms of selection criteria, methods and data availability.
- The IAAF's work is "*plagued by significant errors that work against its call for regulation*" and it has "*strayed far from scientific norms in this instance*".
- Even if the data relied on by the IAAF were correct, they show larger differences in performance in several events which are not covered by the DSD Regulations. In addition, the results show that in some instances athletes with lower testosterone concentrations significantly outperform athletes with higher testosterone. The DSD Regulations are therefore inconsistent with the supporting evidence and are potentially arbitrary.
- The IAAF's reliance on in-house researchers and consultants creates a perception of conflict of interest that can only be resolved by permitting independent researchers access to data and evidence in order to replicate findings. With the exception of the small quantity of data shared with Prof. Pielke, however, the IAAF did not permit this. The IAAF's approach is therefore akin to cigarette companies providing the scientific basis for the regulation of smoking or oil companies providing the scientific basis for regulation of fossil fuels.

136. Prof. Pielke provided a supplementary expert report in response to the IAAF's evidence. In that report he explained that he had analysed the data from the 2011 and 2013 World Championships which the IAAF had disclosed during this proceeding. That analysis identified several further errors in those data, which have a "*material impact*" on the reliability of the results in BHKE18. In particular, the reported difference in performance between the high and low testosterone tertiles in the 800m event reduces from 1.7% to 1.2% once those further errors are corrected. In Prof. Pielke's opinion, the errors are unlikely to be restricted to the data for a single event. Rather, "*the magnitude and nature of the errors identified warrant the retraction of (or at least a complete independent re-analysis of) BHKE18*". He added that the errors render BHKE18 "*wholly inadequate*" as a basis for supporting any regulation.

137. Prof. Pielke also sought to replicate the results of BHKE18 by applying the methodology described in BHKE18 to the data disclosed by the IAAF. That replication exercise found that in 13 out of 44 examples the values in BHKE18 did not match the values in Prof. Pielke's replication. In particular, the reported and replicated values for *all* of the Restricted Events did not match up. These discrepancies suggest either that the data disclosed by the IAAF are not the data used in BHKE18, or alternatively that the results in BHKE18 were not the product of the methodology described in that paper. Prof. Pielke stated that his inability to replicate approximately 30% of the reported

results in BHKE18 using the data disclosed by the IAAF "*raises significant concerns*" and makes the paper "*highly questionable as the basis for regulatory policies*".

138. Prof. Pielke stated that it was a "*misuse of science*" for the IAAF to cite the results of BG17 to support the assertion that high levels of endogenous testosterone in athletes with DSD can significantly enhance performance. Quite apart from the errors summarised above, he stated that the IAAF had "*taken results from what it now characterizes to be merely an exploratory study and relied upon them in public pronouncements as though they confirm a statistically significant causative relationship between higher testosterone levels and athletic performance.*" Prof. Pielke described this as both "*scientifically inappropriate*" and "*publicly misleading*".

139. During cross-examination, Prof. Pielke accepted that he was not an expert regarding testosterone or 5-ARD. He went on to explain his proposed solution to the question of how to fairly determine eligibility to compete in the female category. He suggested that there is "*a natural demarcation*" between those individuals who have never changed their sex or gender and those individuals who have. He drew an analogy with rules governing nationality, which establish different procedures for individuals who have never changed nationality and those who have. Accordingly, in cases where an individual has continuously lived and identified as a woman from birth, it is "*unnecessary*" for a sports regulator such as the IAAF to second guess this, since "*society has done most of the work*" already. By focusing on individuals who have changed their sex or gender at some point, the process for regulating eligibility to compete in the female category becomes more manageable.

140. Prof. Pielke went on to draw a further comparison with the procedures established in the sport of gymnastics for tracking the age of young gymnasts. He suggested that it might be possible to establish a similar procedure for recording certain "*signposts*" and "*formal markers*" during a person's life to enable a "*record of continuity*" to be produced, so that it would be straightforward to determine whether a particular aspiring athlete had ever changed their sex or gender or whether they had consistently lived in accordance with the sex they were assigned at birth.

141. Prof. Pielke stated that it is "*entirely appropriate*" for the IAAF to make policies governing the eligibility of individuals who have changed categories at some point during their life. However, if an athlete was born female and consistently raised, lived and competed as a female, then in his opinion the IAAF should not seek to go back through their life and question this.

Dr. Alun Williams

142. Dr. Alun Williams is the Director of the Sports Genomics Laboratory at Manchester Metropolitan University. He provided expert evidence on behalf of Ms. Semenya concerning the genetic variations and mutations that affect athletic performance.

143. Dr. Williams explained that the human genome contains millions of polymorphisms that collectively create a mosaic that constitutes the genetic disposition of each individual. Mutations are comparatively rare genetic variations, although they do not necessarily

differ from polymorphisms in terms of how the DNA molecule is changed in structural terms. It is likely that all humans carry multiple different genetic mutations.

144. Dr. Williams explained that success in elite sport depends on a combination of genetic and environmental factors. The influence of genetics means that sport is not "*fair*" in the sense that the greatest commitment and effort will not necessarily entail the greatest sporting success. On one view, therefore, elite competitive sport is effectively a search for genetic outliers.

145. According to Dr. Williams, numerous polymorphisms have been associated with human physical performance, although researchers have not replicated many of those associations. The "*most convincing*" evidence of a polymorphism that affects athletic performance is for a variant of the ACTN3 gene. That variant has been repeatedly associated with superior sprint/power performance. The magnitude of the performance change attributable to this gene is "*at most 2-3% and probably much less*".

146. While many genetic mutations have significant detrimental effects on physical performance, a small number are known to be likely to enhance physical performance. For example, there are mutations in the MSTN gene that dramatically increase muscle mass, while mutations in the EPOR gene can dramatically increase the production of red blood cells. (The concentration of blood haemoglobin in individuals with that particular mutation is often one third higher than in individuals without the mutation.) In Dr. Williams' opinion, it is "*highly likely*" that many elite athletes possess mutations that provide substantial advantages over their competitors who lack those mutations. However, the research necessary to identify those mutations has not yet been carried out as a result of the relative infancy of this area of study.

147. Dr. Williams went on to address the effects of DSD. He stated that:

- From a scientific perspective, sex is not easily divisible into two categories based on genetics or anything else. While societies categorise individuals in a binary manner, genetic and biological variations between individuals mean that in reality sex is "*a much more diverse spectrum*".

- The genetic differences that cause DSD which affect testosterone levels "*are not qualitatively different from other genetic differences that are accepted in sport, whether they affect competitive performance or not*". There is no clear qualitative distinction between the types of genetic variations that cause DSD and those that cause individuals to be particularly tall or short, especially strong or weak, to have large or small skeletal muscles etc. It follows that from the perspective of a sports geneticist, the rationale for treating genetic variations that cause DSD as a unique category "*is not scientifically sound*".

- The IAAF asserts that some female athletes with DSD enjoy an 8-12% advantage in competitive performance due to their elevated endogenous testosterone levels. However even if this is accurate, this is considerably lower than the >30% higher haemoglobin concentration caused by the mutation in the EPOR gene. Accordingly, there is no scientific basis for treating a DSD mutation as an unfair performance advantage while treating the EPOR mutation as an acceptable performance advantage. Similarly, the examples cited by the IAAF

of an adult beating a child or a heavyweight boxer bearing a flyweight boxer are "*much more extreme*" in terms of the magnitude of differential physical ability than where a DSD individual competes against a non-DSD individual.

- It is likely that many elite athletes possess other genetic mutations that provide comparable magnitudes of performance advantage in respect of certain physical traits compared to individuals who lack those mutations. Indeed, this is probably why they are elite athletes; they are already competing against other elite athletes "*with a similar magnitude of aggregate genetic advantage that distinguishes them, as a group, from the vast majority of the general population*". The only difference is that in most cases it is not presently known which elite athletes have which advantageous genetic variations.

148. Dr. Williams concluded his expert report by stating that much more information is required before it is possible to consider whether the IAAF's assertions concerning the representation of female athletes with DSD in elite level athletics are scientifically sound.

149. Dr. Williams provided a short supplementary report in response to the IAAF's evidence. He began by contesting the IAAF's characterisation of women with 46 XY DSD as "*biological males*". He then went on to draw a contrast between the effect of 46 XY DSD and the effect of a particular variation of the ACTN3 gene (the "ACTN3 R-allele"). He explained that the need to possess an ACTN3 R-allele in order to succeed in elite sprinting and power events is "*almost absolute*" and "*almost certainly very close to 100%*". It follows that athletes who possess at least one ACTN3 R-allele are likely to "*sweep the podium*" in numerous sprint/power events in much the same way that the IAAF contends female athletes with 46 XY DSD will do in middle-distance running events. Further, there is a "*firm*" scientific expectation that there are a "*multitude*" of other genetic variations which have a similar association with athletic performance, but which have yet to be identified.

150. In his oral evidence, Dr. Williams stated that testosterone was an "*important component*" in explaining the physiological and anatomical differences that typically exist between men and women. He noted, however, that muscle mass "*varies hugely*" between individuals, in part as a result of factors such as training and diet. He also noted that there are "*huge variation[s]*" within the male and female populations and that these intrapopulation variations could not be attributed solely to variations in testosterone levels.

151. Dr. Williams went on to discuss the effect of DHT. He cited a paper in the Journal of Physiology that showed that DHT in physiological concentrations improved the strength and power of fast twitch muscle fibres by around 25%, while simultaneously reducing the strength and power of slow twitch muscle fibres by 15%. For individuals who have a greater proportion of fast twitch fibres than slow twitch fibres, the effect of DHT would therefore cause an increase in overall athletic performance.

Dr. Eric Vilain

152. Dr. Eric Vilain is the Professor of Molecular Genetics and the Director of the Center for Genetic Medicine Research at Children's National Health System in Washington, DC. He is also a Professor and Chair of the Department of Genomics and Precision Medicine at George Washington University. Since 2010, Dr. Vilain has served as an advisor to the IOC on the development of regulations concerning female athletes with elevated natural testosterone levels and transgender athletes.

153. Dr. Vilain provided expert evidence on behalf of Ms. Semenya addressing both the policy-making process followed by sports governing bodies in respect of regulations concerning athletes with DSD and the scientific basis for the DSD Regulations.

154. Dr. Vilain described how, in his view, the meetings held by the IAAF to consider policies and regulations for athletes with DSD were conducted in a manner that resulted in a lack of diversity of representation. In particular:

- The ethnic composition of the committees was "*overwhelmingly White Caucasian*".
- No current elite or Olympic-level athletes with DSD attended the meetings. In contrast, three white European cisgender athletes without DSD were invited to attend at least one meeting.
- Only a small number of trans or intersex advocates were invited to attend certain meetings.
- There was "*limited consideration given to dissenting voices*" while the outcomes of the meetings were reported in a way that "*did not always reflect the complexity and variety of opinions expressed during these meetings*".

155. In respect of the scientific basis for the DSD Regulations, Dr. Vilain explained that while he had previously "*cautiously supported*" the IAAF and IOC regulations on hyperandrogenism, his views "*have evolved over several years in parallel not only with advances in medical and scientific understandings of DSDs but also with changing societal norms concerning sex and gender*". As a result of that evolution and the current state of the scientific evidence, Dr. Vilain does not support the DSD Regulations. In this regard, Dr. Vilain stated that:

- He was "*surprised*" to discover that the *Restricted Events* in the DSD Regulations do not align with the events that BG17 identified as events where athletes with elevated testosterone enjoy a performance advantage. This inconsistency "*raised questions*" regarding the neutrality of the IAAF's policy making.
- He was also "*surprised*" that the testosterone threshold had been reduced to 5 nmol/L. This threshold is "*arbitrary*" and he is aware of no evidence that 5nmol/L of endogenous testosterone is a proven threshold above which actual athletic performance will be enhanced in female athletes.

- It is clear that the 5nmol/L threshold "*has nothing to do with unfair performance advantage*". In particular, the DSD Regulations do not apply to females with PCOS even if their testosterone levels are above that threshold. Thus, a female athlete with PCOS and 5.5 nmol/L of endogenous testosterone is permitted to compete as a woman, but a female athlete having the same level of endogenous testosterone as a result of a 46 XY DSD is not permitted to compete as a woman. As a result, the DSD Regulations perpetuate the view that a woman with a 46 XY DSD is not 100% a woman.

156. Dr. Vilain went on to describe an email exchange he had with Prof. Handelsman concerning the DSD Regulations. On 31 June 2018, Prof. Handelsman sent Dr. Vilain an email which stated:

> *The lack of substantial direct evidence of the effects of a high (male) level of serum testosterone on elite female athletic performance will always be a severe limitation so we must rely on the best relevant surrogate evidence - which is what I at least tried to assemble. But there is a fundamental reason why DSDs should NOT be included - basically they have male bodies with testes that make sperm and testosterone and not female bodies that have ovaries that make oocytes and large amounts of estradiol.*

157. On 12 August 2018, Prof. Handelsman sent a further email in which he stated:

> *The threshold of 5 nmol/l ... was formed by making allowance for women with PCOS as they are in all sense female (chromosomal, gonadal, anatomical, endocrinology) but excluded DSDs like 5 reductase deficiency or 17 HSD type 3 deficiency where their impalpable testes produce adult male circulating testosterone levels so should be defined as having a male rather than a female sport sex. It was not, because it could not be, based on athletic performance as there is virtually no (let alone sufficient) relevant data of females with male circulating testosterone levels – it is a rare phenomenon after all. The demand for the threshold to be based on athletic performance is a counsel of perfection that is doomed to fail.*

158. Dr. Vilain stated that as a leading expert in this field he "*fundamentally disagreed*" with the notion that females with DSD should be "*defined*" as male and "*have male bodies*". That proposition is contrary to the current scientific mainstream, which recognises that sex is not binary but rather a spectrum, where no single factor (e.g. presence or absence of testes) prevails above all others. As he explained in an email to Prof. Handelsman, to state that individuals with DSD have male bodies with testes that make sperm "*is a serious misunderstanding of the field*". Many individuals with DSD do not have testes and most do not make sperm. There is a whole complex spectrum of conditions and Prof. Handelsman's position is therefore "*incredibly inaccurate*".

159. Dr. Vilain concluded his report by reiterating that the DSD Regulations are not supported by the current state of medical and sport science. Accordingly, as things presently stand the only fair approach to regulating eligibility in women's athletics is to permit athletes who were assigned the female sex at birth, and who have been raised as women all their lives, to compete in the women's category.

160. During his oral evidence, Dr. Vilain agreed with the IAAF's proposition that without a specific protected category, women would have no chance of winning events and would always lose to male competitors. He also agreed that it is necessary to establish criteria to determine whether an individual may participate in one category or the other and that those criteria should be relevant to performance. Dr. Vilain went on to explain why, in his opinion, the appropriate way to do this was by adopting a rule based on "*continuation*", whereby if an individual was born as a female, assigned the female sex at birth and consistently raised and identified as a female, then they should be permitted to compete in the female category of competition. Dr. Vilain explained that while he had previously supported the Hyperandrogenism Regulations, his views on this issue had evolved over time and he now regarded a rule based on levels of endogenous testosterone as "*simplistic*".

161. Dr. Vilain explained that his views on the preferability of using a "*social*" rather than a "*biological*" solution had changed after attending meetings which made it clear that the maximum level of endogenous testosterone would be reduced from 10 to 5 nmol/L "*with no good evidence*" and that the restrictions would be targeted at specific Restricted Events "*with no good scientific basis*". He added that when it became apparent that the DSD Regulations were designed to target women who had XY chromosomes rather than XX chromosomes, this was "*reminiscent of sex testing used for decades*" that had turned out to be a scientifically erroneous "*disaster*".

162. Dr. Vilain stated that he had never disputed that testosterone is a "*very important factor*" in the difference between male and female sport performance. He added, however, that data concerning the prevalence of 46 XY DSD women in Olympic Games were complicated because it is not known whether that prevalence is caused by their heightened testosterone levels. In particular, a number of such women were androgen-insensitive which suggests that factors other than testosterone might be relevant. He stated that in his view it was "*probably not*" the case that testosterone improved the athletic performance of women with 46 XY DSD to male performance levels.

Professor Anthony Hackney

163. Anthony Hackney is a professor of Exercise Physiology, Allied Health Science & Nutrition at the Schools of Public Health and Medicine at the University of North Carolina at Chapel Hill. Prof. Hackney provided expert evidence on behalf of Ms. Semenya concerning the state of scientific evidence regarding the effects of increased endogenous testosterone on athletic performance in female athletes. In particular, Prof. Hackney was instructed to review and evaluate the Handelsman Paper.

164. In his expert report, Professor Hackney identified various "*reservations*" concerning the Handelsman Paper which, in his view, call into question the scientific rigour and validity of the paper's conclusions. In summary, Professor Hackney stated that:

- Although the authors of the Handelsman Paper attempted to carry out an objective and balanced "*systematic review*", aspects of the paper in fact resemble a "*narrative review*" – a form of analysis that is "*more open to author interpretation (i.e., bias) and perhaps "cherry-picking" research to support the author's hypothesis as opposed to presenting "both sides of an issue*"". In this

regard, the reliability of the Handelsman Paper's conclusions "*is diminished to some extent*" as a result of the authors' decision not to conduct a meta-analysis.

- Although the authors of the Handelsman Paper state that research is only suitable for consideration if it involved the measurement of testosterone using LC-mass spectrometry ("LC-MS"), it is unclear whether all of the research considered in the Handelsman Paper in fact utilised that technique. It is "*highly doubtful*" that this is the case, and at least one of the key papers relied on by the authors (Elbers *et al* (1999)) used a non- LC-MS technique to measure testosterone.

- The authors of the Handelsman Paper rely on several studies involving non-athletes, including studies concerning older persons who in some cases appeared to be sedentary. Since there are likely to be many physiological and endocrinological differences between elderly people and athletes, a comparison between the two groups might not be appropriate.

- The Handelsman Paper does not refer to certain confounding scientific evidence.

- The conclusion of the Handelsman Paper that the sex difference in circulating testosterone explains most, if not all, of the sex difference in sporting performance is based on the existence of a correlation between increased circulating testosterone and increases in muscle mass and strength, bone size and strength, and haemoglobin levels. However, there is "*insufficient evidence*" to conclude either that (a) enhancements in these three physiological factors correlate strongly with athletic performance in track and field events; or (b) that testosterone-related increases in muscle, bone and haemoglobin are proportionate in magnitude to resultant improvements in athletic performance.

165. Prof. Hackney further stated that Prof. Handelsman is incorrect to state in his expert report that 46 XY DSD individuals with functioning androgen receptors will have "*exactly the same*" advantages over female athletes in terms of muscle mass and strength and circulating haemoglobin as non-DSD male athletes enjoy. In particular, that statement cannot be correct in circumstances where Prof. Handelsman acknowledges that women with 5-ARD have functioning androgen receptors but are unable to convert testosterone into the androgen DHT and therefore will produce much less DHT than men.

166. Prof. Hackney went on to explain that DHT is a highly potent androgen and that there is evidence that it affects athletic performance. In this regard:

- The expert report of Dr. Baggish and Dr. Levine (see further below) refers to DHT as having "*similar intracellular effects at an approximately 5-fold higher potency*" compared to testosterone, and describes muscle growth, red blood cell production and cardiac hypertrophy as "*key testosterone and DHT-mediated processes*".

- Prof. Hirschberg's expert report refers to a study that she co-authored that found "*clear positive correlations*" between DHT and physical performance in a group of female Olympic athletes.

- WADA considers DHT to be an anabolic androgenic steroid, the exogenous administration of which is prohibited.

- A study by Hawkins *et al* reported a significant correlation between DHT and body fat mass and a positive correlation between DHT and maximal oxygen uptake in adult men.

- A study by He *et al* reported a negative association between DHT and fat mass in adult men and women.

- A study by Pöllänen *et al* reported that intramuscular hormone levels, including DHT, constituted significant independent predictors of muscle strength and power in women.

167. Prof. Hackney also discussed the relationship between exercise and testosterone levels. He explained amongst other things that when an athlete ceases or reduces their exercise load and their endocrine system recovers "*testosterone levels can increase (sometimes dramatically), including into the extended recovery period (a day or two later)*". In this regard, "*The magnitude of the swing from very low to very high testosterone is usually related to how strenuous the exercise training session was (i.e., harder sessions result in bigger recovery rebounds).*"

Professor Dankmar Böhning

168. Professor Dankmar Böhning is Chair of Medical Statistics and the Director of the Southampton Statistical Sciences Research Institute at the University of Southampton. Prof. Böhning provided expert evidence on behalf of Ms. Semenya concerning the statistics relied on by the IAAF in support of the DSD Regulations.

169. Prof. Böhning began by stressing the importance of an awareness of the risk of "*confounding bias*" and the need to control for variables when assessing the relationship between testosterone levels and athletic performance. Prof. Böhning went on to identify what he considered to be various statistical and methodological flaws in BG17. In summary:

- The study was based on observational data, which means that no causative statements concerning the effect of testosterone on athletic performance could be drawn from those data. Accordingly, the statement in BG17 that females with high testosterone levels have a significant competitive advantage in certain events "*overinterprets the results*" on which it is based.

- The comparison between tertile groups using unpaired testosterone tests was statistically inappropriate.

- The absence of any adjustment to take account of multiple comparisons was also a significant defect in the analysis.

- A better approach would have been to search for a direct and statistically significant correlation between endogenous testosterone and athletic

performance. This is the approach that was taken by Eklund *et al* – a study that found no such correlation.

170. Prof. Böhning quoted from a peer-reviewed letter by Amanda Menier, which criticised the methodology and conclusions of BG17. He also quoted from a peer-reviewed article co-authored by Simon Franklin, which stated that, in light of the sample sizes and number of statistical tests used by BG17, "*any particular significant result in an event is more likely to have arisen by chance*" and that, "*it is reasonably likely that the correlations presented in the paper (even the largest ones) occurred by chance*". Accordingly, the reanalysis of the data led the authors to consider that, "*it is scientifically incorrect to draw the conclusions in [BG17] from the statistical results presented*".

171. Prof. Böhning concluded his expert report by making some brief observations concerning Bermon[5] (2017). He noted that the paper contains "*very little discussion of quantitative analysis of the effects of testosterone on performance in female athletes*". In this regard, Dr. Bermon's statement that reducing testosterone from the normal male range to the normal female range led to an average decrease in performance of 5.7% over a two-year period suffers from several methodological flaws. In particular, it is based on data from just three athletes – a sample size that cannot generate statistically significant results – and there was no control group. As a result, in Prof. Böhning's view it is "*very likely*" that another sample of three female athletes who had unchanged or increased testosterone levels would show a similar decrease in athletic performance.

172. In his supplementary expert report, Prof. Böhning explained that after the IAAF had disclosed certain data in the course of this proceeding he had conducted a regression analysis on those data. That analysis "*indicates that there is no evidence of a statistically significant relationship between testosterone and athletic event performance*" in those data.

173. Prof. Böhning noted firstly that the IAAF dataset contained 50 female measurements above1.68 nmol/L (i.e. there were 50 samples from female athletes that were above the normal reference range for women). 11 of those 50 samples were above 7.7 nmol/L (i.e. they were within the normal reference range for men). Further, there were 41 male measurements that were below 7.7 nmol/L and 24 measurements above 29.4 nmol/L. This showed that the analysis of the Daegu and Moscow data included testosterone measurements that fell outside the normal reference ranges, meaning that no "outliers" were excluded.

174. Prof. Böhning went on to explain that his regression analysis showed "*no evidence of any relationship between testosterone and performance over the entire range of testosterone measurements*" (which, as noted above, ranged from 0.0 nmol/L to 43.6 nmol/L). This conclusion followed from the fact that the regression analysis showed "*no statistically significant relationship between testosterone levels and athletic performance levels for female athletes in 20 of 21 sport disciplines*". He added that while two events (400m hurdles and hammer throw) showed "*a borderline significant*

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[5] Bermon S. *Androgens and athletic performance of elite female athletes*. Curr Opin Endocrine! Diabetes Obes 2017, 24:246-251

result", in each case the "*explained variance of performance by testosterone*" was "*very low*", meaning that "*over 90% of the variance*" in those two events was explicable by factors other than testosterone.

175. Prof. Böhning stated that similarly there was "*no relationship between testosterone and athletic performance in the Male Data, over the entire range of testosterone values*". He explained that for the male data "*none of the 22 disciplines show a significant relationship*". The only "*potential exception*" to this was in the men's 200m event, where the results indicated a "*borderline*" and "*inverse*" relationships, meaning that "*increased testosterone is associated with decreased performance*".

176. Prof. Böhning went on to explain that in addition to undertaking a regression analysis, he had also sought to replicate Dr. Bermon's correlation analysis. That attempted replication showed only "*very minor (not to say none at all) correlation between testosterone and performance*". In 18 of the 21 events there was no significant correlation, while the three remaining events (400m hurdles, 800m and hammer throw) showed a statistically significant correlation. He also stated that he had replicated Dr. Bermon's tertile-based analysis on the female data. While the tertile technique was susceptible to various criticisms, even that technique showed "*only a very minor relationship between testosterone and performance, which will likely disappear after adjusting for multiple comparisons*". Once again, there was no statistically significant correlation in 18 of the 21 events, while the remaining three events (400m hurdles, 800m and hammer throw) showed only "*borderline significant results*".

Dr. Veronica Gomez-Lobo

177. Dr. Veronica Gomez-Lobo is a paediatric and adolescent gynaecologist. She is the founder and director of the Positive Re-evaluation of Urogenital Differences (PROUD) Clinic at the Children's National Health System in Washington DC. The PROUD Clinic is part of the DSD-Translational Research Network.

178. Dr. Gomez-Lobo provided two expert reports in which she summarised the key features of the DSD referred to in section 2.2(a)(i) of the DSD Regulations; described the procedures, protocols and standards for diagnosing those DSD and for assessing the nature and extent of the androgenising effect of elevated testosterone levels caused by those DSD; described the potential adverse effects of medical interventions to reduce endogenous testosterone levels; and discussed the procedures for assessing virilisation in particular individuals.

179. Dr. Gomez-Lobo explained that many of those DSD "*elude clear diagnosis*". DSD conditions tend to be rare, meaning that experts in the field frequently have limited clinical experience of dealing with them. Scientific research in respect of DSD continues to evolve. Accordingly, there is often "*a degree of uncertainty*" associated with each DSD diagnosis – a position further complicated by the fact that some individuals may show a mix of characteristics associated with different DSD.

180. In respect of 5-ARD, Dr. Gomez-Lobo explained that this condition can be diagnosed in several ways, including through an increase in the ratio of testosterone to DHT; an elevated precursor hormone level with a stimulation test of human chorionic

gonadotropin (HCG); and genetic testing. However, there are problems with each of these methods. For example, establishing the cut-off value for the testosterone/DHT ratio is "*controversial*". Likewise, although genetic testing may enable the identification of genetic mutations that enable 5-ARD deficiency to be resolved, it does not enable the full effect of the mutation to be predicted. Dr. Gomez-Lobo added that the equivalent difficulties apply to the diagnosis of 17β-hydroxysteroid dehydrogenase type 3 deficiency and congenital adrenal hyperplasia ("CAH").

181. In respect of PAIS, Dr. Gomez-Lobo stated that there is no simple test that can be used to diagnose PAIS in all individuals. Genetic testing of the androgen receptor gene is not determinative since only between 10% and 20% of PAIS individuals have abnormalities in this gene. Accordingly, diagnosis must often rely on clinical impression based on the presence of high androgen levels with less than expected virilisation (e.g. clitoral enlargement, deepening of voice, male pattern hair growth etc.).

182. Dr. Gomez-Lobo went on to explain that a simple measure of an individual's serum testosterone level is insufficient to understand the effect that circulating androgens exert on the individual's body. The overall androgenic effect in an individual is affected by a number of factors including (a) the biologic activity of each androgen; (b) the functionality of the androgen receptor; (c) circulating levels of each androgen; and (d) whether certain androgens are bound to other substances that preclude their functionality.

183. However, the androgenising effect of a particular DSD condition "*cannot be determined by an objective test*". On the contrary, the techniques used to assess androgenisation are "*inherently uncertain*" and involve the subjective judgment of the physician conducting the assessment. Moreover, markers of virilisation may vary significantly in different populations and across different ethnic groups. As a result, different experts could reach different conclusions regarding the degree of androgenic effect in a particular individual.

184. Dr. Gomez-Lobo concluded her expert report by addressing the adverse effects of medical suppression of testosterone levels. She explained that oral contraceptives significantly increase the risk of VTE, which increases the risk of deep venous clots, pulmonary embolism and stroke. They can also result in other medical side effects such as hypertension, liver dysfunction and tumours, as well as interfering with certain other medications. She also identified various adverse side effects that may arise from other testosterone-reducing treatments such as finasteride and dutasteride, spironolactone, GnRH agonist and gonadectomy.

185. In her reply expert report, Dr. Gomez-Lobo explained why she considered that the IAAF was wrong to suggest that women with 46 XY DSD are "*biological males*". She stated that individuals with 46 XY DSD cannot be generalised as individuals who have 46XY chromosomes, testes and normal male levels of androgens, since the androgens in their bodies "*do not have the same effect as they do in males or transgender women*". She explained in this regard that 5-ARD involves a defect in the conversion of testosterone to DHT, which has various consequences including a possible decrease in the expected virilisation at puberty. The effects of 5-ARD are "*very complex*" and can result in "*significant variation in phenotype*" between different individuals with the condition.

Some individuals with 5-ARD, for example, experience only mild under-virilisation whereas others may have completely female genitalia. Similarly, in cases of PAIS the degree of androgen sensitivity can vary significantly across individuals. In addition, a person with PAIS may experience full effects of androgens in utero, but little or no effects after birth. It follows that the bodies of individuals with 5-ARD and PAIS "*do not produce and/or respond to...androgens in the same way as a man or an untreated transgender woman.*" Accordingly, the IAAF's suggestion that women with 46 XY DSD are biological males is both "*wrong*" and "*oversimplifies the issue*".

Dr. Lih-Mei Liao

186. Dr. Lih Mei Liao is a clinical psychologist. She has written widely on issues relating to DSD. Dr. Liao provided an expert report on behalf of Ms. Semenya concerning various issues regarding sex development and the psychological risks of medical interventions on women with DSD. (Dr. Liao explained that in recognition of the objections to the DSD label by affected individuals, she uses the more "*advocacy friendly term intersex or diverse sex development (dsd).*" The expression "*DSD*" in the summary of her evidence below should therefore be understood accordingly.)

187. Dr. Liao began by explaining that in clinical and scientific literature "*sex*" and "*gender*" are often both expressed in dimorphic terms. However, the perception and experience of femaleness or maleness "*is not a fixed attribute waiting to unveil itself, rather an expression of complex, multiple, interactive and reciprocal developmental processes that are not fixed*".

188. Dr. Liao went on to state among other things that:

- There is no single "*truth*" about sex/DSD. All claims to "*truth*" in this context are "*socially constructed and contested*".
- In the contemporary world DSD are understood in "*contradictory*" ways, either as an "*extraordinary medical diagnosis*" or as "*human diversity that is rather ordinary*".
- The way that medically benign intersex traits have been conceptualised has generally been harmful for affected individuals.
- Many intersex people have described the "*particularly toxic*" psychological effects of being objectified by being placed under mandatory scrutiny without being treated as an equal partner. Consequences of such treatment include anxiety, depression, social withdrawal, substance misuse, self-harm and suicidal ideation (and, in some cases, actual suicide attempts).
- The majority of intersex women whom Dr. Liao has worked with feel under pressure to remain silent about their difference and to choose "*feminizing*" interventions to held them pass as normal, because the psychological risks of being treated differently outweigh the risks of the interventions. Decisions to undergo medical treatment on a healthy body are made in a context of value judgement and social pressure.

- In some situations a person may make choices that cause them physical or mental harm (for example by choosing to undergo hormonal intervention). The choice may not be a free one where it is the product of disadvantage and external influence.

Dr. Payoshni Mitra

189. Dr. Payoshni Mitra is a researcher in the field of women and sports in India. As an Advisor/Mediator appointed by the Sports Authority of India and the Indian Ministry of Youth Affairs and Sports, she assisted Ms. Chand to bring her case against the IAAF before the CAS in 2015.

190. Dr. Mitra provided an expert report on behalf of Ms. Semenya which discussed the issues faced by athletes in the Global South who are affected by the DSD Regulations and which commented on the potential effects of provisions that permit Relevant Athletes to compete without restriction at the national level and at the international level in the male or a (presently non-existent) intersex category.

191. At the outset of her report, Dr. Mitra stated that she considered that the DSD Regulations are "*discriminatory, unnecessary and harmful*". She therefore fairly pointed out that while she was independent of the parties, she already had a pre-existing opinion concerning the DSD Regulations before she provided expert evidence these proceedings.

192. Dr. Mitra began by summarising the history of sex testing in sport. She then went on to address the likely impact of the DSD Regulations. Based on her experience of dealing with athletes affected by earlier regulations, she believes it is likely that the DSD Regulations "*will result in severe stigma and harm to affected athletes*" and will cause "*hopelessness, severe depression, substance abuse, alcoholism and even suicidal tendencies*". She highlighted in particular the following points:

- Under the DSD Regulations, a Relevant Athlete has the options of quitting sport, undergoing medical assessment and intervention, or publicly accepting that she is not fit to be identified as a woman. Such choices stigmatise the affected woman and question her identity and sense of self-worth. This can be humiliating and may result in psychological harm, identity confusion, depression, loss of income and loss of identity.

- The DSD Regulations will result in athletes being coerced into taking medication or undergoing other medical intervention. Dr. Mitra has witnessed the significant pressure that is placed on athletes to accept medical intervention.

- These harmful consequences can arise whether or not the individual's personal information is leaked. While public disclosure significantly exacerbates the harm, many of the harmful consequences arise simply by virtue of being targeted by the Regulations.

- The DSD Regulations will disproportionately affect and burden women from the Global South.

193. Dr. Mitra illustrated these points by reference to specific examples of female athletes who were affected by predecessors to the DSD Regulations. In one case, a young female athlete, [...] committed suicide following her coach's attempts to blackmail her by threatening to publicly divulge information about her intersex or hyperandrogenic status.

194. Dr. Mitra contended that the suggestion that hyperandrogenic females should be restricted to competing at national level is illogical and will not provide much relief for affected athletes. In particular, coaches are unlikely to train athletes if there is doubt whether those athletes will be eligible to compete in elite events at the international level. Accordingly, athletes with no prospects of competing internationally may not even get the kind of coaching and support they need in order to compete at the national level.

195. Dr. Mitra concluded her expert report by stating that the IAAF's suggestion that hyperandrogenic female athletes should compete in the men's category or in a non-existent intersex category causes stigma and harm. There is a widespread belief that the DSD Regulations exist for the purpose of "*gender verification*" or "*sex testing*". Accordingly, compelling affected athletes to compete in male or intersex categories would certainly result in the gender of those athletes being questioned. Requiring women to compete in the male category would impugn their lifelong legal and social identity as women and would be humiliating and stigmatising. Indeed, the mere suggestion that certain women should compete as men will undermine their dignity and sense of self.

196. Lastly, Dr. Mitra commented that if a woman competes in the male category as a consequence of the DSD Regulations then this would necessarily reveal to the world that she has a DSD. This will compromise her privacy and may result in harmful public stigma similar to the speculation that athletes whose confidentiality was breached under earlier regulations had to endure.

Kyle Knight

197. Kyle Knight is a researcher on LGBT rights at Human Rights Watch ("HRW"). Prior to this, Mr. Knight was a fellow at the Williams Institute of the University of California.

198. Mr. Knight submitted an expert report on behalf of Ms. Semenya which explained why HRW considers that the DSD Regulations are an unnecessary and disproportionate interference with the rights of affected female athletes.

199. Mr. Knight stated that the DSD Regulations will force some female athletes to choose between undergoing medically unnecessary intervention to lower their testosterone levels or being precluded from participating in international sport. The DSD Regulations will thereby have the effect of "*coercing*" some women to undergo unnecessary medical procedures to alter their natural, healthy physiology.

200. In addition, Mr. Knight stated that the DSD Regulations discriminate against women by stigmatising those who are subjected to the Regulations. He provided three reasons in support of this position:

- First, the DSD Regulations are open to abuse. They confer absolute authority on the IAAF medical manager to investigate any athlete of their choosing. They also encourage a range of individuals and organisations to report athletes of concern to the IAAF. This will lead to a situations where the bodies of female athletes are "*scrutinized through subjective and discriminatory frameworks and stereotypical understandings*".

- Second, no equivalent scrutiny is applied to men. The DSD Regulations therefore have a discriminatory impact on women.

- Third, the proposed medical intervention is inherently discriminatory. Medical treatment of persons with intersex traits is frequently motivated by prejudice presented as science. There is a history of unscientific, unethical and unlawful promotion and imposition of "*normalizing procedures*" (e.g. procedures to reduce the size of the clitoris, change the size of the vagina, and remove gonads) on intersex people.

201. Mr. Knight further stated that the DSD Regulations violate the right to privacy:

- First, the DSD Regulations entail a judgment on, and questioning of, women's sex and gender identity. The process of detecting and assessing an individual's intersex variation, testosterone levels, and degree of virilisation, are "*inherently subjective and degrading*". The tests and procedures are medically unnecessary. The DSD Regulations effectively coerce athletes into medical treatment that have no health benefit and may indeed have severely detrimental health effects.

- Second, the suggestion that female athletes with DSD should compete in the male category (or in a non-existent "*intersex*" category) contravenes the assurances of confidentiality in the DSD Regulations. It is also insulting and degrading for an individual who was born and raised as a woman, and who has always identified and competed as a woman, to be placed against her will in the male category or in an intersex category.

- Third, the process of undergoing medical examinations can be humiliating for the individual concerned.

202. In addition, Mr. Knight stated that the DSD Regulations violate athletes' right to health. In particular:

- Athletes affected by the DSD Regulations will not provide informed and voluntary consent to the medical intervention suggested by the IAAF. Given that eligibility to compete will be dependent upon undergoing the medical intervention, the DSD Regulations blur the line between consent and coercion.

- The DSD Regulations impose medically unnecessary treatment. In this regard, it is instructive that medically unnecessary interventions on intersex people have been criticised by a diverse array of individuals and bodies, including the World Health Organization, Amnesty International, several former US Surgeons

General and UN experts on children's rights, women's rights and healthcare rights.

203. Mr. Knight went on to state that attempts by the IAAF to suggest that the DSD Regulations are analogous to weight or age divisions were "*misleading and false*". Age categories "*conform perfectly to an athlete's physiological endowment*" and no athlete can be coerced into competing in an age category to which they do not belong. Similarly, an athlete who elects to change their body in order to fall within a specific weight category does so "*in the absence of invasive testing and implicit questioning of an essential characteristic of her identity as a human being*".

204. Mr. Knight concluded his expert report by stating that the DSD Regulations do not uphold the legitimate objective of ensuring that each athlete is qualified to compete in the appropriate category in sports competitions. Instead, in his opinion the DSD Regulations violate internationally protected fundamental rights including by discriminating against females on the basis of both their sex and sex characteristics, by violating their privacy and by coercing them into unnecessary medical treatment.

Isobel Goodman and Ofentse Motlhasedi

205. Isabel Goodman and Ofentse Motlhasedi are both Advocates of the High Court of South Africa. They provided a joint expert opinion on behalf of Ms. Semenya regarding the susceptibility of the DSD Regulations to a legal challenge under the law of South Africa.

206. In overview, Ms. Goodman and Ms. Motlhasedi stated that the application of the DSD Regulations within South Africa would be amenable to a constitutional challenge and that such a challenge would have "*good prospects*" of success. If such a challenge were successfully brought, then ASA would be prohibited from giving effect to the DSD Regulations in South Africa.

207. In explaining that conclusion, Ms. Goodman and Ms. Motlhasedi stated among other things that:

- There is an "*internal contradiction*" within the DSD Regulations. While the Regulations accept that female athletes with DSD are female and that the IAAF has no power to determine otherwise, they also provide that a female athlete who does not meet the eligibility criteria can only compete internationally and set world records in male category events. The formal recognition of Relevant Athletes as female while simultaneously requiring them to compete as male unless they change their innate hormonal levels is hard to reconcile. It also leads to a "*mismatch*" between the objective pursued by the DSD Regulations (*viz.* determining eligibility criteria for female athletes without sex testing) and the ends established (*viz.* treating female athletes with DSD as males and thus determining that their sex is different to that which is stipulated by law). A South African court is therefore likely to find that the effect of the DSD Regulations is to sex test, notwithstanding the IAAF's formal disavowal of sex testing.

- The DSD Regulations differentiate on several legally protected grounds, namely sex, gender and birth. They also indirectly differentiate on the basis of race,

ethnicity and/or social origin, since they disproportionately affect women of colour and athletes from the Global South.

- If the differentiation is rational it is nonetheless presumed to be unfair under South African law. A court is likely to conclude that the DSD Regulations are unfair and, therefore, is "*very likely*" to conclude that they are unlawful.

- Further, the DSD Regulations limit the constitutional right to dignity since the implementation of the Regulations requires female athletes to undergo invasive medical examinations and, in some cases, to manage the biological effects of their DSD condition under threat of sanction. This is premised on an understanding that DSD are conditions that require treatment and correction, rather than an innate biological gift. The DSD Regulations send a clear message that DSD are unacceptable and must be suppressed in the athletic field, in favour of genetic homogeneity. They also undermine the achievements of female athletes with DSD by suggesting that any competitive advantage they have is unfair and unwarranted.

- The DSD Regulations also infringe other constitutional rights including the right to privacy and bodily integrity in a number of other respects. For example, the Regulations provide that female athletes will be investigated and subjected to assessment if officials have "*reasonable grounds*" for believing that they have elevated testosterone levels. However, those grounds are not spelled out; instead the matter is left to the subjective discretion of the officials concerned. This amounts to "*gender policing*" and "*others*" female athletes with DSD. Further, the Regulations compel athletes to submit to testing, medical examination, circulation of medical information and unnecessary medical treatment in circumstances where consent is not informed and freely given.

Ronald Katz

208. Ronald Katz is the founder and Chair Emeritus of the Institute of Sports Law and Ethics at the University of the Pacific. He is a practising attorney and has published various academic works on sport law and ethics. Mr. Katz provided an expert report addressing the likely approach of the US courts to a challenge to the DSD Regulations. In summary, Mr. Katz opined that the US courts would conclude that the DSD Regulations are invalid and unenforceable for the following reasons:

- The DSD Regulations are arbitrary and capricious because (a) they stereotype females in a way prohibited by the US Supreme Court; (b) they discriminate unlawfully on the basis of sex; and/or (c) the purported science supporting the DSD Regulations do not meet the standards of admissibility in the US courts.

- As a result of factors (a) and (b), the DSD Regulations are contrary to the public policies enumerated in the Civil Rights Act of 1964. As a result of (c), the DSD Regulations are also contrary to the public policy set out in Federal Rule of Evidence 702.

209. Mr. Katz explained that in his opinion the DSD Regulations engage in sexual stereotyping in two ways:

- First, Ms. Semenya and other women with endogenous testosterone concentrations of over 5 nmol/L are not permitted to compete against members of their own sex as they naturally are (i.e. without medical intervention) because their level of testosterone is not consistent with the stereotypically female level of endogenous testosterone.

- Second, what the IAAF terms the "*virilisation phenotype*" of females like Ms. Semenya does not conform to the stereotypical virilisation phenotype of a female.

210. Mr. Katz stated that such "*stereotypes*" cannot supply the factual basis for establishing a rational basis to the DSD Regulations. Accordingly, the DSD Regulations are arbitrary and capricious and a US Court would not permit their enforcement.

211. Further, Mr. Katz explained that even when sex discrimination is not based on sexual stereotyping, it is still prohibited in many contexts under US law. In particular, the fact that women like Ms. Semenya are subject to the DSD Regulations, while men are not, means that a US court is likely to prohibit the implementation of the DSD Regulations. In this regard, there is no rational connection between the publicly known and admissible facts relied upon by the IAAF and the content of the DSD Regulations. In particular, the IAAF has not explained by reference to public and admissible evidence why female variations in natural testosterone levels are treated differently from male variations in natural testosterone levels.

212. Mr. Katz went on to explain that US Federal Rules of Evidence set minimum standards for the admissibility of scientific evidence that, in his opinion, the IAAF would be unable to meet. In this regard:

- It is not in dispute that the key empirical data on which the DSD Regulations are based is flawed.

- The studies relied on by the IAAF are also "*rife with speculation*". For example, BG17 acknowledges that the studies do not identify any cause/effect relationship between testosterone and athletic performance. It nevertheless speculates about the cause for the correlation it purportedly identified.

- In addition, the BJSM refused to require the authors of BG17 or BHKE18 to release their data to enable independent replication, while BHKE18 is not a peer-reviewed study.

213. For all these reasons, Mr. Katz states that in his opinion the US courts would refuse to enforce the DSD Regulations.

Marie Demetriou QC

214. Marie Demetriou QC is a senior barrister practising at the Bar of England and Wales. She has extensive experience of UK and EU competition law, equality law, public and human rights law, and sports law.

215. Ms. Demetriou explained why she considers that the enforcement of the provisions of the DSD Regulations by UK Athletics (the governing body for athletics in the United Kingdom) would be vulnerable to legal challenge in the English courts on the basis of possible breaches of (a) the UK Equality Act 2010; (b) EU equal treatment legislation; (c) EU and UK competition law; and/or (d) the restraint of trade doctrine. In Ms. Demetrious' opinion, such a legal challenge "*would have a good prospect of success*" and would (if successful) preclude UK Athletics from giving effect to the DSD Regulations in England and Wales.

216. In support of these conclusions Ms. Demetriou explained why, in her view, the DSD Regulations give rise to direct sex discrimination for the purposes of both UK and EU law. In summary:

- The DSD Regulations apply to women and not to men;
- The DSD Regulations have the effect that women, but not men, are subject to medical testing in order to compete in international competitions; and
- Women who are found to have naturally occurring testosterone higher than a specified level must undergo medical treatment in order to be eligible to compete in international competitions. No such requirement applies to men.

217. Ms. Demetriou went on to explain that, to the extent that it is legally possible to justify direct discrimination, UK Athletics is likely to be able to establish a legitimate aim (*viz.* seeking to preserve a level playing field for athletics competitions within the female category). However, a claimant challenging the DSD Regulations is "*likely to have good prospects of demonstrating that the discrimination is not justified because of the serious implications for the rights of the individual athlete affected*". Ms. Demetriou qualified this observation, however, by commenting that since she had not seen the evidence relied upon by the IAAF to support the DSD Regulations, she was unable at this point in time to provide a conclusive opinion on the probability that an English court would find the DSD Regulations to be disproportionate.

Anand Grover

218. Anand Grover is a Senior Advocate of the Supreme Court of India. Mr. Grover provided an expert opinion concerning the susceptibility of the DSD Regulations to a successful legal challenge before the Indian courts.

219. In his expert report, Mr. Grover explained that in his opinion the DSD Regulations violate a number of rights protected under the Constitution of India, including the rights to equality; non-discrimination; freedom of expression and occupation; and dignity,

autonomy, privacy and health. In explaining these conclusions he stated among other things that:

- Female athletes who are subjected to the DSD Regulations will face "*grave implications*" if they do not submit to testing and comply with the specified eligibility conditions. Accordingly, it is "*misleading*" to suggest that it is the athlete's "*choice*" to undergo such assessment.

- Since the evidence base concerning the link between testosterone and athletic performance by female athletes is "*highly questionable*", the distinction between female athletes with ordinary levels of testosterone and female athletes with high levels of testosterone does not serve the objective sought to be achieved (namely ensuring fair competition). On the contrary, it reduces the opportunity for fair competition for female athletes with high levels of testosterone by disqualifying them because of a naturally occurring variation. Accordingly, the Indian courts would strike down the DSD Regulations as a violation of Article 14 of the Indian Constitution.

- The DSD Regulations are "*arbitrary and lack rigorous scientific basis*". In particular, the threshold of 5 nmol/L has been established on the basis of contested science and a study (BG17) which uses flawed statistics. In addition, there is a "*logical fallacy in ascribing traditional gender levels and expectations to body/sex determinants such as hormones*". Insofar as they selectively target female athletes based on the unfair advantage purportedly caused by high levels of natural testosterone, the Indian courts are likely to hold that the DSD Regulations are manifestly arbitrary and therefore contrary to the guarantee of equality under Article 14 of the Indian Constitution.

- Denying Relevant Athletes the opportunity to participate in Restricted Events at International Competitions on the basis of the level of natural testosterone or a DSD is contrary to Articles 1, 10 and 13 of the Convention on the Elimination of Discrimination Against Women (CEDAW). The Indian courts have "*read in*" various rights under CEDAW into the fundamental rights protected under the Indian Constitution.

- The DSD Regulations reproduce uncritically "*the language and ideology of biological determinism and gender essentialism*". The undertone of the DSD Regulations is that female athletes must not exhibit "*masculine*" traits or behaviours and, if they do, shall be penalised for this. The Regulations are also premised on an idealised notion of the female body, which is rewarded with inclusion and the right to participate. Accordingly, the Indian courts would find that the DSD Regulations engage in manifest "*sex-stereotyping*" which violates the right to freedom from discrimination under Article 15(1) of the Indian Constitution.

- The DSD Regulations have a disparate impact on athletes from the Global South. Female athletes who have been investigated for high testosterone levels are often from the Global South. Both the discourse regarding, and the verification of, Ms. Semenya's "*eligibility*" involves "*racialized and idealized judgments of black*

and brown female bodies' non conformity that emerged in the context of Western colonialism". In this regard, it is significant that the Restricted Events covered by the DSD Regulations are the ones in which female athletes from the Global South dominate.

Dr. Jameson Garland

220. Dr. Jameson Garland is a Doctor of Medical Law at Uppsala University in Sweden. He has previously been commissioned by the Council of Europe's Committee of Bioethics to undertake a review of the risks to children's rights in the field of biomedicine, including with reference to the rights of children with variations in sex characteristics. In his expert report on behalf of Ms. Semenya, Dr. Garland explained why in his opinion the DSD Regulations are "*contrary to both medical science and human rights*" and therefore should not be enforced.

221. In respect of "*Medical and ethical considerations*", Dr. Garland stated:

- There is no scientifically sound model for sex classification based on individual biological sex characteristics. The Global DSD Consortium has concluded, after a decade of reviewing scientific evidence, that there are no adequate data that support the inclusion or exclusion of persons from the categories of male or female on the basis of a single biological measure or characteristic. In this regard, there is "*certainly no established medical, scientific or legal practices that declassifies a person as female on the basis of a single characteristic, including on the basis of androgens or testosterone levels*".

- Excluding females with DSD from competing with other females on the basis of natural testosterone levels is both contrary to medical science and likely to contribute to a climate of hostility to children with DSD. It also reflects "*a disturbing history of subjecting persons born with variations of sex characteristics to degrading, harmful and medically discriminatory treatment*".

222. In respect of "*Legal considerations*", Dr. Garland stated:

- There is a broad international consensus among numerous human rights authorities that discrimination against individuals with variations in sex characteristics is contrary to international law. Various authorities have advocated legal restrictions against such discrimination, including the United Nations High Commissioner for Human Rights, the Parliamentary Assembly and the Commissioner for Human Rights of the Council of Europe, the European Union's Fundamental Rights Agency and the Inter-American Commission for Human Rights.

- The DSD Regulations single out females with DSD for exclusion from competition on the basis of a single biological characteristic. The Regulations do not appear to disqualify all "*non-intersex*" women who have atypical characteristics that might make them more competitive in sports (for example, differences in menstruation cycles or frequency, height, muscle mass etc.). It follows, therefore, that the DSD Regulations are "*discriminatory both by design*

and intent". It is likely that Member States of the Council of Europe will not be able to enforce the DSD Regulations, while the Regulations are also likely to violate national law in countries such as Sweden.

Relief claimed by Ms. Semenya

223. In her statement of claim, Ms. Semenya seeks the following relief:

> *269. Ms. Semenya respectfully requests that the DSD Regulations be declared invalid and void with immediate effect.*
>
> *270. In the alternative, if the Panel were to uphold the DSD Regulations, then Ms. Semenya submits that the Panel should grant a moratorium of at least seven months on the entry into effect of the Regulations. This will give time for the finding of the Panel to be published and disseminated worldwide and will give any potentially affected athletes the opportunity to take advice and decide whether to submit themselves to the procedures and treatment required by the DSD Regulations and give them sufficient time for compliance.*
>
> *271. Such further suspension will ensure that affected athletes will not be prevented from competing in Restricted Event at International Competitions despite being willing to comply with the requirements of the Regulations.*
>
> *272. Finally, Ms. Semenya requests the right to make submissions to the Panel on the issue of costs in accordance with R64.5 following the disposition of the arbitration on the merits.*

B. ASA

224. ASA's submissions, in essence, may be summarised as follows:

225. The IAAF relies on research papers using data derived from analysis of blood samples provided by athletes during doping control tests at the 2011 and 2013 IAAF World Championships in Daegu and Moscow. The athletes who provided blood samples at those World Championships had consented to the use of their samples for anti-doping testing. They were not told that their samples would be used for any other purpose and they did not consent to the use of those samples for research into the effect of testosterone levels on female athletic performance. It follows that the IAAF's use of the samples for that extraneous purpose was unethical, as it was not based upon the voluntary and informed consent of the individuals to whom the samples belonged.

226. ASA submits that the IAAF's use of the samples in these circumstances is unlawful under the law of Monaco, the law of the Republic of Korea and the law of the Russian Federation. The absence of informed consent taints the evidence and the results based upon it. In particular, the research relied on by the IAAF in support of its defence of the DSD Regulations is inadmissible before the CAS since consideration of that illegally obtained evidence would involve an unbearable contradiction with the notion of justice.

227. In support of this submission, ASA referred to Article 3 of the IAAF Constitution, the Fundamental Principles of Olympism, Articles 22 and 23 of the Constitution of Monaco,

Articles 7, 11, 22, 986 and 990 of the Monaco Code Civil, Article 8 of the ECHR, Articles 1, 2 and 5 of the Oviedo Convention, Articles 17.1 and 26 of the ICCPR, Articles 1, 10 and 13 of the Convention on the Elimination of all Forms of Discrimination against Women and Article 161 of the Convention on the Rights of the Child. ASA submits that the DSD Regulations engage the rights to dignity, privacy, bodily integrity and non-discrimination contained in these various instruments.

228. In respect of the connection between testosterone and female athletic performance, ASA submits that no systematic reviews have been carried out that provide evidence to support or reject the claim that increased testosterone levels enhance performance in female athletes. ASA had therefore instructed experts to carry out a systematic review of the current best evidence in relation to this issue. That systematic review found just two studies addressing the role of testosterone in enhancing track performance in elite female athletes. However, neither study was suitable for meta-analysis. ASA's experts had therefore concluded that there was insufficient evidence concerning the link between high testosterone and athletic performance.

229. Regarding the IAAF's reliance on analysis based on blood samples from the Daegu and Moscow Championships, ASA submits among other things that the lack of standardisation in blood sampling procedures at the championships means that the testosterone measurements are inaccurate and unrepresentative of the true position.

230. In respect of BG17, ASA submits among other things that:

- The authors admitted that their study did not permit any conclusions to be drawn regarding the existence of a causal relationship between differences in testosterone levels and athletic performance.

- There are various defects in the authors' approach to the analysis of statistics. For example, there was no formal study design and there was a mixture of dependent and independent data which made the authors' statistical methods inappropriate. Moreover, the paper contained many vague descriptions and there was a lack of descriptive data. There were also dramatic errors in the data cited in the paper as well as un-evidenced assumptions and important methodological omissions. The study has been widely criticised for its poor methodology and lack of scientific integrity.

- In view of these concessions and shortcomings, there is no credible scientific evidence to support the DSD Regulations.

- Further, even if the findings of BG17 were accepted, the paper does not demonstrate a performance enhancement in excess of 2%. The mean difference is in the range of 1.5%. Many simple interventions in training, nutrition or otherwise can yield significantly greater performance advantages than this.

231. ASA further submits that all three of the treatments capable of reducing testosterone levels – namely oral contraceptives, GnRH agonists and cyproterone acetate – have numerous potential side effects, some of which are serious and life threatening. At present there is neither scientific data nor consensus guidelines to instruct a clinician how to use any of these treatments safely to reduce testosterone to under 5 nmol/L and

to keep it consistently below that level. Moreover, many of the potential side effects could adversely affect athletic performance.

232. In addition, ASA submits that there are significant practical impediments to the implementation of the DSD Regulations. For instance, in athletes with PAIS it is unclear how it will be determined whether the individual has sufficient androgen sensitivity to engage the requirements of the DSD Regulations. Since there is presently no means for measuring androgen receptor sensitivity, it is likely that athletes will have to undergo visual inspection of their genitalia or other body parts. This is not, however, addressed in the Regulations.

233. Lastly, ASA submits that the findings of the BG17 are inconsistently reflected in the DSD Regulations. In particular, the 1500m and one-mile events have both been included within the list of Restricted Events despite the fact that no statistically significant performance advantage was found by BG17 in either of those events. Conversely, the hammer and pole vault events have both been excluded despite the fact that significant performance advantages (4.5% and 2.9% respectively) were found for these events in BG17.

234. ASA submits that the DSD Regulations are inherently unfair because they prevent female athletes from competing as females on the basis of a natural physical attribute that is no different in principle from an array of other physical, psychological, social and economic factors that bear upon athletic performance.

235. Further, ASA draws attention to various harms which will be caused by the DSD Regulations:

- Athletes will be put under pressure to conform to heteronormative standards of femininity.
- Athletes who undergo assessment and treatment under the DSD Regulations will not be freely consenting to doing so.
- Athletes who meet the definition of being a Relevant Athlete will bear sole responsible for continued compliance with the eligibility conditions. This places an unfair burden on athletes from humble backgrounds who are unable to afford the cost of the necessary treatment and monitoring.
- The DSD Regulations will result in stigmatisation of female athletes; serious damage to the self-esteem and gender-identity of female athletes with hyperandrogenism; female athletes having to undergo medical interventions without informed consent; and female athletes undergoing unnecessary and harmful medical procedures.

236. Accordingly, the DSD Regulations cause more harm than is reasonable in pursuit of their stated purpose and disproportionately interfere with the rights to human dignity, privacy and equality.

237. In its reply submissions responding to the IAAF's Answer, ASA submits that the IAAF's invocation of the concept of "*biological males*" is "*over-simplistic*" and an

example of exactly what the Panel in *Chand* had cautioned against. The IAAF's new position "*converts the DSD Regulations into a cover transgender regulation*". It treats women with certain conditions – most notably 5-ARD – as individuals who are "*female in name only*". Accordingly, the statement that the DSD Regulations are not intended to judge or question the sex or gender of any identity is "*mere lip service to the rights of those athletes*", since this is precisely what the DSD Regulations do. ASA submits that, as a result, the DSD Regulations are "*false and misleading*".

238. ASA characterises the IAAF's explanation for the decision to remove athletes with CAH from the definition of Relevant Athletes as "*most astounding*". This proposed change shows that there was no scientific basis to justify including such women in the scope of the DSD Regulations in the first place, yet this is what the IAAF did. As a result, the Panel should apply even greater scrutiny to the evidence relied on by the IAAF to justify the inclusion of the remaining DSD. In this regard, the IAAF has not adduced evidence of cases falling into the majority of categories of DSD listed in the DSD Regulations and has therefore failed to make out a case for why those DSD are included.

239. ASA submits that the evidence concerning the athletic advantage supposedly enjoyed by women with 5-ARD is flawed and does not address the questions posed in *Chand*. At the same time, there are "*no data*" before the Panel that women with any of the other listed DSD have any performance advantage over other females. ASA also points out that the category of DSD described in Reg. 2.2(a)(i)(G) ("*any other genetic disordered gonadal steroidogenesis*") is a blanket catch-all category devoid of any specific description. Given the seriousness of the consequences imposed by the DSD Regulations, the inclusion of such a non-specific category cannot be justified.

240. In support of its request for relief, ASA brought forward the following fact and expert witness statements and evidence:

a. Expert Witnesses

Professor Marc Blockman

241. Professor Marc Blockman is a Professor at the Department of Internal Medicine at the University of Cape Town and Groote Schuur Hospital. He is a specialist clinical pharmacologist and bioethicist. He holds various academic and professional posts, including serving as the chairperson of the pharmacovigilance expert committee and as a member of the clinical expert committee of the South Africa Medicines Control Council. He is an international consultant for the World Health Organisation and Chair of the University of Cape Town's Faculty of Health Sciences Human Research and Ethics Committee.

242. In his expert evidence Prof. Blockman addressed (a) the adequacy of the ethics oversight and conduct by IAAF researchers utilising blood samples obtained from elite athletes for non-doping related research; and (b) the "off-label" use of certain medicines to reduce testosterone levels in hyperandrogenic female athletes.

243. With respect to (a), Prof. Blockman stated:

- Participation in medical scientific research must be voluntary and predicated on informed choices.

- The research in question – which was concerned with analysing the effect of endogenous testosterone on athletic performance – had nothing to do with research into doping. It was therefore "*unacceptable*" for the authors of that report to proceed on the basis that the signed approvals given by each athlete when they provided samples for doping control at the relevant World Championships were sufficient to provide informed consent for their data to be used for purposes unrelated to doping testing.

- Instead, the nature of the previously obtained consent should have been determined in order to ascertain whether the athletes envisaged any subsequent usage of their data and, if so, whether the intended use fell within the scope of what was envisaged. Athletes whose samples were used for the purposes of research into the relationship between testosterone and athletic performance should have been given the opportunity to agree to the use of their data for this separate research purpose.

- Further, the IAAF's research is "*directed at one individual with hyperandrogenism who has been all over the media; and been subjected to world scrutiny*". It is unlikely that athletes would have permitted their data to be used for this "*punitive*" purpose had they been aware of it. The IAAF's researchers had therefore behaved in a "*misleading and deceptive*" way and their research was therefore "*unethical*".

- In conclusion, Prof. Blockman considered that the rights of the athletes whose data were used for the IAAF's research were infringed and therefore the publications and conclusions based on those data "*are unethical and should be discarded*".

244. Prof. Blockman next turned to address the ethical implications of the off-label use of medication to reduce testosterone levels in females with hyperandrogenism. He stated among other things that:

- Off-label prescribing of medication for healthy individuals requires a strong evidentiary basis in order to be ethically justified. Unless and until there are long-term data for the safety and efficacy of off-label use of medication to reduce testosterone levels of female athletes with hyperandrogenism, the practice is "*ethically unjustified*".

- The use of anti-androgens to treat hyperandrogenism can have potentially debilitating side effects for an athlete, such as excessive thirst, electrolyte imbalances, liver toxicity, headache, fatigue and insulin resistance.

- GnRH agonists have various possible adverse effects including convulsions, increased loss of bone mineral density (resulting in osteoporosis and bone fractures) and increased risk of cardiovascular disease.

- Combined contraceptive pills also have various possible adverse effects including a threefold to fivefold increase in the risk of developing VTE. This is a serious condition that can cause stroke and even death.

- Cyproterone acetate, finasteride and dutasteride all also have possible serious adverse side effects.

- Athletes with hyperandrogenism will not be able to provide properly informed consent to the off-label use of testosterone-suppressing medication because there is "*a dearth of data*" and, since their careers depend on being eligible to compete, any decision to undergo such treatment will inevitably be "*coerced*".

- The DSD Regulations may also promote doping by encouraging female athletes with testosterone below 5 nmol/L to use off-label medication to elevate their blood testosterone concentration to that level.

245. During his oral evidence, Prof. Blockman expanded upon his concerns regarding the effects of off-label prescription of medication in the context of the DSD Regulations. He stated that there was a risk that clinicians would commit malpractice by making off-label prescriptions to athletes affected by the DSD Regulations. Such athletes do not, in his view, have a clinical disorder that requires treatment. They therefore cannot properly be characterised as "*patients*". Prof. Blockman went on to explain why in his opinion such athletes are not truly able to provide informed consent. First, the DSD Regulations are "*coercive*" since they put pressure on athletes to do something that is harmful that they would not normally do. Second, there is an absence of clinical consensus concerning the relevant benefits and harms. This makes it impossible for clinicians to make a properly informed decision about whether to make an off-label prescription. In addition, there is a paucity of data concerning the use of oral contraceptives to reduce testosterone levels and there is no real understanding of the dosages required in order to lower testosterone to below a specified threshold. For these reasons, the DSD Regulations could not be safely and ethically implemented in practice.

Prof. Joel Dave

246. Prof. Joel Dave is the Head of the Division of Endocrinology at the University of Cape Town and Groote Schuur Hospital. He has held various academic and clinical posts, including acting for several years as the Chairperson of the South African Endocrine Society and of the Association of Clinical Endocrinologists of South Africa.

247. Prof. Dave began his expert report by explaining that multiple factors affect testosterone levels in men and women, with the three factors considered to have the greatest effect being (a) circadian rhythm; (b) menstruation; and (c) use of medication, particularly oral contraceptives. In order to obtain reliable measures of testosterone levels in women and men, each of these three factors needs to be standardised before blood samples are taken and analysed. In addition to standardising those three key factors, efforts must also be made to standardise as far as possible other factors that affect testosterone levels in individual athletes. Those factors include (i) type, duration and level of recent exercise; (ii) circannual variation; (iii) recent sexual activity; (iv) age; and (v) health.

248. Prof. Dave stated that the blood sampling procedures employed at the Daegu and Moscow World Championships did not adhere to the criteria established by the IAAF for collecting samples from athletes for the purpose of measuring testosterone levels. The lack of standardisation in the blood sampling procedures resulted in testosterone measurements "*that are not valid and not representative of many of the athletes' true level*" of testosterone.

249. In respect of the specific methodology used to measure serum testosterone at the Daegu and Moscow World Championships, Prof. Dave stated among other things that:

- Equilibrium dialysis is the "*gold standard*" for measuring serum free testosterone. Given the time-consuming and laborious nature of equilibrium dialysis, however, various formulae (such as the Sodergard and Vermeulen formulae) have been devised for approximating the level of free testosterone. The Sodergard and Vermeulen formulae have been validated for approximating the serum free testosterone in every day clinical practice. The formulae have not, however, been validated for approximating the serum free testosterone in elite athletes of varying ethnicities and ages.

- When applying these formulae, it is important to measure the levels of albumin and sex hormone binding globulin ("SHBG") in particular individuals, as these values may have a significant effect on the end result. The athletes who participated in the Daegu and Moscow Championships did not have their albumin levels measured. Instead, their albumin levels were presumed to be normal.

- In addition, while athletes' SHBG levels were measured, factors that affected levels of SHBG were not considered. It follows that the levels of free testosterone used in studies based on data derived from blood samples taken at the Daegu and Moscow World Championships "*are possibly inaccurate*" since it is unclear whether the SBHG was the true normal value for the individual athlete or a "*false*" value that was influenced by other factors which were not taken into consideration (e.g. use of medication, endocrine disorders, diet and body weight).

- In addition, factors that affected SHBG were not considered, despite the fact that these factors can significantly affect the levels of free testosterone predicted by the Sodergard and Vermeulen formulae.

250. Prof. Dave also provided expert evidence concerning the medications that can be used to lower testosterone levels. He explained that:

- There are three pharmaceutical agents that can be used to reduce testosterone levels, namely oral contraceptives, GnRH agonists and cyproterone acetate. All three agents have "*numerous potential side-effects, some serious and life-threatening*".

- There are currently no scientific data or consensus guidelines to instruct a clinician how to use any of these agents safely in order to reduce testosterone level in a woman to below 5 nmol/L and to keep it at that level.

- It is likely that high levels of each of the three agents will be needed in order to reduce testosterone to below that level, further increasing the risk of serious side-effects.

- The agents are not indicated for reducing testosterone to a target value. Accordingly, their use for this purpose will necessarily be "*off label*".

251. In respect of oral contraceptives, Prof. Dave further explained that:

- There are "*numerous*" potential side effects to use of the oral contraceptive pill. Serious potential side effects include increased risk of blood clots in veins and arteries; retinal vein thrombosis (a condition which affects the eyes); haemolytic uraemic syndrome (a condition which affects the blood and kidneys); pancreatitis; and erythema multiforme. Common side effects include headaches, abdominal pain, breast pain or tenderness, painful periods, vaginal infection, bleeding between periods, altered mood including depression or changed sexual appetite, nervousness, nausea and vomiting, weight loss or gain, rash, hair loss. Rarer side effects include changes to appetite, excessive body hair growth, exacerbation of varicose veins, heart attack, stroke, blood clots in the liver, liver or biliary disorders, worsening of immune system disease (lupus), ischaemic bowel disease and jaundice.

- Use of oral contraceptives can also adversely affect exercise performance by increasing body weight, increasing fat mass, decreasing VO2 peak, decreasing functional aerobic capacity and altering thermoregulation.

252. Prof. Dave provided a supplementary expert report in reply to the IAAF's evidence. He began by responding to the IAAF's assertion that athletes with 5-ARD are "*biologically indistinguishable from male athletes without a DSD*". Prof. Dave stated that:

- Testosterone is responsible for the normal development of the male testes and ejaculatory ducts. DHT is responsible for the development of the prostate and typical male external genitalia. In individuals with 5-ARD there is under virilisation of male external genitalia. Affected individuals are exposed to varying amounts of DHT in utero. Accordingly, there is phenotypic variability: the most virilised individuals may have hypospadias or micropenis, while in the most severe cases of 5-ARD the external genitalia appear as normal female genitalia.

- Masculinity and the feeling of being a male are determined by a combination of sex chromosomes, hormonal status, degree of virilisation, external phenotype, gender identity and psychosocial awareness.

- For a 46 XY athlete with 5-ARD to be "*biologically distinguishable*" from a male athlete without a DSD, both athletes would have to be equal in all respects

that determine "*maleness*". While both athletes have the same sex chromosomes and similar levels of serum testosterone, there are "*distinct differences*" in virilisation, external phenotype and gender identity.

253. Prof. Dave identified several specific factors that, in his view, make athletes with 5-ARD "*biologically different*" to male athletes without DSD:

- The majority of 5-ARD babies appear female at birth and are reared as females.
- Adolescents with 5-ARD experience significant masculinisation at puberty; however this is usually "*distinctly different*" to males without a DSD. In particular, individuals with 5-ARD have a smaller prostate, abnormal testes and less virilisation.
- Despite that masculinisation, many individuals with 5-ARD retain their female gender identity. This signifies "*significant differences in psychosocial awareness and brain "sex"*". It is likely that 5-ARD athletes who identify as females will have a different brain phenotype to males without a DSD.
- Athletes with 5-ARD who have been raised as females are likely to experience "*distinct differences in psychosocial development*" compared to male athletes without a DSD.
- In addition, DHT has a performance enhancing effect. Consequently, the lack of DHT in athletes with 5-ARD will place them at a disadvantage compared to those athletes who do not have a DHT deficiency.

254. In Prof. Dave's opinion, these biological differences "*are translated into a functional disadvantage*" which is evidenced by the fact that no 46 XY athlete with 5-ARD has ever achieved a performance that significantly approximates a performance achieved by a male athlete without a DSD. As matters stand, it has not been established that 46 XY athletes with 5-ARD are similar to males without DSD with respect to lean body mass, muscle size and muscle strength.

Prof. Mark Engel

255. Prof. Mark Engel is a Research Epidemiologist and an Associate Professor in the Department of Medicine at the University of Cape Town and Groote Schuur Hospital. Prof. Engel provided an expert report on behalf of ASA addressing the role of hyperandrogenism in improving athletic performance, with a focus on a thematic review of published studies.

256. Prof. Engel began his expert report by stating that while it has been suggested that increased testosterone levels in female athletes enhance athletic performance, no systematic reviews have been conducted to date to provide evidence to support or reject this claim. (A "*systematic review*" is "*a summary of research evidence in which bias has been reduced by the systematic identification, appraisal and synthesis of all relevant studies on a specific topic according to a predetermined and explicit method*".)

257. Prof. Engel went on to explain that in order to understand the available evidence, he had conducted "*a systematic review of the current best evidence for the role of hyperandrogenism in improving athletic performance*". To this end, he had employed keyword search terms to seek out all published studies of original data that included a comparison group and which assessed whether increased testosterone levels improve athletic track performance among female athletes.

258. Prof. Engel explained that of 23 articles identified by the search, no systematic reviews were found and just one article (BG17) fulfilled the inclusion criteria. In respect of the BG17, Prof. Engel noted however that:

- No data were supplied in respect of athletes who were excluded due to missing data.
- Information on menstrual status and phase were not provided.
- There was no indication of the times when samples were collected, which may affect testosterone levels.
- The inability to classify six samples may affect the overall results.
- There was no separate analysis of the effects of doping compared with endogenous testosterone.
- Data were duplicated in respect of 17.3% of athletes, who took part in both the Daegu and Moscow World Championships.

259. In conclusion, Prof. Engel stated that his systematic review identified only one study that addressed the role of testosterone in enhancing track performance of elite female athletes. Meta-analysis of published studies was "*unsuitable*" as a result of "*Heterogeneity in study design, and methodological concerns of potentially-includable studies*". Accordingly, Prof. Engel concluded that, "*there is insufficient evidence upon which to base fair policies and recommendations concerning hyperandrogenism in female athletes.*"

260. Prof. Engel submitted a further expert report in reply to the IAAF's evidence which set out his conclusions on the Handelsman Paper. In summary, Prof. Engel stated that Prof. Handelsman's review was apparently conducted for the purpose of providing evidence to justify the adoption of a new 5 nmol/L eligibility criterion. The Handelsman Paper "*fails to meet peer-review standards*", while the findings in the papers cited by Prof. Handelsman "*have limited generalizability to elite female athletes*". It is difficult to assess the risk of bias since the Handelsman Paper did not provide details of the search strategy and tables of included/excluded papers or criteria for inclusion and exclusion. It also failed to assess the quality of included studies. Consequently, the results of the Handelsman Paper "*must be interpreted in light of this paper failing to meet the peer-reviewed recommended standards for conducting a review*".

Professor Ariane Spitaels

261. Prof. Ariane Spitaels is a paediatrician and endocrinologist at the Faculty of Healthy Sciences, University of Cape Town. Prof. Spitaels provided an expert report on behalf of ASA in which she addressed the challenge of objectively measuring androgen sensitivity.

262. In overview, Prof. Spitaels explained that:

- Under the DSD Regulations, a female athlete who is assessed to have hyperandrogenism because of a DSD will be tested for androgen sensitivity and material androgenising effect.
- Androgen effect is mediated through the androgen receptor and post-receptor pathways. Female athletes with a DSD caused by disorders of androgen synthesis or sex determination have normal androgen receptors and do not require any assessment for androgen sensitivity and material androgenising effect.
- For female athletes with PAIS, however, there is no objective and precise means for measuring *sensitivity* to androgen. Nor is there an objective and precise means of measuring the *effect* of androgen on their bodies.
- All scales of masculinisation are visual and therefore involve subjective assessment. The scales do not measure androgen sensitivity. Genital appearance does not correlate with androgen programming elsewhere in the body. Further, appearance is not an acceptable measure as it is discriminatory. It is also not binary, but rather "*a spectrum with no clear delineation of female from male*".
- There is no scale of androgen sensitivity and effect that establishes an easily defined, objective and repeatable point at which a female athlete with a DSD moves from "*not sensitive enough to gain advantage*" to "*sensitive enough to disqualify*".
- In conclusion, it is not possible to define androgen sensitivity and effect in an objective, precise and reliable manner.

Professor Carl Lombard

263. Professor Carl Lombard is a biostatistician who has worked for more than 30 years at the South African Medical Research Council. Prof. Lombard provided expert evidence on behalf of ASA regarding statistical issues arising from the scientific evidence relied on by the IAAF.

264. Prof. Lombard began his expert report by noting that BG17 clearly states that no causality between female testosterone and athletic performance could be established from their study. The authors of BG17 also state that no other factors that could be linked to female testosterone and athletic performance were adjusted for in the analysis. Prof. Lombard went on to identify several "*shortcomings*" in BG17. For example:

- There was no formal study design. The absence of a formal study design is clear from the fact that no sample size calculations were provided to reflect the power of the study and the expected differences. Instead, this was simply a study using the available athletes and available data from two international events.

- The report was based on a mixture of dependent and independent data, with participants being evaluated across different times and different events. The only information concerning the mixture was that 17% of the athletes whose data were analysed competed in both the Daegu and Moscow World Championships. However, there is no information concerning multiplicity across specific events. The authors' failure to take account of the inherent correlation of data obtained from the same athletes leads to an overstatement of the significance of the correlations found by the study.

- The report also used statistical methods that, while adequate for exploratory analysis, were not appropriate statistical tools for the mixture of independent and dependent data present in the study.

- The report did not find any differences in female testosterone levels across the sporting groups. Accordingly, the tertiles used for comparative purposes should have been created across the pooled data of all participants, rather than on an event-specific basis. It is unclear whether this was done; it appears instead that tertiles were based on small group-specific event data of males and females.

- Similarly, the authors' approach of splitting the predictor into tertiles and then comparing performance between the lowest and highest tertile is adequate for exploratory analysis. However this approach results in a loss of statistical efficiency of between 10% and 20% for "*normal data*" (a loss which could be even higher in respect of "*non-normal*" data).

- The report contains "*many vague descriptions*" and very little descriptive data are provided. While some descriptive data are provided in respect of the 24 female athletes that had a testosterone level exceeding 3.08 nmol/L, no equivalent descriptive data or breakdown is provided in respect of female athletes with concentrations lower than this value.

- There is a concern regarding the extent of missing blood data. The extent and main reason(s) for the missing data are unclear.

- It is unclear whether a single measurement was taken from each athlete, or whether there was a repeat measurement following two hours of intense exercise. It is unclear how these criteria were checked in order to ensure standardisation.

265. In light of these above points, Prof. Lombard concluded that BG17 "*lacks scientific rigor*" and therefore "*any interpretation, conclusion or translation made of the findings should be considered bad science*".

Dr. Jeroen Swart

266. Dr. Jeroen Swart is the Head of the Sports & Exercise Management programme at the University of Cape Town and the Sports Science Institute of South Africa. He is also the Chair of the Scientific, Technical & Research Commission of the South African Sports Confederation and Olympic Committee.

267. Dr. Swart produced an expert report which examined the current scientific evidence concerning the relationship between serum testosterone concentrations and athletic performance. He began by summarising the existing scientific research concerning androgenic steroids and athletic performance by female sportspersons. According to Dr. Swart:

- Prior to 2010 only two studies had investigated the association between serum testosterone levels and explosive performance in female athletes. The first study by Cardinale and Stone (2006) found a positive correlation between testosterone concentrations and countermovement jump in 22 female athletes. The magnitude of the difference, however, was not quantified. The second study by Crewther and Christian (2010) measured salivary testosterone in four female Olympic weightlifters. It found no correlation between pre-exercise testosterone concentration and athletic performance.

- A review of the existing research concerning hyperandrogenism and athletic performance by Teetzel in 2014 found no conclusive evidence that any significant performance advantage existed.

- In 2014, Bermon *et al* conducted a study on testosterone levels in female athletes at the 2011 World Championships. The study found that median testosterone levels amongst the athletes was similar to that of non-athlete matched females. Three female athletes had testosterone concentrations exceeding 10 nmol/L. However, the highest performing athletes did not have higher testosterone levels than the non-athletes.

- In 2016, Sönksen concluded that the majority of the difference in lean body mass between males and females was due to non-specific genetic factors, but that other factors such as growth hormone contribute to these differences.

- In 2017, Eklund *et al* conducted an analysis of the relationship between athletic performance and androgenic steroids and precursors in 106 Swedish female athletes and matched female sedentary controls. Although the study identified correlations between steroid precursors and androgenic steroids, and between LBM and performance, it did not identify any correlation between testosterone concentration and either athletic performance or LBM. Further, the magnitude of the performance differences for the other steroids and precursors was not quantified, although in general the correlations were weak.

- In 2018, Betancourt examined data from Ms. Chand and Ms. Semenya and compared their performances to general performances in elite 200m and 800m races respectively. Ms. Semenya's results prior to her suspension in 2009 and

following her resumption in 2011 were found to be respectively 1.24% and 1.49% faster than the predicted performances for the 800m event. In Ms. Chand's case a lack of available data precluded analysis.

268. Dr. Swart went on to critique BG17. He stated:

- The Restricted Events covered by the DSD Regulations showed a maximum difference of athletic performance of 2% in respect of the highest and lowest tertiles of testosterone. The mean difference was just 1.57%. Accordingly, it is unclear how the authors of the report reach the conclusion that the range of performance enhancement is 1.8% to 4.5%.

- Two of the five events which demonstrated a statistically significant difference in performance between high and low tertiles for testosterone were not included in the scope of the DSD Regulations.

- Two of the five events where athletes were found to have a performance advantage related to testosterone demonstrated "*rather low testosterone concentrations*".

- Further, nine events demonstrated the opposite of the hypothesis proposed by the report's authors.

- Accordingly, 18 of the 21 events examined in the study do not establish a performance advantage associated with higher free testosterone while nine of those events in fact demonstrate a performance *disadvantage* associated with increased testosterone. Accordingly, the three events in which a statistically significant finding was established "*are clearly spurious false positives*".

269. Dr. Swart explained that subsequent papers had criticised BG17:

- Sönksen (2018) found that BG17 could only show association, not causality. It also noted that individuals with free testosterone in the highest tertile outperformed those in the lowest tertile in only five events. At the same time, individuals with testosterone in the lowest tertile outperformed those in the highest tertile in nine events. Accordingly, the majority of events found associations between lower testosterone and higher performance. In any event, however, comparing tertile groups with an unpaired testosterone test is statistically inappropriate and does not adjust for multiple comparisons.

- Meiner (2017) observed that before they undertook their analysis, the authors of BG17 did not identify a particular value as constituting "*high*" or "*normal*" testosterone. Accordingly, the study design did not enable a conclusion to be drawn regarding whether female athletes with "*high*" testosterone enjoy a competitive advantage over female athletes with "*normal*" testosterone.

- Pielke, Tucker & Boye (2018) attempted to recreate some of the data published by BG17. They were unable to replicate the results for the events which are being regulated by the DSD Regulations. The authors found that 32.8% of the data used by BG17 for the 400m event contained anomalies. Data concerning

other events to which the DSD Regulations apply also contained a high proportion of anomalies. As a result of these anomalies, the authors recommended that BG17 should be retracted.

270. Dr. Swart also identified various non-testosterone-related interventions which have an effect on athletic performance. For instance, he explained that:

- A paper by Thomson *et al* (2002) established that post-exercise ingestion of a beverage containing leucine improved sprinting performance by a margin of 2.5%.

- A paper by Peeling *et al* (2018) found that caffeine consumption resulted in increases in athletic performance of 3.8% (in endurance sports) and 4% (in sprint power). Further, combined use of caffeine and carbohydrates improved time trial performance by up to 10% compared to controls. In addition, other supplements such as creatine, nitrates and beta-alanine resulted in performance improvements of between 2% and 15% dependent on the particular form of exercise being undertaken.

- A paper by Levine and Stray-Gunderson (1997) found that a four-week stay at an altitude of 2.5km enhanced VO_2 max by an average of 5%.

271. In conclusion, Dr. Swart stated that:

- The DSD Regulations "*have not been based on the available scientific evidence*".

- Apart from BG17, none of the research specifies the degree of performance enhancement purportedly caused by androgenic anabolic steroids.

- BG17 "*has been widely criticized for its poor methodology and lack of scientific integrity*". A recent assessment of the study "*highlighted dramatic errors in the data incorporated in the study*" and "*called for its retraction*".

- Even if the results of BG17 are accepted, the paper fails to demonstrate a performance increase for elevated free testosterone concentration in excess of 2%, while the mean difference was in the range of 1.5%.

- Many simple interventions in sports training, nutrition or otherwise can result in significantly greater performance enhancement than that demonstrated by the existing research concerning elevated testosterone concentrations in female athletes.

Professor Ross Tucker

272. Professor Ross Tucker is an Adjunct Professor at the School of Management Studies at the University of Cape Town. Prof. Tucker provided an expert report addressing the issue of what constitutes an unfair advantage in the context of elite competitive sport.

273. Prof. Tucker began by opining that what constitutes an "*unfair advantage*" is "*to large degree philosophical*". One approach to athletes with DSD would be to contend that they have a performance advantage which derives from a source (*viz.* naturally high levels of testosterone) that renders their advantage "*unfair*". An alternative approach would be to compare the degree of the advantage attributable to that source with a typical margin of victory/defeat in the relevant event. This is the approach that Prof. Tucker's report considered. In particular, he examined data from previous elite level international athletics competitions to establish a typical margin of victory and then compared this to the performance advantage purportedly enjoyed by female athletes with hyperandrogenism.

274. Prof. Tucker analysed the margin between first, second and third place finishers in seven track events ranging between 100m and 1500m at 16 World Championships (from 1983 to 2017), seven Olympic Games (from 1992 to 2016) and 18 World Best lists (from 2001 to 2018). In total 574 performances were evaluated. This analysis revealed that:

- The average margin between first and second place was 0.57% to 0.60%. This average did not differ significantly when comparing men and women.

- Six outliers (i.e. outside the 99th percentile performance) were identified. Three of those performances were by one male athlete (Usain Bolt) whose margins of victory in the 200m were 3.42%, 3.23% and 2.90%. The other three were by Genzebe Dibaba (2.6% margin of victory in 1500m), Michael Johnson (2.57% margin of victory in the 400m) and Allyson Felix (2.43% margin of victory in the 200m).

- Ms. Semenya featured ten times in the 574 performances evaluated by Prof. Tucker. Her margins of victory ranged between 0.26% (at the 2012 Olympic Games) to 2.12% (at the 2009 World Championships).

- Ms. Semenya's average margin of victory was 1.03%. The performances ranged between -0.6 and 2.67 standard deviations from the mean. Accordingly, her average margin of victory was "*not a statistical outlier in comparison to the history of the track events*" analysed.

- Ms. Semenya's two most dominant results were more than two standard deviations greater than the mean, while one other performance was greater than one standard deviation from the mean. All her other margins of victory were either within one standard deviation (0.57%) of, or were lower than, the overall mean of 0.60%.

- Ms. Semenya's three most "*dominant*" victories ranked 11th, 14th and 56th in the 574 analysed performances. Two of those victories ranked outside the 95th percentile, while none were outside the 99th percentile. By way of contrast, Usain Bolt had three margins of victory outside of the 99th percentile, with another two between the 95th and 99th percentiles.

- Since a number of athletes with DSD have competed over the period of analysis, it appears that no athletes with DSD have enjoyed a margin of victory that could be characterised as an unfair or insurmountable advantage.

275. Prof. Tucker cautioned that the utility of comparing athletes' performance is limited by several factors For example, the margin of victory may be affected by extraneous factors such as injuries, fluctuations in the competitiveness of fields over time and weather conditions.

276. Nevertheless, on the basis of this analysis Prof. Tucker opined that the purpose of the DSD Regulations – namely to ensure fair competition – is not entirely supported by the available data, since whatever advantage that does exist does not put athletes with DSD in a position of "*insurmountable advantage*". In particular, in the last 35 years no athlete with a DSD has enjoyed an advantage that is either historically unprecedented, a significant outlier, or one that would be considered insurmountable compared to the advantage enjoyed by other athletes who do not have a DSD. Accordingly, he stated that it is "*questionable*" whether the purported performance advantage enjoyed by female athletes with DSD does create an unequal playing field. On the contrary, to justify the DSD Regulations then the performance advantage would need to be "*considerably larger*" than what the historical data appear to suggest is the case.

277. Prof. Tucker provided a further short expert report that responded to aspects of the IAAF's evidence. Prof. Tucker explained amongst other things that "*as a global determinant of performance, testosterone is clearly vital*". However it is "*much more difficult*" to identify a performance advantage attributable to testosterone with respect to a particular group of females or males. With respect to female athletes with DSD, Prof. Tucker considers that the IAAF's evidence regarding the alleged performance advantage caused by elevated testosterone is "*poor, inadequate and fails to meet the standards set out...in the Chand case*".

Prof. Steve Cornelius

278. Professor Steve Cornelius is the Head of the Department of Private Law at the University of Pretoria, the Co-Director of the Centre for Sports Law in Africa and an Advocate of the High Court of Australia. Prof. Cornelius provided an expert report on behalf of ASA that set out his opinion concerning (a) the legal implications if samples obtained for doping control purposes were used for research on hyperandrogenism without the consent of the athletes concerned and (b) the legality of the DSD Regulations.

279. Prof. Cornelius observed that athletes who provided blood samples at the Daegu and Moscow World Championships were apparently not notified that those samples would be used for any purpose other than the doping control programme. The athletes did not provide informed consent to the use of their samples in the research that led to the adoption of the DSD Regulations. This is not a trivial or technical matter, but rather "*a blatant disregard for any national and international laws that might be applicable*" and a "*flagrant disregard for the individual autonomy and fundamental rights of the athletes concerned.*"

280. Prof. Cornelius stated that the IAAF's use of blood samples without the necessary informed consent of the athletes who provided them violates the Monegasque law on the protection of individuals in biomedical research and the Monegasque law relating to the protection of nominative information. It is also a breach of the Republic of Korea's Bioethics and Safety Act and the Russian Federation's Federal Law of 21 November 2011 (N 323-FZ) and Federal Law of 27 July 2006 (N 152-FZ). In addition, he stated that evidence or results based on blood samples obtained without proper informed consent are inadmissible under Swiss law.

281. Prof. Cornelius went on to address the substantive legality of the DSD Regulations. He opined that the Regulations violate Article 5 of the Convention on Human Rights and Biomedicine by providing for medical intervention "*under duress*". He also considered that the Regulations violate Article 17.1 (right to privacy) and Article 26 (equality before the law) of the International Covenant on Civil and Political Rights; Articles 1, 10 and 13 of the Convention on the Elimination of all Forms of Discrimination against Women; and Article 16 of the Convention on the Rights of the Child. Monaco has ratified all of these international legal instruments. Accordingly, Prof. Cornelius stated that it was "*inconceivable*" that a Monegasque court would uphold the validity of the DSD Regulations.

282. Prof. Cornelius provided a short reply expert report dated 1 February 2019. In that report he stated that:

- The IAAF's suggestion that Monegasque law applies only subsidiarily is misconceived. The IAAF does not have any regulatory authority save what is granted and permitted under Monegasque law. Therefore, the primary source for determining the legality of the DSD Regulations is Monegasque law.

- The IAAF does not contest ASA's submission that the DSD Regulations violate Article 22 of the Monegasque Civil Code. Nor does it contest ASA's submission that the research on which it relies violates various provisions of Monegasque legislation.

- The IAAF's submission that using legal sex to determine classification in athletics does not work in all contexts does not permit the IAAF to establish its own basis for determination of sex for the purposes of athletics. Article 31 of Monegasque law No. 1,448 of 28 June 2017 on Private International Law provides that the status and capacity of persons are governed by the law of the state of which such persons are nationals. For these purposes status and capacity includes sex and gender. As a result, an athlete's sex and gender can only lawfully be determined in accordance with the law of the nationality of the athlete. It follows that the IAAF cannot avoid the fact that different jurisdictions adopt different definitions of gender and sex.

- The IAAF's suggestion that affected athletes have a free choice whether to comply with the DSD Regulations ignores the fact that there are presently some athletes who have been eligible for at least a decade to participate in international sport, who must now forfeit that right to particulate or subject themselves to

treatment mandated by the DSD Regulations. This is undoubtedly coercive and does not constitute a free choice.

Relief claimed by ASA

283. In its statement of claim, ASA sought the following relief:

165 It is submitted that a proper case has been made out for an order declaring the DSD Regulations invalid and void. ASA reserves the right to make submissions to the panel in relation to the issue of costs that should follow the result upon disposition of the matter.

C. The IAAF

284. The IAAF's submissions, in essence, may be summarised as follows:

285. The IAAF began its written submissions by contending that the arguments advanced by Ms. Semenya and ASA do not engage with the facts at the heart of the case. Those facts demonstrate that the DSD Regulations are "*an extremely progressive and fair compromise*" between, on the one hand, the right of female athletes to compete separately from men so that they have the same opportunity to excel, and, on the other hand, the desire of "*certain biologically male athletes with female gender identities*" to compete in the female category of competition.

286. The IAAF submits that the DSD Regulations are based on a strong scientific, legal and ethical foundation. The Regulations establish a framework governing the eligibility of 46 XY DSD athletes to compete in the female category that is logical and rational and fully respects the requirement that like cases should be treated alike and different cases should be treated differently. They respect the gender identity and dignity of affected athletes while simultaneously protecting the right of female athletes to fair and meaningful competition.

287. The IAAF identifies various points which it contends are (or should be) common ground:

- The IAAF is both entitled and required to provide male and female athletes with an equal chance to excel in elite-level athletics.
- The substantial physical advantages that males have over females mean that the very best male athletes beat the very best female athletes by around 10-12% in track events, while thousands more of the next best male athletes also beat the very best female athletes (albeit by a smaller margin).
- Exposure to higher levels of circulating testosterone is the primary cause of the physical advantages that account for the sex difference in sport performance. It results directly in men having bigger and stronger bones, 18% larger and stronger muscles, and 12% more serum haemoglobin ("HGB"), than women.

- In light of this, the only way to enable female athletes to have an equal opportunity to excel is to have separate categories of competition, so that they do not have to compete against adult male athletes.

- For these reasons, in *Chand* the CAS Panel held that it is "*legitimate and necessary to divide athletes into male and female categories*" in order to safeguard the right of female athletes "*to engage in meaningful competition by competing on a level playing field*". The Panel added that 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.*" The criteria employed to this end must be objective and relevant.

288. The IAAF submits that while using legal sex as a proxy for the male-female divide in competitive athletics mostly works well, there are two situations where it does not:

- First, where an individual has male chromosomes (i.e. XY, not XX), male gonads (i.e. testes, not ovaries) and adult male levels of circulating testosterone – and therefore has all of the biological advantages that biological males have over biological females – but has a female legal sex and/or a female gender identity (i.e. male-to-female transgender).

- Second, where an individual has 5-ARD and therefore has male chromosomes (XY), male gonads (testes) and adult male levels of circulating testosterone, but their external genitals may not have been fully masculinised. While many individuals falling in this category are given a male legal sex, some are assigned female sex at birth and have a female gender identity.

289. The IAAF states that while it fully supports the right of individuals to be accepted on the basis of their chosen legal sex and/or gender identity, and while it wishes to support athletes to participate in sport on that basis as far as possible, "*there are some contexts where biology has to trump identity*". In this respect, the IAAF submits that the evidence is clear that athletes with 5-ARD have a significant performance advantage when they compete in the female category. In particular:

- Approximately 1 in 20,000 of the general population have a 46 XY DSD. In elite women's competition, however, the proportion is approximately 7 in 1,000 – a prevalence that is 140 times higher. This is strong evidence of a performance advantage.

- Athletes with 5-ARD are "*biologically...the same in every material respect as male athletes without DSDs*". In particular, they have the same chromosomes, which produce the same gonads (i.e. testes) that produce the same adult male level of serum testosterone, which has the same virilising effect on the body. They therefore experience "*exactly the same*" increases in bone and muscle size/strength and levels of HGB as males without DSD experience.

- Because they are "*biologically indistinguishable...in all relevant respects*", athletes with 5-ARD experience the same ergogenic effect from these physiological changes as males without DSD experience. The only material physical difference between 5-ARD athletes and male athletes without DSD is "*the size and shape of their external genitals*", which has no impact on athletic performance.

- While no 5-ARD athlete has yet won a women's event by a margin of 10-12%, this fact has nothing to do with their condition. Rather, it reflects the fact that, "*the particular [5-ARD] athletes we have seen thus far are not as good as the best males. Like many other (non-elite) males, they still beat the very best biological females, just by a smaller margin.*"

- Accordingly, as long as males and females compete separately for reasons of fairness, eligibility to compete in the women's category must be based on the relevant differences between biological males and biological females. In this regard, while in contexts that have nothing to do with sex-specific traits, "*it does absolutely no harm and only good to ignore these traits and instead to sort individuals according to their identity*", the position is different in contexts where sex-specific traits are "*outcome determinative*".

- The requirement to treat like cases alike and different cases differently requires 5-ARD athletes to be treated in the same way as male athletes without DSD and as transgender male-to-female ("MTF") who have not undergone hormone treatments or gonadectomy. The contrary approach (i.e. permitting 5-ARD athletes and transgender MTF athletes to compete in the female category simply because they have a female legal sex or gender identity) is both arbitrary (because gender identity is fluid and legal sex is also becoming fluid) and irrational (because it disregards the reasons why it is necessary to have separate competition categories in the first place).

290. Drawing on the expert scientific evidence, the IAAF submits that:

- A marked difference in serum testosterone levels between men and women emerges at the same time as the sex difference in sport performance emerges.

- The sex difference in serum testosterone levels causes the male physical advantages that drive the sex difference in sports performance.

291. In respect of the latter point, in addition to the scientific evidence provided by the IAAF's expert witnesses, the IAAF refers to a joint statement recently published by 42 leading sports science and sports medicine scientists concerning the role that testosterone plays in athletic performance. (The text of the statement is set out below.)

292. The IAAF states that unlike in *Chand*, the present case "*is not about biological females and how their bodies respond to testosterone; it is about biological males with 5-ARD (and other 46 XY DSDs), how their bodies respond to testosterone, and the performance advantages of that response when they compete against biological females*".

293. In its submissions on the law, the IAAF contends that:

- The Claimants have the burden of establishing that the DSD Regulations are invalid.

- The IAAF is a private body, not a state body. It is therefore not subject to human rights instruments such as the UNDHR or the ECHR. The IAAF has, however, committed itself to the principle of equal treatment and non-discrimination.

- The commitment to equal treatment is what mandates the creation of a female-only competition category, on the basis that the biological differences between men and women mean that this is the only way of guaranteeing female athletes an equal opportunity to excel and to access the social and other benefits that elite sport can provide.

- Anti-discrimination laws in the US, UK and Australia recognise the need for positive discrimination in favour of biological females in the context of competitive sport and make express provision allowing female "*set aside*" in sport. The Australian legislation extends this to DSD athletes by stipulating that nothing in the statute "*renders it unlawful to discriminate on the ground of sex, gender identity or intersex status by excluding persons from participation in any competitive sporting activity in which the strength, stamina or physique of competitors is important*".

- Nothing in the applicable law makes it unlawful for the IAAF to exclude 46 XY DSD athletes from the female category of athletic competition on the basis that their biological advantages make their inclusion unfair.

- In any event, even if the DSD Regulations did prima facie discriminate between "like" cases (which the IAAF denies), the right to equal treatment may lawfully be restricted where the differential treatment is necessary, reasonable and proportionate to the achievement of a legitimate objective. That is the case here.

294. The IAAF submits that the DSD Regulations do not give rise to any improper discrimination. As a result, the Claimants' challenges to the DSD Regulations fall at the first hurdle and there is no need for the Panel to consider the issues of necessity or proportionality.

295. The IAAF submits that unlawful discrimination occurs when like cases are treated differently without any objective justification. However, if people are objectively different in relevant ways, then different treatment may be necessary in order to secure fairness and equality. The concept of "*likeness*" must be determined by factors relevant to the context. In the context of competitive sport, athletes' size, power and endurance are outcome-determinative. Accordingly, in order to fulfil its commitment to ensure that female athletes have the same opportunity as males to excel, the IAAF must address "*the fact that biologically 5-ARD (and other 46 XY DSD) athletes are identical to male athletes, and fundamentally different from female athletes, in the one trait that drives the sex difference in sport performance and therefore necessitates division of competition into sex categories*". In other words, the IAAF is required "*to prioritise biology over gender-identity*".

296. In this regard, the IAAF contends that since 5-ARD athletes are "*biologically identical*" to male athletes (save with respect to virilisation of external genitals) they derive performance benefits from their physiology that are indistinguishable from the advantages derived by male athletes. It follows that since it is testes and testosterone that give rise to the need for separate male and female categories in the first place, "*treating like cases alike and different cases differently means it is objectively justifiable to treat 5-ARD athletes differently from biological female athletes*". Just as it is unfair for a female athlete with ovaries to have to compete against a male athlete with testes that produce 15 times more performance-enhancing endogenous testosterone than she does, equally it is not fair for that female athlete to have to compete with a 5-ARD athlete with those same physical traits. Accordingly, treating like cases alike and different cases differently means requiring 5-ARD athletes who wish to compete in the female classification in Restricted Events to reduce their endogenous testosterone levels down from the adult male range to below 5 nmol/L in order "*to remove or at least to minimise as much as possible those ergogenic advantages*".

297. Conversely, it would be irrational and arbitrary to treat 5-ARD athletes in the same way as 46 XX female athletes simply because they have the same legal sex and/or gender identity. Legal sex and gender identity each have no bearing on athletic performance. Nor do the appearance of the external genitals. Levels of serum testosterone, on the other hand, do have such a bearing. In particular, 5-ARD individuals have all the ergogenic physiological advantages of high testosterone levels that adult males have, irrespective of their natal or legal sex, their gender identity or the appearance of their genitals. It follows that allowing individuals to participate in the female category simply on the basis of their legal sex or gender identity would not deliver the protection from unfair competition that the broad class of female athletes is entitled to.

298. The IAAF further submits that there are clear and objectively justifiable reasons why the DSD Regulations treat 46 XY DSD differently from other natural physical characteristics that also have an ergogenic effect (e.g. height and lung capacity). Specifically:

- Athletics does not have different competition categories for variations in height, lung capacity etc. because it does not consider that those biological differences make it unfair for such athletes to have to compete against each other, nor does it consider that the variations undermine or detract from "*the essential characteristics that are valued by the sport of athletics*". Rather, those variations are regarded as aspects of "*the natural talents that are celebrated in sport, that (together with commitment and courage) make competition meaningful and compelling).*"

- In contrast, sport does consider that competition between men and women is not fair or meaningful because men's testes produce 15 times more testosterone than women's ovaries produce, triggering physiological changes that provide insurmountable physical disadvantages. That difference is not "*celebrated*"; rather, separate male and female classifications have been established in order to obviate it.

299. For all these reasons, the IAAF submits that the DSD Regulations do not give rise to any improper discrimination.

300. In any event, the IAAF submits that even if the DSD Regulations do discriminate, the restrictions they impose are necessary since without them biological females would be denied the same opportunities as male athletes to reach finals and win championships.

301. The IAAF contends that the broader the restriction that is imposed by a particular measure, the stronger the justification that is required. In this respect, the DSD Regulations are "*dramatically*" different to the Hyperandrogenism Regulations which they replace. Specifically:

- The DSD Regulations do not apply to non-international competitions.
- The DSD Regulations only apply to a narrow selection of track events at international competitions, which have been selected on the basis that they are the events where the greatest performance-enhancing benefits are derived from elevated levels of endogenous testosterone.
- The DSD Regulations only apply to athletes who have one or more of 5-ARD, 17β-HSD3 deficiency, PAIS or another genetic disorder involving disordered gonadal steroidogenesis. They do not apply to other conditions such as PCOS.
- Under the DSD Regulations, the benefit of any doubt concerning the degree of an athlete's androgen sensitivity is resolved in favour of the athlete.
- Under the DSD Regulations, Relevant Athletes who do not wish to reduce their serum testosterone levels are not excluded from participating in the sport of athletics; nor are they excluded from the female category. On the contrary, they may still compete in the female category in any event at non-international competitions and in any non-restricted event at international competitions. Alternatively, they may compete without any restriction in the male category in any event at any level of competition, or they may compete in any "*intersex*" category that the event organiser may offer.
- Under the DSD Regulations, the IAAF no longer makes any distinctions among athletes who are all biological females. Instead, the Regulations only distinguish between "*biological females on the one hand and biological males with DSD on the other*".

302. In light of these factors, the IAAF submits that the "*very narrow*" restrictions imposed by the DSD Regulations do not exceed what is necessary in order to achieve equality of opportunity between male and female athletes, and are therefore proportionate.

303. In this connection, the IAAF submits that both civil law and common law legal systems afford sports bodies a significant margin of appreciation in determining what is necessary and proportionate to achieve their legitimate objectives. Accordingly, the IAAF must decide what is necessary and proportionate to achieve its aims on the basis of an honest and good faith view that has a reasonable basis. As long as that test is met, it is irrelevant that others may disagree with that view, or may cite other contrary

scientific evidence. Rather, in order to succeed in their challenge, the Claimants must establish that a reasonable person acting in good faith could not hold the view that the DSD Regulations are necessary and appropriate to achieve the IAAF's legitimate objectives.

304. The IAAF contends that the evidence it relies on clearly meets both the reasonableness and good faith standards. There is a "*very broad*" scientific consensus, founded on a substantial body of interventional and observational evidence, in favour of the principles that underpin the narrow restrictions contained in the DSD Regulations.

305. The IAAF submits further that the DSD Regulations deliver a number of important benefits. First, by protecting female athletes racing over 400m to a mile from unfair competition, the DSD Regulations:

- give effect to the IAAF's commitment to give female athletes the same opportunities to excel and profit from the sport as male athletes;
- facilitate fair and meaningful competition within the female category, in which the outcome of events is determined by "*talent, dedication, hard work, and the other values and characteristics that the sport values and presents*"; and
- enable society more generally to benefit from the numerous social goods (e.g. development of leaders and creation of inspirational role models) that are achieved when women are able to excel in sport.

306. Secondly, the DSD Regulations help DSD athletes from countries that lack developed healthcare systems to identify and understand their conditions and to provide them with options to address some of their symptoms (should they wish to do so). The DSD Regulations also establish opportunities to detect serious medical conditions such as tumours that need urgent medical intervention.

307. Lastly, the IAAF submits that the DSD Regulations facilitate the ability of DSD athletes to compete in their chosen gender identity, subject only to a requirement to reduce their testosterone levels in "*very narrow circumstances*", where this is clearly necessary to protect fair competition.

308. In addition to the benefits summarised above, the IAAF notes that the protective features contained in the Hyperandrogenism Regulations have been retained and in some cases supplemented with further protective features in the DSD Regulations. For instance:

- The DSD Regulations expressly confirm that the Regulations do not involve any judgment on, or questioning of, an individual's sex or gender identity.
- The DSD Regulations confer exclusive jurisdiction on the IAAF in respect of all cases arising under the Regulations (including those that concern athletes who have not yet competed at international level). All cases will be handled confidentially by the IAAF Medical Manager.
- The DSD Regulations expressly emphasise that no athlete will be compelled to undergo any assessment or treatment under the Regulations, and that it is the

athlete's responsibility to decide whether to proceed with any such treatment/assessment.

- The guidelines for assessment of cases under the DSD Regulations now incorporate the 2016 update to the 2006 Consensus Statement on Management of Intersex Disorders.

- The DSD Regulations contain a new provision concerning the appointment of an independent ombudsman to assist the affected athletes in understanding the Regulations and the options available to them.

- Although "*not advertised*" by the IAAF, it has historically "*tended to bear some of the costs of treatment*" in cases arising under the predecessor to the DSD Regulations and "*would be likely to continue to do so, on a case by case basis*" in future.

- The DSD Regulations expressly provide that they will be kept under review and that changes will be considered in order to take account of any new evidence or relevant scientific/medical developments.

- The DSD Regulations contain an express mechanism for affected athletes to challenge the legality of the DSD Regulations and/or to appeal a decision imposing special eligibility requirements before the CAS.

309. In response to the Claimants' arguments concerning the likelihood that affected athletes will be stigmatised by the DSD Regulations, the IAAF submits that no such stigmatisation should arise if cases are kept strictly confidential (as the IAAF has always done in the past). The IAAF rejects the suggestion that the DSD Regulations will encourage witch-hunts against athletes whose appearances do not conform to gender stereotypes. In particular:

- The DSD Regulations provide that the only person who may open an investigation is the IAAF Medical Manager, who may only do so when acting in good faith and on reasonable grounds based on information derived from reliable sources.

- Everyone who provides information to the IAAF Medical Manager is under an obligation to ensure the information is accurate and complete and must not provide information "*in bad faith, to harass, stigmatise or otherwise injure an athlete, or for any improper purpose*".

- The DSD Regulations further provide that any breach of confidentiality or incident of abuse or harassment will be considered a serious breach of the IAAF Integrity Code of Conduct.

- The DSD Regulations also expressly state that no stigmatisation or improper discrimination on grounds of sex or gender identity will be tolerated and that "*persecution or campaigns against athletes simply on the basis that their appearance does not conform to gender stereotypes are unacceptable*".

Accordingly, it is absolutely clear that stereotypes about femininity will play no role in decision-making under the Regulations.

310. The IAAF also strongly rejects the contention that the DSD Regulations force affected athletes to undergo surgery or harmful medical treatment:

- The claim that the IAAF previously required athletes to undergo genital surgery as a condition of eligibility to compete is "*a lie*".
- In regular clinical medicine, gonadectomy or hormonal treatment to reduce testosterone levels are the recognised standard of care for individuals with 46 XY DSD. This shows that such treatment does not constitute "*torture*" or present unacceptable health risks.
- The IAAF has consulted doctors with extensive experience of dealing with DSD cases. Those experienced clinicians are not aware of any evidence that lowering the serum testosterone levels of DSD athletes to the normal female range has any significant harmful health consequences for those individuals.
- It is simply untrue to suggest that affected athletes have no choice but to undergo treatment if they wish to continue competing in the sport. If they do not wish to suppress their serum testosterone levels, they may still compete in the female category in all events at any level, save only for the handful of Restricted Events at international level. In this regard, no athlete has a right to compete (still less to win) in international level sport unless they respect the eligibility rules. Requiring acceptance of those rules as a condition to participation does not vitiate consent.

311. In conclusion, the IAAF submits that the DSD Regulations have a strong scientific, legal and ethical foundation. They respect gender identity while also acknowledging and addressing essential biological facts. The Regulations protect the personal dignity of individual athletes and the right of all female athletes to fair and meaningful competition. In the absence of the DSD Regulations, the divide between the male and female categories would be policed by legal sex or self-declarations of gender identity, thereby denying female athletes an equal chance to excel in sport.

312. In support of its request for relief, the IAAF adduced the following evidence:

Dr. Stéphane Bermon

313. Dr. Stéphane Bermon is the Director of the IAAF's Health and Science Department. He is also a medical advisor for the Union Internationale Motonautique and the International Bobsleigh and Skeleton Federation. Between 2006 and 2014 he was a member of the IAAF's Medical and Anti-Doping Commission. In 2015, Dr. Bermon gave evidence on behalf of the IAAF before the CAS in *Chand*.

314. In the present proceedings, Dr. Bermon provided a detailed witness statement on behalf of the IAAF in which he explained the background to, evidential basis of, and rationale

for the DSD Regulations, and responded to a number of criticisms of the DSD Regulations made by the Claimants' witnesses and experts.

315. Dr. Bermon began his witness statement by discussing the need for separate male and female categories in competitive athletics. He explained that the average difference between male and female world records for the same athletics events is 11.7%. This "*enormous gulf in competition*" makes competition between male and female athletes as unfair as a fight between a heavyweight boxer and a flyweight boxer. He illustrated this by explaining that in 2018 the longstanding female world record for the 800m event was matched or surpassed more than 7,000 times by some 2,350 male athletes. Accordingly, if men and women did not compete in separate categories then male athletes would win all prizes and scholarships on offer, deterring females from participating in competitive athletics at all. It is therefore essential to have separate female and male categories to ensure females can compete on a level playing field.

316. Dr. Bermon stated that there is "*no debate*" among experienced sports scientists that the main reason for males' superior athletic performance is the fact that following puberty men are faster, stronger and taller than women and have greater reach and leverage and a greater muscle-to-weight ratio. These advantageous physical characteristics are mainly caused by the vastly higher levels of testosterone that males' testes start to produce from puberty onwards, which boosts accretion of lean body mass, reduces fat mass and stimulates an increase in the number of red blood cells. Females do not experience that huge increase in circulating testosterone because they have ovaries rather than testes.

317. Dr. Bermon stated that he was "*astonished*" that the claimant's experts in *Chand* had disputed the existence of a sex difference in circulating testosterone. The evidence clearly demonstrates that there is a "*striking dimodal distribution*" in the circulating testosterone levels of adult women and men. The normal adult male range is 7.7 to 29.4 nmol/L, while the normal adult female range is just 0.06 to 1.68 nmol/L. It is this difference that accounts for the physiological differences that cause the difference in athletic performance between men and women.

318. Dr. Bermon went on to discuss the "*conundrum*" presented by 46 XY DSD athletes. He explained that in rare cases a baby with a male karyotype (XY) will have normal male gonads (testes) but due to an enzymatic disorder such as 5-ARD or PAIS the process by which foetal tissue is triggered to produce the external male genitals is disrupted, meaning that the baby's testes remain undescended and the external genitals develop into an ambiguous or female appearance. This can result in the baby being assigned a female sex at birth and being raised with a female gender identity. Upon reaching puberty, however, their testes will then produce the same 15-fold increase in testosterone as males without DSD produce. They will therefore have serum testosterone in the normal male range (7.7 to 29.4 nmol/L) with the same virilising effect in males without DSD. If that person retains their female legal sex/gender identity, the question then arises as to whether they should be eligible to participate in the female category.

319. Dr. Bermon went on to explain that the IAAF wishes both to be inclusive as possible and to respect athletes' dignity, privacy and gender identity. Accordingly, it does not

wish to exclude 46 XY DSD athletes with a female gender identity from participating in the female category of competition (just as it does not wish to exclude 46 XY male-to-female transgender athletes from participating in the female category). At the same time, however, the IAAF is obliged to safeguard fair competition in that category. To this end, it cannot ignore the fact that 46 XY DSD athletes have testes that produce the same adult male levels of testosterone that males without DSD produce, which is what creates the need for the separate male/female categories in the first place. In this regard, Dr. Bermon stated that, "*the only biological difference between androgen-sensitive 46 XY DSD athletes and males without DSDs is (or may be) the appearance of their external genitalia*" – something that has no effect on athletic performance.

320. Dr. Bermon stated that individuals with 46 XY DSD are around 140 times more prevalent among elite international athletes than among the general female population. (He illustrated this by explaining that at the 2017 IAAF World Championships in London, at least [...] out of 958 female athletes had a 46 XY DSD.) According to Dr. Bermon, this statistical overrepresentation of 46 XY DSD individuals constitutes clear, albeit indirect, evidence of the performance enhancing effect of adult male levels of circulating testosterone.

321. Dr. Bermon provided a table in his expert report which contained details of [...] female athletes who had (or were likely to have had) a 46 XY DSD. He observed that [...]% of those athletes compete(d) in track races between 400m and 800m. This indicated that these are the events where 46 XY DSD athletes derive the greatest performance enhancing benefits from their elevated levels of endogenous testosterone. He added, however, that many female 400m or 800m athletes also regularly compete in other races over 600m, 1000m, 1500m and a mile because "*aptitude for one [event] will lend itself easily to the others*". In this regard, he cited various statistics demonstrating the extent to which female athletes have successfully "*doubled up*" by performing competitively in both the 800m and 1500m events.

322. Dr. Bermon went on to explain how performance data demonstrate that female athletes with 46 XY DSD are "*hugely over-represented*" in top performances across various athletics events. For instance:

- [...]
- [...]
- [...]
- [...]
- [...].

323. Dr. Bermon next discussed the reasons why higher levels of circulating testosterone lead to increased athletic performance. He explained that testosterone is erythropoietic, which means that it causes the body to produce more erythrocytes and thereby to produce more of the protein HGB. This protein, in turn, has a clear performance-enhancing effect. In particular, oxygen dissolves in blood by binding to HGB within red blood cells. The higher the level of HGB in blood, the more oxygen is dissolved in the

blood. The more oxygen that is carried by the blood to the muscles, the better an athlete is able to perform. In this connection, Dr. Bermon explained that a comparison of (i) three 46 XY DSD elite athletes, (ii) three elite male athletes, (iii) three elite female athletes with no DSD and no suspicion of doping, and (iv) three elite female athletes without DSD who were known to be doping with EPO, showed that the 46 XY DSD athletes had:

- significantly higher HGB concentrations than the non-doped female athletes; and
- similar average HGB concentrations to the male athletes and the female athletes who were known to be doping with EPO.

324. Dr. Bermon stated that the best way of gauging the effect of elevated testosterone levels on athletic performance is to compare the respective performance of 46 XY DSD athletes when their serum testosterone levels are suppressed and not suppressed.

325. Dr. Bermon proceeded to provide a detailed analysis of the decrease in athletic performance observed in four 46 XY DSD athletes following the commencement of testosterone-suppressing medical treatment. He observed that the changes in performance, which ranged from 5.7% to 7.8%, constituted an "*enormous gulf*" in performance at the elite level of competition. To put these percentages in context, he highlighted that:

- At the 2016 Olympic Games, the difference between first and fourth place in the women's 800m event was just 1.5%, while the difference between first and last place was 3.7%. Similar margins of victory were seen in the women's 400m event.
- A 2014 study by Malcata and Hopkins found that for running events below 3000m, the average variability of elite athletes' performance over the course of a whole season was just 0.8%.
- The average performance difference between the IAAF's under-20 female category and the senior female category is 4.79%.
- The International Weightlifting Federation has established various female weight categories. The world records for different weight categories differ by as little as 2.46%.
- The International Paralympic Committee has created impairment categories. The difference between the female world records across different impairment categories is as low as 0.7%.

326. Dr. Bermon explained, however, that it is the source of the advantage (*viz.* testes producing male levels of testosterone) that makes the advantage unfair, rather than the degree of advantage *per se*. While some biological males will beat biological females by upwards of 10%, many more biological males will beat biological females by a much smaller margin (e.g. as little as 0.1%).

327. Dr. Bermon next addressed the Claimant's treatment at the time of the 2009 World Championships. He explained why in his view ASA was entirely responsible for the way Ms. Semenya's case had become public. While he acknowledged that the case confirmed that the IAAF's own policy needed to be revisited, it was ASA's "*manipulation of the situation*" that resulted in it becoming public.

328. Dr. Bermon addressed the Hyperandrogenism Regulations and the findings of the CAS in *Chand*. He explained (among other things) that out of concern to respect the female athlete's gender identity in *Chand*, the IAAF had not focused on "*the biological reality, which is that 46 XY DSD athletes have male chromosomes that produce male gonads that produce adult male levels of testosterone from puberty onwards*". However, it is the "*biological reality*" of the situation, rather than legal sex and gender identity, which is the reason why it is necessary to divide males and females for the purposes of competitive athletics.

329. Dr. Bermon explained that the IAAF had carefully considered the findings in *Chand* and had made various changes to in the DSD Regulations to reflect this. In particular:

- The finding in *Chand* that the burden is on the IAAF to establish that every restriction is both necessary and proportionate led the IAAF to review all the previous restrictions and to abandon all of those restrictions which the IAAF could not clearly show were absolutely necessary to protect fair sport in the female category.

- The IAAF accepted the criticism in *Chand* that the threshold of 10 nmol/L in the Hyperandrogenism Regulations appeared arbitrary and risked producing false negatives. The IAAF had therefore reviewed all reliable data and established a new, lower threshold of 5 nmol/L on the basis of that review.

- The IAAF accepted that in assessing the degree of androgen sensitivity of a 46 XY DSD athlete, the benefit of the doubt should be given to the athlete. This is now expressly reflected in the DSD Regulations.

330. Dr. Bermon also explained that whereas the Hyperandrogenism Regulations applied to all females with hyperandrogenism including 46 XX females with ovaries, the IAAF now considers that it is not appropriate or necessary to include those individuals within the scope of regulation. In this regard:

- The data show that 99% of females with PCOS have testosterone levels of less than 3.47 nmol/L – a level at which the ergogenic impact of testosterone is normally "*extremely limited*".

- There are various reasons why elevated testosterone levels produced by 46 XX DSD are unlikely to be performance enhancing. For instance, CAH causes circulating testosterone into and even above the normal male range, but it is accompanied by health problems such as obesity, insulin resistance and lack of cardiopulmonary endurance. Accordingly, if the condition is not controlled with medication then the individual is "*unlikely to be highly competitive*" in athletics. Conversely, drugs can be used to control those symptoms and, if they are effective, the individual will no longer have elevated testosterone levels.

- Testosterone-secreting adrenal or ovarian tumours are not performance enhancing. Women with such tumours develop levels of circulating testosterone within or sometimes above the normal adult male range. This leads to rapid hirsutism and virilisation and a significant risk of ovarian cancer.

331. Dr. Bermon next explained why, in his view, the definition of Restricted Events in the DSD Regulations is not arbitrary. The evidence shows that the overwhelming majority of 46 XY DSD athletes winning at the elite level have competed in the 400m or 800m events. The evidence also suggests that athletes who competed strongly over those distances "*compete very well*" in other track events between 400m and one mile. The Restricted Events therefore have a rational basis.

332. Dr. Bermon went on to address the rationale for the reduction in the testosterone threshold from 10 nmol/L to 5 nmol/L. In short, he explained that:

- The 5 nmol/L threshold will exclude any woman with normal physiological levels of circulating testosterone and any woman with PCOS. The threshold means that only 46 XY DSD athletes, athletes with an adrenal or ovarian tumour, or doped female athletes will be investigated under the DSD Regulations.

- There is good evidence that even testosterone concentrations significantly below 10 nmol/L can deliver a material performance advantage. Increasing testosterone from the normal female range to just 7.3 nmol/L (just below the normal male range) increases muscle mass by 4.5%, increases muscle strength between 12% and 26%, and increases HGB levels by 7.8%. Therefore, retaining the 10 nmol/L threshold would have created false positives.

333. Dr. Bermon explained that the introduction of the six-month suspension period while a Relevant Athlete is receiving treatment to reduce their testosterone levels is intended to minimise the "*lingering advantages*" that a 46 XY DSD athlete may enjoy by virtue of having previously had serum testosterone above 5 nmol/L. (He noted that the life cycle of a red blood cell is typically about 120 days, meaning that a period of six months should be sufficient to see a reduction in HGB following the reduction in the individual's circulating testosterone.) While the benefits of increased muscle mass will endure beyond that, the six-month period is intended to represent a "*compromise*" in the interests of being as fair as possible to 46 XY DSD athletes.

334. Dr. Bermon rejected the Claimants' contention that the DSD Regulations cause harm that outweighs their benefits. In particular, he stated that:

- It is categorically untrue to suggest that the IAAF has previously required any women to undergo genital surgery in order to compete in the female category.

- In regular clinical practice, individuals with DSD are offered surgery or hormone treatment if they wish to avoid further masculinisation. This is the recognised standard of care for individuals with such conditions. The IAAF consulted doctors who have significant experience in dealing with DSD cases. Those specialists are unaware of any evidence that lowering serum testosterone levels to the normal female range has any adverse health effects for those athletes.

- The DSD Regulations do not stigmatise athletes with DSD. The DSD Regulations stress the importance of strict confidentiality. These confidentiality provisions are effective. The IAAF dealt with [...] cases under the Hyperandrogenism Regulations and at least [...] further cases prior to that. The IAAF has never leaked any information about any of those cases; the identity of the athletes, their nationality and the number of cases all remain unknown outside the IAAF.

- The DSD Regulations expressly and emphatically stress that they do not connote any judgment or questioning of an individual's sex or gender identity. They are also careful not to spell out that they apply only to 46 XY individuals with fully functioning testes.

- The DSD Regulations do not exclude affected individuals from competing in the female category.

335. Dr. Bermon added that the DSD Regulations are "*extremely clear on the need for informed consent*". He had personally been involved in multiple DSD cases. In each case the IAAF invested a "*huge amount*" of time and effort in ensuring that the athlete understood the regulations and their situation. The IAAF always made sure that each athlete was provided with the necessary information in order to make an informed and properly considered decision on how they wished to proceed.

336. Dr. Bermon went on to respond briefly to Mr. Vazel's evidence concerning his presentation to the French Athletics Federation in late 2018. He described Mr. Vazel's testimony as a "*partial and misleading account*" and an attempt to "*smear*" Dr. Bermon's reputation by wrongly implying that he devalues women who do not conform to a particular notion of femininity.

337. Dr. Bermon emphatically rejected the suggestion that the IAAF was improperly targeting athletes from the Global South. He stressed that the IAAF Medical Manager and the members of the expert panel are experienced medical professionals with extensive experience of treating individuals with DSD from all over the world. The suggestion that they or the IAAF are racist or prejudiced against women from the Global South is unfounded.

338. Finally, Dr. Bermon provided a summary of the findings of BG17 and his response to the key criticisms levelled by the Claimants' experts at its conclusions and methodology. The principal findings of BG17 were as follows:

- In five athletics disciplines women with concentrations of free testosterone in the highest tertile performed significantly better than women whose free testosterone concentrations were in the lowest tertile. In particular, the highest tertile outperformed the lowest tertile in the 400m (by a margin of 2.73%); 400m hurdles (by a margin of 2.78%); 800m (by a margin of 1.78%); hammer throw (by a margin of 4.53%); and pole vault (by a margin of 2.94%).

- In three athletics disciplines women with concentrations of total testosterone in the highest tertile performed significantly better than women whose concentrations were in the lowest tertile. Those events were the 400m (by a

margin of 1.50%); 400m hurdles (by a margin of 3.13%); and 800m (by a margin of 1.60%).

- There was "*no correlation*" between testosterone levels (whether free or total) and performance in other athletic disciplines.

- Because the researchers were examining correlation rather than causation, they did not exclude data relating to female athletes who had testosterone levels above the normal female range (due to known/suspected DSD or doping).

339. Dr. Bermon discussed his hypothesis for the correlation that the statistical analysis in BG17 had revealed. He explained that increased muscle mass and HGB levels are highly beneficial to athletes competing in long sprint and middle distance running events. In contrast, while increased HGB is also an advantage in long distance running (3000m and upwards) such events also require a light body frame, which is "*almost impossible*" to achieve with a high level of circulating testosterone.

340. Dr. Bermon went on to explain that, in his opinion, if small differences in testosterone concentration at very low levels can be a factor in sports performance in particular disciplines then it follows that (assuming the dose-response relationship follows a sigmoid curve) a 46 XY DSD athlete with testosterone levels above the normal female range would be expected to experience a "*very significant increase*" in athletic performance.

341. Dr. Bermon stated that the Daegu and Moscow athletes had consented to the use of their samples and related data "*for purposes of anti-doping research*". The data had been used for such purposes, namely (a) "*establishing normal serum androgen values in elite female athletes, which has informed development of the endocrine module of the Athlete Biological Passport system and helped support at least three anti-doping cases for the IAAF to date*"; and (b) "*exploring correlations between those serum androgen values and performance, which helps to determine the extent to which endogenous testosterone is performance-enhancing and so to assess the justification for including on the WADA list those substances...that block the conversion of endogenous testosterone into estrogen*". Dr. Bermon added that the fact that such analysis may also "*shed light*" on other issues is "*irrelevant*".

342. Dr. Bermon responded to Prof. Dave's criticisms of the sampling procedure and methodology followed at Daegu and Moscow. He emphasised that the JCEM is a highly respected and peer-reviewed journal whose researchers made no criticism of the procedure and methodology. Further, while serum testosterone can vary according to season and time of day, these confounding factors would be largely cancelled out by the fact that (a) there were a large number of samples taken at various times from morning to night; (b) most athletes arrived at least a week before their respective events at the World Championships; and (c) athletes came from north, south, east and west. Dr. Bermon also explained why the influence of confounding factors such as age, recent exercise, sexual activity and health problems had a "*negligible*" impact on the outcome of the analysis.

343. Dr. Bermon went on to address the criticisms based on the study's focus on free testosterone, rather than total testosterone. He began by explaining that there was a

sound rationale for using free testosterone, which enabled more confounding factors to be taken into account than an analysis based on circulating testosterone. He then explained that since the researchers also had the data showing the total testosterone concentrations for the female athletes in Daegu and Moscow, they had conducted a fresh analysis using those total testosterone values. Once again, the women in the highest tertile of total testosterone performed significantly better in the 400m (1.50%), 400m hurdles (3.13%) and 800m (1.60%) (but not in pole vault or hammer throw) than women in the lowest tertile of total testosterone.

344. Dr. Bermon rejected the criticism that there had been "*double counting*". He explained that blood samples, rather than individual athletes, were the relevant "*unit of analysis*". Given the passage of time (two years) between the two World Championships, including some athletes again was "*effectively the same as adding a distinct person*". In any event, the double counting was limited (only 17.3%) and any oversampling bias was negligible having regard to the fact that outliers at Daegu were not outliers at Moscow.

345. Lastly, Dr. Bermon addressed the criticisms levelled at (a) the measure of statistical significance used in BG17; (b) the decision to focus on athletes' single best performance in the relevant event, rather than overall performances including all heats; and (c) the inclusion of elevated testosterone concentrations from nine athletes known to have a DSD and 15 athletes who were either known or suspected to have doped. Dr. Bermon contended that none of these criticisms of BG17 had any merit.

346. During the hearing Dr. Bermon was cross-examined at length by Ms. Semenya's representative. Dr. Bermon accepted that he had a conflict of interest given his employment by the IAAF and his involvement in the development and implementation of the Hyperandrogenism Regulations and the DSD Regulations. He also accepted that, apart from analysing the prevalence of individuals with 46 XY DSD in the population of elite athletes, the IAAF had not undertaken any similar analysis comparing the relative incidences of other genetic conditions in the elite athletic population and the general population. Nor had it conducted any study of whether athletes from certain geographic regions are over-represented in the elite athletic population.

347. Dr. Bermon agreed with Ms. Semenya's representative that the DSD Regulations were judging the biological sex of women with DSD.

348. Dr. Bermon acknowledged that in the last five Olympic Games Jamaican sprinters had won 10 medals in the 100m event, [...]. Dr. Bermon stated, however, that it was not necessary to protect non-Jamaican women from having to compete against Jamaican women in the 100m event.

349. Dr. Bermon accepted during cross-examination that his witness evidence contained a number of errors. For example:

- He had "*overstate[d]*" the position when he said that the only women who had run the 800m in under two minutes and then improved their performance by over 1% were athletes who were doping or had 46 XY DSD. This statement was not correct.

- He was wrong to say that all [...] of the athletes who underwent testosterone-suppressing treatment under the Hyperandrogenism Regulations had subsequently returned to competition.

- He was wrong to say that all of the athletes who had undergone medical treatment under the Hyperandrogenism Regulations had experienced a material decrease in their performance.

350. Dr. Bermon explained that, in determining which events should be designated as Restricted Events, an "*important criterion*" was whether women with 46 XY DSD were currently known to be competing in those events. He was asked how the IAAF would decide whether other events needed to be designated as Restricted Events in future. He replied that there would need to be about six to eight cases of women with 46 XY DSD competing in that event over a period of around three to five years in order for an event to be designated as a Restricted Event. He conceded, however, that there was no published policy that set out the criteria that the IAAF would use to make this determination.

Professor David Handelsman

351. Prof. Handelsman is the Professor of Reproductive Endocrinology and Andrology at the University of Sydney. He is also the Director of the ANZAC Research Institute and the founder and Head of the Andrology Department at Concord Hospital in Sydney. He has published more than 400 peer-reviewed articles on endocrinology and reproductive medicine and has held a wide range of academic and professional positions. Since 2010 he has served on WADA's Health, Medicine and Research Committee.

352. Prof. Handelsman provided expert evidence on behalf of the IAAF. His testimony addressed (a) the existence of a sex difference in levels of circulating testosterone and its effect on the difference in athletic performance between men and women; and (b) whether an androgen-sensitive 46 XY DSD athlete would have a performance advantage over female athletes with levels of testosterone in the normal female range (and, if so, whether the magnitude of that advantage can be quantified).

353. In his expert report. Prof. Handelsman stated:

- There is a "*wide and complete*" bimodal separation in the normal range of testosterone in adult male bodies (7.7 nmol/L to 29.4 nmol/L) and in adult female bodies (0.06 nmol/L to 1.68 nmol/L). Adult males have on average 15 times the level of circulating testosterone as adult females.

- This difference in circulating testosterone "*largely accounts for*" the clear sex differences in average muscle mass and strength, circulating haemoglobin levels and bone size, strength and density.

- These factors are key contributors to the significant sex difference in athletic performance. They make it impossible for women to compete effectively against men in power-based and endurance-based sports.

- It follows that the sex difference in circulating testosterone concentrations is "*a major determinant*" of the sex difference in athletic performance.

- There is clear scientific evidence that in both men and women there is a "*strong*" dose-response relationship between circulating testosterone and muscle mass, muscle strength and circulating haemoglobin.

- There is at least an 8-12% (and up to 20%) ergogenic advantage in having circulating testosterone levels in the male range. In contrast, the typical winning margin in elite athletics events is consistently less than 1%.

- Athletes with 46 XY DSD are "*gonadally male*", meaning they have functioning testes that produce sperm and circulating testosterone levels within the normal male range. The only physical/biological differences between androgen-sensitive 46 XY DSD athletes and non-DSD male athletes are that their testes are not descended and their external genitalia may be undervirilised. Such individuals may have a female legal sex and/or gender identity; however this does not affect athletic performance. Therefore if their androgen receptors function properly, they will have exactly the same performance advantages over female athletes as non-DSD males athletes have. On average, this advantage is between 10% and 12% in running events, while it may be as high as 20% in jumping events.

354. Prof. Handelsman noted that while it is important that an individual's dignity, legal sex and gender identity should always be respected, this does not mean that biological factors can always be ignored. In particular, in the context of sport, where biology is "*of the essence*", eligibility to participate in the female category should be determined by reference to the factors that make a separate division necessary. In this regard, he considered that the IAAF's approach is logical, rational and well-grounded in science.

355. Prof. Handelsman next addressed the reference ranges for testosterone levels of men and women. He explained among other things that:

- In establishing an eligibility threshold for the female category, it is necessary to make allowance for women with PCOS, a condition that affects 6% to 16% of women of reproductive age. The scientific data shows that the upper limit of serum testosterone in women with PCOS is 3.1 nmol/L (95% confidence level) or 4.8 nmol/L (99% confidence level). Fewer than 1 in 10,000 women with PCOS might have circulating testosterone greater than 5 nmol/L. Accordingly, if the objective is to require 46 XY DSD athletes that have serum testosterone concentrations in the normal male range to bring those levels down to the same range as other female athletes, then a threshold of no more than 5 nmol/L should be used.

- In this connection, the evidence is clear that an increase in serum testosterone from under 5 nmol/L to above 5 nmol/L would have a "*significant*" performance enhancing effect even if the concentration remained below 10 nmol/L.

356. Prof. Handelsman disagreed with Prof. Holt's contention that the reference ranges set out in the Handelsman Paper may not be applicable to elite athletes. In summary:

- The range derived from data from non-athletes is "*remarkably consistent*" with the range derived from samples provided by more than 1,600 female athletes at the 2011 and 2013 World Championships.

- The reference ranges were established on the basis of 1:10,000 reference ranges, which accord with the *Veerpalu* standard of +/- 3.7 standard deviations. Prof. Holt is wrong to suggest otherwise.

- Prof. Holt's criticisms ignore the fact that the reference ranges were based on a meta-analysis of data across 33 published studies, which included 3,754 men, 2,983 women without PCOS and 4,100 women with PCOS.

- Prof. Holt is wrong to criticise the exclusion of athletes with DSD from the analysis. That exclusion was necessary since proper distinctions cannot be made when the samples used to determine reference ranges include abnormalities such as DSD that confound the analytical procedure.

- Prof. Holt is wrong to criticise the decision not to take into account the values for male athletes reported by BG17 when establishing the reference range for men. It would be wrong to include those values in determining a general male population reference range because the samples were taken from men who had undergone severe exertion (which transiently reduces serum testosterone). In any event, the data for male athletes in BG17 would not materially change the male reference ranges.

- Accordingly, the appropriate testosterone reference ranges are 0.06 to 1.68 nmol/L (for normal adult females, including female athletes) and 7.7 to 29.4 nmol/L (for normal adult males, including male athletes).

357. Prof. Handelsman went on to explain in greater detail why the sex difference in circulating testosterone is the cause of the difference in athletic performance between men and women:

- Prior to male puberty there is little or no difference between male and female athletic performance. However, after the onset of puberty, male testosterone levels increase to around 15 nmol/L while female testosterone levels remain under 2 nmol/L. At the same time, males become 10-12% better at running events and 20% better in jumping events.

- The striking correlation between rising testosterone in males and the sex difference in athletic performance must either mean that one causes the other or that they are both attributable to a third unspecified factor. There is, however, no known third mechanism which could credibly cause both increases in circulating testosterone and increases in athletic performance in males only. Accordingly, "*the only plausible interpretation*" is that increases in testosterone lead to increases in athletic performance. The increase in testosterone at puberty

therefore provides "*a major, ongoing, cumulative and durable advantage in sporting contests*" by causing men to have "*greater muscle mass and strength, higher circulating hemoglobin, and larger and stronger bones*".

- On average, women have 50-60% of men's upper arm muscle cross-sectional area, 65-70% of men's thigh muscle cross-section area; 50-60% of men's upper limb strength and 60-80% of men's leg strength.

- While numerous genes and environmental factors may contribute, testosterone is "*the key determinant*" of muscle mass and lean body mass and, accordingly, is the cause of the sex difference in muscle mass and strength.

- There is a reasonable body of evidence that suggests that women experience the same dose-relationship response to increases in testosterone as men experience. Both BG17 and Eklund *et al* support this. The study conducted by Prof. Hirschberg also provides evidence in support of this relationship, as does an earlier study by Huang *et al* that involved the administration of exogenous testosterone to healthy older women. That study was well designed and produced strong evidence that, at least up to testosterone concentrations of 7.3 nmol/L, women have the same dose-response relationship as men. The women whose testosterone concentrations were increased to 7.3 nmol/L achieved increases in performance ranging from 4.4% (in respect of muscle mass) to 12% - 26% (in respect of muscle strength).

358. Prof. Handelsman stated that the best evidence of the impact of testosterone on muscle is found in dose-response studies which show that administration of testosterone causes material increases in muscle mass and strength. He referred to studies by Bhasin *et al* (2005) and Finkelstein *et al* (2013) which showed that testosterone has "*unequivocal dose-dependent effects on muscle mass and strength*" in males. This "*strongly suggest[ed] that the sex difference in lean body mass (muscle) is largely, if not exclusively, due to the differences in circulating testosterone between men and women*". He also discussed the observational and interventional data relating to the effect of testosterone on women, which although "*more limited*" nonetheless "*clearly indicates that the same dose-response relationship exists in women as in men*".

359. Prof. Handelsman rejected Prof. Holt's challenges to the conclusion that the sex difference in testosterone levels is the principal cause of the difference in muscle mass and strength between males and females. Prof. Handelsman also rejected Dr. Vilain and Prof. Holt's contention that the evidence in the Handelsman Paper is insufficiently robust. In this regard, he stated:

- Individuals with 5-ARD, 17β-HSD3 and PAIS "*have male gonads (testes) and adult male circulating testosterone concentrations*" that will have the same virilising effect on their bodies as it has on the bodies of 46 XY males without DSD. Accordingly, in biological terms they are not materially different from 46 XY non-DSD males and therefore all of the evidence of the ergogenic effect that testosterone has for 46 XY non-DSD males applies equally to individuals with those 46 XY DSD.

- The argument based on the absence of the same evidence in respect of female athletes is "*a poorly thought out counsel of perfection*", since objective interventional studies involving the administration of significant doses of exogenous testosterone would not be feasible or ethical.

- The evidence that the dose-response relationship is the same in men and women is "*sufficiently persuasive*" that it is "*very doubtful*" that women's bodies would respond differently to men's bodies in terms of their muscle or haemoglobin response to testosterone. As a result, there is no scientific justification for undertaking a randomised clinical trial involving the administration of large doses of testosterone to elite female athletes.

360. Prof. Handelsman also "*strongly disagree[d]*" with Prof. Holt's suggestion that increased circulation of endogenous testosterone would not necessarily have the same physiological effects as increased concentrations of exogenous testosterone. Exogenous and endogenous testosterone have an identical chemical structure and exert the same biological and clinical effects on androgen-responsive tissue and organs (aside from spermatogenesis, which is merely a matter of degree). Any purported differences between endogenous and exogenous testosterone are due exclusively to the size of the endogenous production rate or the exogenous dose. In this connexion, Prof. Handelsman strongly rejected certain aspects of the expert evidence adduced on behalf of the claimant in *Chand*. For example, he stated that the hypothalamic-pituitary axis operates as a powerful negative feedback system, which operates in exactly the same way with endogenous testosterone as it does with exogenous testosterone.

361. Prof. Handelsman proceeded to explain that Prof. Holt is wrong to argue that testosterone cannot be a driver of athletic performance because many female athletes have very low testosterone or are insensitive to testosterone:

- Prof. Handelsman is unaware of any sound evidence that CAIS is more prevalent in elite athletes than in the general population. It is unlikely that such individuals have any significant advantage or disadvantage by virtue of their condition and therefore they are unlikely to be over represented among the population of elite female athletes.

- The normal female range for testosterone is very narrow (0.06 to 1.68 nmol/L). The range is so small that being at or close to the bottom of it has little or no difference on relative athletic performance. In addition, such levels of testosterone are too low to have a virilising effect.

362. Prof. Handelsman rejected the alternative mechanisms suggested by Prof. Holt as possible causes of the difference in athletic performance between men and women:

- In respect of growth hormone, Prof. Handelsman observed that while this is Prof. Holt's area of specialisation, there is no scientific evidence to support his hypothesis that sex differences in growth hormone could account for the sex difference in LBM. In fact, this is contradicted by uncontroversial high quality evidence compiled from multiple studies over more than 30 years by Veldhuis, which demonstrates that growth hormone secretion in young women is

consistently as much as twice as high as in young men. It is therefore illogical to claim that growth hormone could explain the sex difference in lean body mass. Even accounting for Prof. Holt's assertion that women are less sensitive to growth hormone than men, young women still have more effective exposure to growth hormone than young men. A recent study by Hermansen *et al* found that administration of growth hormone "*elicits significant changes in body composition, but does not increase either muscle strength or aerobic exercise capacity in healthy, young subjects*".

- In respect of the Y chromosome, Prof. Handelsman stated that possession of a Y chromosome does not per se confer any performance advantage. The only recognised function of this chromosome is to trigger the development of testes. Once a testis is fully developed and functional, it produces male levels of testosterone. So while the Y chromosome is linked to increased height, muscle mass and strength and haemoglobin, this link arises solely through the formation of a testis which secretes male levels of testosterone after puberty.

363. Prof. Handelsman next addressed some of the process-based criticisms of the Handelsman Paper. In summary:

- He rejected any allegation of bias, which he described as an unwarranted slur on his integrity. He stressed that his involvement in the present proceedings was unpaid and based solely on his academic interests and expertise. The Handelsman Paper was not written, commissioned or funded by (or at the behest of) the IAAF or anyone else. Moreover, Prof. Handelsman did not show the draft of the paper to the IAAF's lawyers until well after the peer-review process had finished and the manuscript content was finalised. The IAAF's lawyers merely made "*stylistic suggestions for clarity*". No concepts or arguments were added or removed from the Handelsman Paper as a result of their input.

- Prof. Hackney is wrong to suggest that the Handelsman Paper omitted relevant evidence. Prof. Handelsman carefully reviewed all papers that he could find that were of a sufficiently high quality and which contained relevant novel and sound findings. This process inevitably involved a degree of judgement. The draft of the paper underwent "*stringent peer-review*" in the most frequently cited and highly respected international endocrinology journal. None of the reviewers or editors had any concerns about the format or content of the paper.

- In respect of Prof. Hackney's criticism regarding the absence of meta-analysis, this is a controversial technique which requires the existence of multiple studies of similar design and quantitative estimates of the same endpoints. With the exception of the studies which were used to establish testosterone reference ranges, there were too few suitable studies to undertake such a meta-analysis.

- Prof. Hackney's complaint about the occasional reliance on data measured using immunoassays, rather than LC-MS, is "*confused*". While LC-MS data are essential where a measurement of absolute testosterone concentration is required, data derived from immunoassays may be "*acceptable, if sub-optimal*"

where the measurements are used in correlational analysis or regression models with non-testosterone variables.

364. Prof. Handelsman concluded by explaining why in his opinion the DSD Regulations have a strong scientific basis:

- Individuals with 46 XY DSD have male chromosomes and testes, meaning that from puberty onwards they produce normal adult male levels of testosterone. Provided that they are sufficiently androgen-sensitive, their elevated testosterone levels will have "*exactly the same effect on their muscle size and strength, their bone size and strength, and their levels of circulating hemoglobin, as it would have on any male without a DSD*".

- Since biology is of the essence in sport, eligibility to participate in the female category needs to be determined by reference to the factors that make a separate division necessary, namely "*the presence in an androgen-sensitive athlete of testes that produce adult male levels of testosterone, with the same virilising effects as are experienced by non-DSD adult males*".

- The DSD Regulations are a fair and rational response to the fact that 46 XY DSD individuals have bodies that contain testes that produce male levels of testosterone. Requiring such individuals to reduce their testosterone levels to below 5 nmol/L if they wish to compete at international level in events where testosterone appears to provide the most advantage is logical, rational and grounded in science. It is the only way to ensure fairness to all others who are entitled to compete in the female category in those events.

365. Prof. Handelsman rejected the argument that the threshold of 5 nmol/L makes no sense because it is designed to allow for women with PCOS, who also derive a performance advantage from their elevated testosterone levels:

- Women with PCOS have female chromosomes, female gonads (ovaries) and female reproductive systems. Their testosterone concentrations may extend into the 2 – 4 nmol/L range, but they never overlap with the much higher male rage. Even if a very small minority (fewer than 1 in 10,000) have testosterone levels that exceed 5 nmol/L, they will not extend into the normal male range (7.4 to 27.4 nmol/L) "*which is when the virilising effects on the body...become manifested*".

- The "*over-representation*" of women with PCOS in elite female athletics "*suggests that they may get a modest performance advantage from those slightly elevated testosterone levels*". However, the level of circulating testosterone in most women with PCOS never consistently exceeds 5nmol/L, which is the level that males must consistently exceed in order to gain the masculinising effects of male puberty.

- Accordingly, women with PCOS fall into a very different category than 46 XY DSD athletes who, because they have testes, have circulating levels of

testosterone that extend into the normal male range and who have the virilising effects and performance advantages caused by this.

366. Lastly, Prof. Handelsman expressed doubt about whether the requirement in the DSD Regulations for a Relevant Athlete to maintain their testosterone levels below 5 nmol/L for at least six months was long enough. He would have supported extending that period to at least 12 months, consistent with the IOC's new regulations for transgender athletes.

367. Prof. Handelsman gave oral testimony at the hearing prior to the expert hot tubs. In response to questions put during cross-examination, Prof. Handelsman stated that while he was an independent expert, whether he claimed and received remuneration from the IAAF for providing expert evidence in this proceeding would depend on the outcome of this proceeding. He also reiterated that while the IAAF's lawyers had provided assistance during the drafting of the Handelsman Paper, that assistance was limited to making stylistic suggestions and comments on the draft text.

Professor Angelica Lindén Hirschberg

368. Angelica Hirschberg is a professor of obstetrics and gynaecology at the Karolinska Institutet in Stockholm, Sweden. She is also the head of gynaecological endocrinology at the Department of Gynaecology and Reproductive Medicine at Karolinska University Hospital in Stockholm. She is a member of the board of the International Society of Gynaecological Endocrinology and has authored a significant number of scientific publications concerning female athletes, DSD and physical performance. Since 2009 she has been consulted by the IAAF and the IOC on the formation of their respective regulations governing athletes with DSD. She provided expert evidence on behalf of the IAAF in *Chand*.

369. Prof. Hirschberg began her expert evidence by reiterating her evidence in *Chand* that:

- There is a substantial sex difference in adult levels of circulating testosterone with a dimodal, non-overlapping distribution. The normal range of testosterone is 7.7 to 29.4 nmol/L for adult males and 0.06 to 1.68 nmol/L for adult females without PCOS. (The upper limit for females with PCOS is 3.1 nmol/L at the 95% confidence level or 4.8 nmol/L at the 99.9% confidence level.)

- The sex difference in adult levels of circulating testosterone is the main driver of the marked sex difference in athletic performance that emerges during puberty.

370. Prof. Hirschberg went on to address two relevant studies concerning the relationship between testosterone and athletic performance that she had been involved in. First, a study by Eklund *et al* (2017) compared 106 Olympic female athletes from Sweden with 117 age and weight matched sedentary control women. The study found that:

- Female athletes had greater muscle and bone mass than the group of sedentary control women. The results of strength tests correlated strongly with muscle mass, which in turn correlated with androgens and androgen precursors.

- There was no correlation between serum testosterone and physical performance. Female athletes, however, had higher serum levels of several precursor androgens that are produced by the adrenal glands. There were clear positive correlations between the androgens dehydroepiandrosterone (DHEA) and dihydrotestosterone (DHT) and athletes' physical performance.

- Serum testosterone levels of all of the Olympic athletes were very low and squarely within the normal female range. The question is what happens when you compare an athlete with testosterone within that range with a female athlete whose level of testosterone is in the normal *male* range. It is not possible, however, to conduct interventional studies in young women because there is no way of increasing female athletes' levels of endogenous testosterone, while administering high doses of exogenous testosterone would be ethically impermissible and would pose a serious risk to their health.

371. Prof. Hirschberg explained that following *Chand* she had conducted a double-blind, randomised, placebo-controlled study involving 48 healthy, physically active young women who received a daily dose of either 10mg of testosterone cream or a placebo. The serum testosterone levels of the women who received the testosterone cream increased from a mean of 0.9 (± 0.4) nmol/L to 4.3 (± 2.8) nmol/L. Over the same period, their aerobic performance increased by 8.5%; their anaerobic performance improved by 3.2%; their lean body mass increased significantly; and their body fat percentage decreased. (Their muscle strength and bodyweight, however, remained unchanged.) Prof. Hirschberg's study found positive correlations between serum testosterone and lean body mass, and between lean body mass and anaerobic performance. This constitutes "*direct interventional evidence that increasing serum testosterone levels, even only to 4.3 nmol/L, i.e., still below the normal adult male range, significantly increases muscle mass and enhances physical performance in young physically active women*".

372. Prof. Hirschberg stated that while it is unlikely to be possible to carry out studies involving the administration of larger doses of testosterone to females, a woman's body would respond to increased testosterone in a similar way to a man's body, whether the testosterone is endogenous or exogenous.

373. Prof. Hirschberg went on to explain why in her opinion if a woman with a 46 XY DSD wishes to compete in the female category, she should be required to reduce her testosterone levels to below the normal adult male range. In summary:

- The most common DSD in elite female athletes are 5-ARD and PAIS. Such individuals have male karyotypes (XY chromosomes) and during foetal development the Y chromosome has triggered their primitive gonads to develop into testes. From puberty those testes will generate levels of testosterone in the adult male range.

- If an adult androgen-sensitive individual with a 46 XY DSD does have a female sex/gender identity, "*the fact remains that from a biological perspective (which is what determines athletic performance) that individual has male chromosomes (XY), male gonads (testes not ovaries), and testosterone in the male range, with*

all of the usual bone, muscle and HGB effects." Accordingly, in terms of the physiological advantages that give rise to the need to separate male and female competition, such individuals "*are no different from 46 XY males without DSDs. The only difference is the appearance of the external genitalia, which is a difference of degree only, and has no impact on athletic performance.*"

- This is borne out by Dr. Bermon's observational data, which show that the HGB levels of 46 XY DSD athletes who have not suppressed their testosterone are essentially the same as in 46 XY males without DSD. Similarly, the changes in athletic performance seen when such individuals start and stop taking testosterone-suppressing treatment "*are exactly what you would expect given the impact of adult male levels of circulating testosterone on performance*".

374. Prof. Hirschberg next discussed the health consequences of hyperandrogenism. She stated that there is a "*clinical consensus*" that women with "*severe*" hyperandrogenism should be diagnosed and treated in an appropriate way, which may include suppressing serum testosterone levels by surgical or medical means. Oral contraceptives, which are used by up to 40% of young women in the Western world, are the simplest and most direct way to lower testosterone levels. Oral contraceptives are usually well tolerated with few side effects and are generally a "*very safe*" medication. While they do increase the risk of VTE, the background risk is "*very low*" and if properly administered medical complications arising from their use are "*very rare*". Oral contraceptives are associated with a lower lifetime risk of ovarian, endometrial and colorectal cancer, while the lifetime risk of breast cancer is "*not significantly increased*" by their use. Prof. Hirschberg stated that she was unaware of any evidence that hormonal treatments to suppress testosterone cause renal dysfunction or cardiovascular disease.

375. For all these reasons, Prof. Hirschberg considered that the DSD Regulations "*are strongly supported by the science, and are logical, rational and fair*".

Professor Aaron Baggish and Professor Benjamin Levine

376. Professor Aaron Baggish is the founder and director of the Cardiovascular Performance Programme at the Massachusetts General Hospital in Boston, USA. He is also an Associate Professor of Medicine at Harvard Medical School and a fellow of the American College of Cardiology and the American College of Sports Medicine. Professor Benjamin Levine is the founder and director of the Institute for Exercise and Environmental Medicine at Texas Health Presbyterian Hospital in Dallas, USA. He is a Professor of Internal Medicine/Cardiology and Professor of Exercise Sciences at the University of Texas Southwestern Medical Center.

377. Prof. Baggish and Prof. Levine provided a joint expert report on behalf of the IAAF concerning (a) the physical attributes that contribute to performance in elite sport and (b) the factors that contribute to the performance advantage that male athletes typically enjoy over female athletes. In respect of the former, they stated that:

- The factors that determine elite athletic performance are "*complex*" and vary between sporting disciplines. Principal determinants include maximal oxygen uptake (VO2 max), maximal steady state (MSS) and exercise economy/anaerobic capacity as a reflection of skeletal muscle capacity (SMC).

- Each of these traits is determined partly by genetic factors and partly in response to epigenetic factors such as training and other measures designed to improve sport performance.

378. Prof. Baggish and Prof. Levine proceeded to explain that there is "*no single factor*" that explains the difference between elite male and female athletic performance; rather there are "*numerous complementary factors*". In the field of endurance sports, the factors include higher average VO2 max, larger cardiac ventricular volumes and higher red blood cell count and haemoglobin concentration. In the field of strength-based sports, the factors include larger lean body mass and skeletal muscle fibre size, less ligamentous laxity and higher absolute values of active androgen molecule. They also include non-androgenic differences in Y-gene availability and activity that may partly determine stature and body composition (these differences "*are not known, likely exist, but play a relatively small role compared to androgenic factors*"). In addition, other hormonal factors such as growth hormone do affect sport performance but are not different between men and women (and therefore do not contribute to sex-based differences in sport performance).

379. In addition, Prof. Baggish and Prof. Levine emphasised that there are certain "*historical factors and common misconceptions*" which should *not* be regarded as contemporary determinants of sex-based performance differences. Those historic factors and misconceptions include:

- Women having less access to competitive athletics than men;
- Women undertaking less intense or comprehensive training regimes than men;
- Less competitive drive among women than men. (Prof. Baggish and Prof. Levine stressed that the notion that women lack the same competitive drive as men is "*simply inaccurate*".)

380. In respect of the role of testosterone as a factor that influences athletic performance, Prof. Baggish and Prof. Levine stated that:

- Testosterone has "*myriad effects*" and its impact on actual sport performance would be expected to vary across sporting disciplines.
- Testosterone supplementation results in increased muscle size, lean body mass and muscle strength.
- Increased testosterone levels on average "*support a persistently expanded red blood cell mass and facilitate enhanced oxygen-carrying capacity*".
- Testosterone also affects cardiac hypertrophy, which plays a critical role in sport performance in events that depend on maximal cardiac input.
- On average, the available data and observational experience of female athletes who have used exogenous testosterone suggest that differences in testosterone levels between men and women "*underlie a substantial proportion of the sex-based gap*" in elite athletic performance.

- In events where there would be an expected benefit from increased testosterone, one would not expect there to be a significant difference in the size of the effect between exogenous and endogenous testosterone.

381. Prof. Baggish and Prof. Levine added that scientific research concerning the effect of growth hormone on athletic performance has led to "*mixed results*". Most studies present data that both support and refute a link between growth hormone and athletic performance. In their opinion, the effect of growth hormone would be expected, on average, to be "*relatively small*" compared to the effect caused by endogenous or exogenous testosterone.

382. Prof. Baggish and Prof. Levine also explained that non-androgenic genes on the Y-chromosome (such as the SRY gene) may influence athletic performance. There are many Y-chromosome genes whose functions remain unknown. Indirect evidence that some of those genes influence factors such as height and lean body mass independently of androgenic effects has been suggested by analyses of small groups of 46 XY female athletes with androgen insensitivity syndrome and non-athletes with androgen insensitivity syndrome, which in both cases were taller than the average female population. This suggests "*a role of the Y-chromosome in determining body size and composition that is Y chromosome dependent but independent of androgen activity*". While Prof. Baggish and Prof. Levine are unaware of any definitive science that has identified such Y-chromosome genes, in their opinion it is "*plausible if not probable that the Y chromosome may impact body morphology in a manner that affects elite sport performance in a significant fashion*".

Professor Richard Auchus

383. Prof. Richard Auchus is a Professor Internal Medicine, Endocrinology, Metabolism and Pharmacology at the University of Michigan and the Section Chief of Endocrinology at the Ann Arbor VA Medical Center in Michigan, USA. He has a particular expertise in steroid hormone biosynthesis and steroid disorders. Prof. Auchus provided an expert report on behalf of the IAAF in which he responded to several specific questions concerning the meaning and determination of sex and the features of certain DSD.

384. Prof. Auchus began by explaining that while for most people sex is binary, for approximately 0.1% of the population an abnormality in chromosomal or gonadal development results in sexual characteristics that are "*not clearly male or female*". Accordingly, "*sex is not strictly binary for all human beings*". (Prof. Auchus stressed, however, that sex is not equivalent to gender, and his use of the words "*male*" and "*female*" throughout his evidence referred to biological sex, not gender.)

385. Prof. Auchus went on to explain that a person with a 46 XY DSD has a 46 XY chromosomal complement with "*under-masculinized external genitalia compared to population norms for males*". Likewise, a 46 XX DSD individual has "*some degree of masculinization of the external genitalia compared to population norms for females*".

386. Prof. Auchus next discussed the prevalence and effects of 5-ARD. He explained that:

- 5-ARD is a genetic deficiency of an enzyme that is critical for the formation of male external genitalia. The condition manifests in males with "*a 46 XY chromosome complement, normal testosterone production from their testes, and normal androgen receptors that allow androgen responsivity*".

- 5-ARD is a "*very rare disease*". Its prevalence is unknown but it is likely to be found in fewer than 1 in 100,000 people. It is more commonly found within certain geographically restricted populations; however cases of 5-ARD have been reported all over the world.

- Individuals with 5-ARD may have either a 46XX or 46 XY karyotype. Individuals with a 46 XX karyotype are "*normal females with ovaries [and] normal female testosterone production*". In contrast, individuals with 5-ARD and a 46 XY karyotype are "*under-masculinized males*".

- There is no typical birth sex for individuals with 5-ARD. The sex that is assigned to such individuals at birth depends on the degree of genital masculisation, the cultural tendencies of the parents' families, the expertise of the physicians and the extent of medical evaluation undertaken at birth.

- Individuals with 5-ARD might not be diagnosed with the condition at birth, and so might be assigned a female sex of rearing. As they begin puberty, however, their bodies produce normal male amounts of testosterone and significant amounts of DHT, resulting in the development of secondary male characteristics.

- The physiologic effect of endogenous testosterone on a 46XY 5-ARD individual is the same as the physiologic effect of testosterone on a normal 46 XY male.

- A 46 XY male with 5-ARD who wishes to live permanently in the gender of a woman will usually undergo gender-affirming hormone therapy, which results in a reduction of testosterone "*into the normal female range, which is <2 nmol/L*".

- The main side effect of oral estrogen treatment for 5-ARD is the risk of venous thrombosis, which is estimated to be approximately 1% over a period of eight years.

387. Prof. Auchus explained that similar answers would apply to individuals with ovotesticular DSD, 17β-hydroxysteroid dehydrogenase type 3 (17β-HSD3) deficiency and any other genetic disorder involving disordered gonadal steroidogenesis.

388. Prof. Auchus also provided expert evidence about CAIS and PAIS. He explained that:

- CAIS is found only in 46 XY individuals, who have testes and make normal amounts of testosterone. Individuals with CAIS cannot respond to androgens, however, and therefore they are phenotypically females with normal female genitalia.

- The prevalence of CAIS is approximately 2 to 5 per 100,000 people. PAIS is at least as common. It is found all over the world and is not specific to any particular race or ethnicity.

- PAIS is also found only in 46 XY individuals who have testes and make normal amounts of testosterone and DHT. Individuals with PAIS do respond to androgens, but do so incompletely. The degree of response can vary considerably from one individual to another. The spectrum of PAIS phenotypes extends from "*nearly completely female*" to "a *slightly under-virilized male*".

- Diagnosis of PAIS is "*somewhat a diagnosis of exclusion*". There is no single biochemical test that can diagnose PAIS; instead "*an overall clinical appraisal*" is required.

- While an individual's degree of androgen insensitivity cannot be defined with a precise number, an experienced physician can make "*a good estimate*" based on a combination of physical examination and laboratory evaluation.

- The level of androgen insensitivity will vary amongst individuals with PAIS. To a variable extent, a 46 XY individual with PAIS will not respond to androgen as well as an unaffected 46 XY individual. An athlete with "*severe*" insensitivity will not experience the same enhancement in athletic performance from male levels of circulating testosterone as 46 XY athletes without PAIS. If the insensitivity is mild, however, the effect may not be very different.

- Patients with PAIS who unequivocally identify as women would typically receive gender-affirming hormone therapy, which has the goal of stopping testosterone production and using estrogen to develop female secondary sexual characteristics.

389. Prof. Auchus concluded his expert report by stating that in his opinion the DSD Regulations are based on sound endocrinological principles. In particular, 46 XY DSD individuals with normal androgen responsiveness and serum testosterone above 5 nmol/L "*will derive advantages in sports performance from having testes that are indistinguishable from the advantages derived by any normal male*". Accordingly, "*sound endocrinological principles would conclude that it is not appropriate for this individual to compete with 46 XX females*". Moreover, in respect of individuals with PAIS, each case should be handled individually and eligibility "*can be determined based on degree of virilization in individuals near the male and female ends of the spectrum*".

Prof. Doriane Lambelet Coleman

390. Professor Doriane Lambelet Coleman is a Professor of Law at Duke Law School in Durham, North Carolina. She is also a former elite track athlete, having competed at national and international level in the 800m event between 1976 and 1992. Her academic specialities include sex discrimination, medicine and law, and sports law.

391. Prof. Lambelet Coleman began her expert report by discussing the purpose and importance of the female category in elite sport. She explained that the division of competitive athletics into male and female categories reflects the widely held view that women are entitled to parity with men in the distribution of sporting opportunities. This commitment to equality facilitates female empowerment and has numerous consequential benefits for both individual women and for society at large. She added that it is well understood that if there were not a separate category for girls and women based on inherent differences between the sexes, the best athletes would always be boys and men. The commitment to female equality in competitive sport is therefore a profoundly important, but also fragile, commitment.

392. Prof. Lambelet Coleman explained that biological sex – specifically possession of testes – affects physical performance in ways that other biological differences do not. Accordingly, it is necessary to have an eligibility rule based on gonadal sex, rather than identity. The overwhelming dominance of male-bodied athletes over female-bodied athletes is not the product of culture, resources, training or gender identity. Instead, it is "*simply the result of having male gonadal sex, specifically testosterone and bioavailable testosterone in the male range rather than the female range*". While the performance gap between the best females and the best males averages 10-12%, it is significant that even non-elite males routinely outperform the best female athletes. When those groups are compared, the performance gap is much smaller than 10-12%; however, collectively it is still determinative.

393. Prof. Lambelet Coleman's report compared the lifetime best performances of three elite female athletes in the 400m event with the performances of male athletes in the same event during a single year (2017). This showed not only that the elite females would have lost to the best men by a margin of about 12%, but also that even at their absolute best the elite females would have lost to thousands of other boys and men by a much smaller margin. For example, in 2017 some 6,959 male athletes ran between 0.01% and 1% faster than the lifetime best of one of the female athletes. According to Prof. Lambelet Coleman, this analysis shows that: "*(a) biologically male athletes however they identify don't have to be elite to surpass even the very best biologically female athletes; (b) a whole lot of biologically male athletes routinely surpass these females at degrees from 0.01% to 15%; and (c) because it doesn't take a sea of them to obliterate the females competitive chances at every level of competition, if only a very small subset turn out to identify as women, we will be overwhelmed*".

394. On the subject of discrimination, Prof. Lambelet Coleman said that it is "*not at all obvious*" that the DSD Regulations will have a disparate impact on individuals in the Global South, since DSD occur among all races and ethnicities. Further, because elite athletics is "*mostly populated at the elite level by athletes of colour*", it is that group of women who will be most affected however the female category is defined. The women who will *benefit* most from the DSD Regulations will therefore also be biological females of colour. It follows that, "*There is discrimination either way, but it's about sex not race.*"

395. Prof. Lambelet Coleman explained that the reason why there are policies against sex discrimination is because females have been subordinated on the explicit basis of their sex-specific biology. Accordingly, she argued that the DSD Regulations are necessary

in order to ensure that females' different, sex-specific biology does not become the cause of inequality in the arena of elite sporting participation and achievement. She stated further that:

- The concept of hyperandrogenism refers to "*normal T levels in biological males who identify as women*".
- Certain elite female athletics events are "*dominated by biologically male athletes with DSDs*".
- Female athletes have been bullied into not expressing their concerns about this state of affairs by vilification and misogynistic false accusations of racism, ignorance and bad sportsmanship.
- It is reasonable to assume that most elite female athletes do not support a situation where eligibility to compete in the female category is based solely on gender identity.

396. Prof. Lambelet Coleman responded to statements regarding the law made by the UN Special Rapporteurs and Working Group and Mr. Katz. She stated among other things that:

- As the law currently stands, the IAAF is not formally subject to international human rights law.
- In most legal regimes, "*sex*" is defined according to reproductive biology.
- The doctrine of informed consent usually requires proof that a decision was made knowingly and voluntarily. This does not require proof that a decision was the product of entirely free will in the absence of external influences. Consent can be vitiated where it was the product of unlawful physical (but not economic) threats.
- There is no basis for assuming that US courts would hold that the DSD Regulations contravene US public policy. There is no statute or precedent that supports that proposition. Indeed, under US law public policy supports efforts of regulatory bodies to protect the playing field for female athletes. US law permits the exclusion of biological males who identify as women where this is necessary to protect female athletes' competitive opportunities.
- The DSD Regulations discriminate in favour of biological females on the basis of biological sex traits. They do not discriminate on the basis of any socially constructed notions of femininity or masculinity.
- In any challenge to the DSD Regulations a US court would adopt a "*highly deferential standard of reasonableness*". The science relied on by the IAAF would "*easily*" meet that standard.

397. Prof. Lambelet Coleman concluded by observing that if the DSD Regulations are struck down then both male-bodied DSD athletes and transgender athletes would be able to

dominate female athletics without restriction. If the female category cannot be restricted to those with female levels of testosterone, then the goal of empowering women and girls through sport will fail.

398. During her oral evidence, Prof. Lambelet Coleman was asked to comment on the proposals adduced by various witnesses during the hearing for how to regulate entry into the female category. She explained that the concepts of being born as a woman and being raised as a woman were both "*social construct[s]*". While those attributes were "*important and valuable*" in respect of how an individual constructs their personhood, "*they are not traits or attributes that are relevant to biology of sport*". The separate women's category in competitive athletics exists because of "*a biological reality*". To the extent that the women's category is intended to create a space where women with "*female reproductive sex*" (which she defined as a reference to "*endocrine sex and gonadal sex*") can succeed, then the inclusion of individuals who do not have female sex traits is "*category defeating*". She added that while Prof. Pielke's suggestion of a test based on whether a person has been born and continuously raised as a woman has "*theoretical and academical appeal*", the practical administration of such a test would be very difficult, since it would be hard to investigate and decide whether a particular individual had consistently sustained a particular gender identity for an extended period of time.

399. Prof. Lambelet Coleman described the question of how to regulate entry into the female category as "*extraordinarily difficult*" and "*excruciatingly hard*". It is a matter that involves a "*heart breaking choice or set of policy choices*". She emphasised that the issue involves "*heartbreak on both sides*", with both DSD athletes and other non-DSD female athletes being deeply impacted by the matters at stake. She reiterated that regulatory bodies must be "*extraordinarily careful*" about how they make those policy choices. She explained that notwithstanding the exceptionally sensitive issues, she remained of the view that eligibility to compete in the female category must be based upon biological traits that affect sport performance.

Joanna Harper

400. Ms. Joanna Harper is a medical physicist and a former national-level track athlete. Since 2005 she has been an advisor to the IOC on the subject of transgender and DSD athletes. For the first 30 years of her distance running career Ms. Harper raced in her assigned male gender. Since 2005, however, she raced in her preferred female gender.

401. In her witness statement Ms. Harper explained why, in her view, the DSD Regulations are "*an appropriate attempt to deal with a very complex subject*". She began by discussing the historical aspect of female eligibility rules, summarising the evolution from crude physical examinations to chromosome testing and the more recent iterations of the IOC and IAAF's regulations on this subject. Ms. Harper then described her experience of undergoing testosterone suppression as part of her hormone therapy during her gender transition. She described how her athletic performance was "*noticeably slower*" within one month of commencing testosterone suppression. Following the completion of her transition, Ms. Harper's times were "*far slower*" than the times she had previously achieved while competing as a male athlete. She did, however, perform as well relative to other female athletes as she had previously

performed relative to male athletes. The only factor that had changed was her level of testosterone.

402. Ms. Harper subsequently began compiling data for the purpose of studying whether transgender women who reduce their testosterone levels to normal female levels have a performance advantage over cisgender female athletes. She collated data from eight transgender distance runners. The data showed that:

- All ran significantly slower times when competing as females with reduced testosterone levels than they had run when they were competing as males with normal male testosterone levels.
- All performed no better against their cisgender peers than they had previously performed against male runners.
- Accordingly, a change in a transgender person's testosterone levels is sufficient to change their athletic performance from competitive male to equally competitive female.

403. Ms. Harper explained that she is currently conducting an ongoing study examining the performance of two transgender athletes during transition. One of the subjects lost around 15% of her aerobic capacity during the first nine months of testosterone suppression, while the other athlete saw her aerobic capacity reduce by 9% during a period of three months.

404. Ms. Harper stated that her studies provide support for the DSD Regulations since the "*extreme and rapid*" changes in athletic performance encountered by transgender women undergoing testosterone suppression therapy demonstrate how important testosterone is to athletic performance. She believes that testosterone is "*without much doubt, the single most important differentiating factor between male and female athletic achievement*". Accordingly, she cannot conceive of a better criterion for determining eligibility to compete in the female classification. Ms. Harper added that, based on her personal experience and research, "*if you're competing in the women's division, you should do so with women's hormone levels*".

405. Ms. Harper went on to suggest that the concept of "*athletic gender*" or "*sports sex*" should be used to determine eligibility to compete in the female classification. She stated that athletic gender should be determined on the basis of a biomarker that is both "*an important factor in differentiating male athletic performance and female athletic performance*" and "*mostly dimorphic*". Testosterone meets both conditions.

406. Ms. Harper explained why, in her opinion, it is wrong to suggest that an individual's "*athletic gender*" or "*sports sex*" must match their legal sex, the gender they were assigned at birth or their gender identity:

- In respect of gender at assigned at birth, this is almost always determined by a cursory examination of external genitalia (a method of determining gender that the IOC and IAAF rejected decades ago). It follows that arguments based on the paramount need to respect that a person was "*born female*" do not hold water.

- In respect of legal sex, there has been a rapid move away from a world where legal sex is binary (*viz.* male or female) to a more nuanced system with non-binary legal status (i.e. not male or female) becoming increasingly common. The advent of non-binary legal sex and the ability of people to change their legal sex at will necessarily means that legal status cannot alone determine sports sex.

- In respect of gender identity, this should be respected in social contexts; however, a person's gender identity has no bearing on their athletic performance. Therefore it should not play an important role in determining their sports sex.

407. Ms. Harper considered the DSD Regulations to be the most rational and fair way of drawing a line between male athletes and female athletes. In this regard:

- The DSD Regulations only apply to events that athletes with DSD "*have dominated, to a degree out of all proportion to their incidence in the general population*" and in so doing have "*tested the notion of fair and meaningful competition for all women*". [...].

- The DSD Regulations recognise that athletic gender is only one among many ways to separate men from women.

- The results of BG17 and the Handelsman Paper are both "*convincing*". They accord with the findings of Ms. Harper's own research, which show that moving from the female to the male range of testosterone has a "*substantial*" effect on athletic performance.

- While the Claimants suggest that any natural advantage is fair, it is very difficult to decide precisely what is and is not fair. Women deserve to compete against one another with some semblance of a level playing field. In Ms. Harper's view, the best way to achieve this is to require all female athletes to be "*hormonally similar*". The DSD Regulations are therefore a reasonable attempt to deal with the "*very complex*" process of assigning a sports sex to athletes with DSD.

408. Lastly, Ms. Harper stated that the side effects of testosterone suppressing hormone treatments are not as serious as the Claimants' witnesses suggest. She described her own very positive experience of taking testosterone suppressing medication, which brought significant benefits with only minor undesirable side effects. She also noted that testosterone suppression treatment is the generally accepted treatment for women with high testosterone and female gender identity.

409. During cross-examination, Ms. Harper accepted that she was not a qualified physician and did not have any experience or qualifications in the fields of endocrinology, gynaecology or exercise physiology. She also accepted that there were limitations to the data that were the focus of her study described above. In particular, she accepted that none of the subjects of the study competed over distances under 5 kilometres and that the study did not report the actual testosterone levels of any of the subjects either before or after their transition from male to female. She also accepted that the study was reliant on subjects self-reporting their race times, although she explained that approximately 50% of those data could be independently verified. She agreed that self-reporting by

subjects reduced the strength of the study's findings. She accepted that one of the athletes who was the subject of the study had actually run a faster time as a female than they had run as a male. She also accepted that none of the eight subjects was a world class elite athlete (she stated that four of the subjects were "*second tier*" athletes while the other four were "*third tier*").

Jan Kowalski

410. Mr. Jan Kowalski is a biostatistician and a former athlete. He is a member of the IAAF Health & Science Commission and the Chairman of the board for the IAAF Diamond League event in Stockholm, Sweden. Mr. Kowalski provided an expert report on behalf of the IAAF which responded to the statistical concerns raised by Ms. Semenya and ASA in respect of BG17 (which he had no involvement in producing) and a paper responding those criticisms (Bermon (2018))[6] which he co-authored.

411. In respect of BG17, Mr. Kowalski stated that:

- BG17 was an exploratory observational study in a real-life setting and all findings and interpretations should therefore be considered in light of this. The findings of the study nevertheless provide "*an important contribution to the total picture of the correlation between testosterone levels and physical performance in athletics*". In particular, it suggests that the effect of testosterone on athletic performance is "*substantial*" and influences the likelihood of victory.

- The findings in BG17 could be used for the design of a "*confirmatory study*" to "*demonstrate and confirm efficacy in terms of performance of pre-defined testosterone levels*", using a double-blind randomised controlled trial. If such a confirmatory study demonstrated superior performance in athletes with high testosterone levels, this would provide "*very strong supportive evidence for the hypothesis that enhanced testosterone levels improve physical athletic performance*".

- The paper establishes that there is an association between female athletic performance and higher levels of testosterone in certain events. It is difficult to find explanations for these associations other than increased testosterone.

412. Mr. Kowalski went on to respond to some of the criticisms levelled against BG17. He stated:

- Comparing groups with the highest testosterone levels with groups with the lowest testosterone levels was an appropriate statistical approach in circumstances where the data were not obtained to confirm effects in accordance with predetermined experimental conditions.

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[6] Bermon *et al, Serum androgen levels are positively correlated with athletic performance and competition results in elite female athletes* (2018) British Journal of Sports Medicine 52:1531-1532.

- Critics who say BG17 disregarded confounding factors have not identified any specific matter that could even theoretically constitute a confounding factor.

- In respect of missing data, this is something that occurs in almost all studies. Before analysing the data, the authors reviewed all data and rejected some as invalid due to doping or where laboratory analysis was impossible (e.g. because of insufficient sample volume). This process of "*data cleaning*" is typical when dealing with observational data which have already been collected.

- The suggestion that the authors failed to exclude duplicate data is misconceived. The data were not "*true*" duplicates.

413. In respect of Bermon (2018), Mr. Kowalski stated that BG17 and the "*sensitivity analysis population*" in Bermon (2018) showed "*similar results and findings*". The sole reason for excluding 230 subjects from the analysis in Bermon (2018) was to ensure that the analysis was confined to individuals that are strictly independent (i.e. to remove duplicates). There was nothing erroneous about this.

414. Mr. Kowalski concluded his report by stating that the statistical measures in BG17 were "*appropriate for this exploratory study*" and that the further analysis in Bermon (2018) corroborated BG17 and "*confirm[ed] that there is a statistical[ly] significant correlation between testosterone levels and the best performances in the 400m, 400m hurdles, 800m and hammer throw, with a similar trend observed for the 1500m and pole vault*". Since these statistical findings were found to exist in multiple independent sub-groups of events/disciplines, it is "*very unlikely to be found by chance*" and is more likely to reflect "*a true relationship*". Accordingly, Mr. Kowalski considered the criticisms of the statistics relied on by the IAAF to be meritless.

Relief claimed by the IAAF

415. In its answer, the IAAF sought the following relief:

6.1 The IAAF asks the CAS Panel: (1) to rule that the DSD Regulations do not infringe any athlete's rights, including the right to equal treatment, but instead are a justified and proportionate means of ensuring consistent treatment, and preserving fair and meaningful competition within the female classification; (2) to order the Claimants to pay the costs of the arbitration within the meaning of CAS Code R64.4, including reimbursing the IAAF for any such costs that it has been required to advance; and (3) to order the Claimants to pay an appropriate contribution towards the legal costs and other expenses that the IAAF incurs in defending the DSD Regulations in these proceedings, further to CAS Code R645.5.

VI. JURISDICTION

416. Article R27 of the Code provides as follows:

These Procedural Rules apply whenever the parties have agreed to refer a sports-related dispute to CAS. Such reference may arise out of an arbitration clause contained in a contract or regulations or by reason of a later arbitration agreement (ordinary

arbitration proceedings) or may involve an appeal against a decision rendered by a federation or sports-related body where the statutes or regulations of such bodies, or a specific agreement provide for an appeal to CAS (appeal arbitration proceedings).

417. Clause 5.2 of the DSD Regulations provide as follows:

[a]ny dispute arising between the IAAF and an affected athlete (and/or Member Federation) in connection with these Regulations will be subject to the exclusive jurisdiction of the CAS. In particular, (but without limitation), the validity, legality and/or proper interpretation or application of the Regulations may only be challenged (a) by way ordinary proceedings filed before the CAS; and/or (b) as part of an appeal to the CAS made pursuant to clause 5.3.

418. The IAAF accepts that Ms. Semenya is, for purposes of this dispute, an affected athlete and that ASA is the Member Federation to which she is affiliated. Neither Ms. Semenya nor ASA object to jurisdiction as set out in Clause 5.2 of the Regulations. Moreover, the parties confirmed the jurisdiction of the CAS when signing the order of procedure and explicitly confirmed it at the commencement of the hearing.

419. The Panel, therefore, is satisfied that it has jurisdiction over this dispute.

420. Notwithstanding the foregoing, the Panel notes the IAAF's letter of 5 March 2019 which seeks to incorporate amendments to the DSD Regulations. The Panel considers that such new elements to the DSD Regulations are untimely in accordance with Article R44.1 of the Code and, therefore, does not consider them in the context of its reasoning or ultimate decision as set out below.

VII. APPLICABLE LAW

421. Article R45 of the Code provides as follows:

The Panel shall decide the dispute according to the rules of law chosen by the parties or, in the absence of such a choice, according to Swiss law. The parties may authorize the Panel to decide ex aequo et bono.

422. In both their oral and written submissions, the parties have expressly referred to and relied upon the Olympic Charter, the IAAF Constitution, as well as the IAAF Rules and Regulations, including the DSD Regulations. In subsidiary arguments, the parties also mutually rely upon the law of Monaco (and, on various points, ASA relies on various National laws of Korea and Russia).

423. Moreover, during final submissions, the Panel asked the parties if they would consent to the Panel exercising power under Article R45 of the Code. The IAAF declined to provide such consent at the time. During subsequent post-hearing written submissions, the IAAF modified its position by suggesting that it would consent to a limited exercise of that power. The Claimants did not agree to the power under Article R45 being exercised on a limited basis as proposed by the IAAF. Accordingly, in the absence of unanimous agreement between the parties, the power under Article R45 is inapplicable.

424. Accordingly, in deciding this dispute and unless otherwise specifically mentioned, the Panel finds no reason to deviate from the law agreed upon by the parties and will apply the IAAF's Constitution and Rules in conjunction with the Olympic Charter and in subsidiary, where necessary, Monegasque law.

VIII. THE DSD REGULATIONS

425. The DSD Regulations the subject of the hearing are the Regulations that have been narrowed by deletion of the references to CAH and the CAH variant. For purposes of completeness and ease of reference, the Panel hereby sets out the operative sections of the DSD Regulations at issue, as follows:

426. Regulation 1.1 of the DSD Regulations ("*Introduction*") explains that:

> *These Regulations reflect the following imperatives:*
>
> *(a) To ensure fair and meaningful competition in the sport of athletics, competition has to be organised within categories that create a level playing field and ensure that success is determined by talent, dedication, hard work, and the other values and characteristics that the sport embodies and celebrates. In particular:*
>
> *(i) The IAAF wants athletes to be incentivised to make the huge commitment and sacrifice required to excel in the sport, and so to inspire new generations to join the sport and aspire to the same excellence. It does not want to risk discouraging those aspirations by having unfair competition conditions that deny athletes a fair opportunity to succeed.*
>
> *(ii) Because of the significant advantages in size, strength and power enjoyed (on average) by men over women from puberty onwards, due in large part to men's much higher levels of circulating testosterone,1 and the impact that such advantages can have on sporting performance, it is generally accepted that competition between male and female athletes would not be fair and meaningful, and would risk discouraging women from participation in the sport. Therefore, in addition to separate competition categories based on age, the IAAF has also created separate competition categories for male and female athletes.*
>
> *(b) The IAAF also recognises, however, that:*
>
> *(i) Biological sex is an umbrella term that includes distinct aspects of chromosomal, gonadal, hormonal and phenotypic sex, each of which is fixed and all of which are usually aligned into the conventional male and female binary.*
>
> *(ii) However, some individuals have congenital conditions that cause atypical development of their chromosomal, gonadal, and/or anatomic*

sex (known as differences of sex development, or DSDs, and sometimes referred to as 'intersex').

(iii) As a result, some national legal systems now recognise legal sexes other than simply male and female (for example, 'intersex', 'X', or 'other').

(c) The IAAF respects the dignity of all individuals, including individuals with DSDs. It also wishes the sport of athletics to be as inclusive as possible, and to encourage and provide a clear path to participation in the sport for all. The IAAF therefore seeks to place conditions on such participation only to the extent necessary to ensure fair and meaningful competition. As a result, the IAAF has issued these Regulations, to facilitate the participation in the sport of athletes with DSDs.

There is a broad medical and scientific consensus, supported by peer-reviewed data and evidence from the field, that the high levels of endogenous testosterone circulating in athletes with certain DSDs can significantly enhance their sporting performance. These Regulations accordingly permit such athletes to compete in the female classification in the events that currently appear to be most clearly affected only if they meet the Eligibility Conditions defined below.

(e) These Regulations exist solely to ensure fair and meaningful competition within the female classification, for the benefit of the broad class of female athletes. In no way are they intended as any kind of judgement on or questioning of the sex or the gender identity of any athlete. To the contrary, the IAAF regards it as essential to respect and preserve the dignity and privacy of athletes with DSDs, and therefore all cases arising under these Regulations must be handled and resolved in a fair, consistent and confidential manner, recognising the sensitive nature of such matters. Any breach of confidentiality, improper discrimination, and/or stigmatisation on grounds of sex or gender identity will amount to a serious breach of the IAAF Integrity Code of Conduct and will result in appropriate disciplinary action against the offending party.

427. Regulation 1.2 provides that the DSD Regulations "*operate globally*" and therefore "*are to be interpreted and applied not by reference to national or local laws, but rather as an independent and autonomous text, and in a manner that protects and advances the imperatives identified above*".

428. Regulation 1.3 provides that all cases arising under the DSD Regulations "*will be dealt with by the IAAF Health and Science Department*" and that, "*Each National Federation is bound by these Regulations and is required to cooperate with and support the IAAF in the application and enforcement of these Regulations...*"

429. Regulation 1.4 provides that the DSD Regulations take effect on 1 November 2018 and apply both to cases that arose before and after that date. It adds that the Regulations "*are binding on and must be complied with by athletes, National Federations, Areas, Athlete Representatives, Member Federation Officials, and all other Applicable Persons.*"

430. Regulation 2 is headed "*Special Eligibility Requirements for Restricted Events at International Competitions*". Regulation 2.1 explains that the special rules set out in the DSD Regulations

> *apply only to participation by a Relevant Athlete in the female classification in a Restricted Event at an International Competition. They do not apply to any other athletes, or to any other events, or to any other competitions (although f a Relevant Athlete does not meet the Eligibility Conditions then she will not be eligible to set a World Record in a Restricted Event at a competition that is not an International Competition).*

431. Regulation 2.2(a) defines a "*Relevant Athlete*" as follows:

> *(a) A Relevant Athlete is an athlete who meets each of the following three criteria:*
>
> *(i) she has one of the following DSDs:*
>
> *(A) 5α-reductase type 2 deficiency;*
>
> *(B) partial androgen insensitivity syndrome (PAIS);*
>
> *(C) 17β-hydroxysteroid dehydrogenase type 3 (17β- HSD3) deficiency;*
>
> *(D) congenital adrenal hyperplasia;*
>
> *(E) 3β-hydroxysteroid dehydrogenase deficiency;*
>
> *(F) ovotesticular DSD; or*
>
> *(G) any other genetic disorder involving disordered gonadal steroidogenesis; and*
>
> *(ii) as a result, she has circulating testosterone levels in blood of five (5) nmol/L or above; and*
>
> *(iii) she has sufficient androgen sensitivity for those levels of testosterone to have a material androgenising effect.*

432. As explained above, during the course of this proceedings the IAAF indicated that the reference to congenital adrenal hyperplasia (CAH) would be deleted from the list of DSD in Regulation 2.2(a)(i).

433. Regulation 2.2(b) defines "*Restricted Events*" as follows:

> *Restricted Events are 400m races, 400m hurdles races, 800m races, 1500m races, one mile races, and all other Track Events over distances between 400m and one mile (inclusive), whether run alone or as part of a relay event or a Combined Event.*

434. Regulation 2.3 specifies certain "*Eligibility Conditions*" that apply to Relevant Athletes:

> *To be eligible to compete in the female classification in a Restricted Event at an International Competition, or to set a World Record in a competition that is not an International Competition, a Relevant Athlete must meet each of the following conditions (the Eligibility Conditions):*
>
> > *(a) she must be recognised at law either as female or as intersex (or equivalent);*
> >
> > *(b) she must reduce her blood testosterone level to below five (5) nmol/L8 for a continuous period of at least six months (e.g., by use of hormonal contraceptives); and*
> >
> > *(c) thereafter she must maintain her blood testosterone level below five (5) nmol/L continuously (i.e., whether she is in competition or out of competition) for so long as she wishes to maintain eligibility to compete in the female classification in Restricted Events at International Competitions (or to set a World Record in a Restricted Event at a competition that is not an International Competition).*

435. Regulations 2.4 and 2.5 provide further that:

> *2.4 For the avoidance of doubt, there are no other special conditions that a Relevant Athlete must satisfy in order to participate in the female classification in a Restricted Event at an International Competition (or to set a World Record in a Restricted Event at a competition that is not an International Competition).9 In particular, surgical anatomical changes are not required in any circumstances.*
>
> *2.5 For the avoidance of doubt, no athlete will be forced to undergo any assessment and/or treatment under these Regulations. It is the athlete's responsibility, in close consultation with her medical team, to decide whether or not to proceed with any assessment and/or treatment.*

436. Regulation 2.6 sets out the consequences that arise where a Relevant Athlete does not meet the Eligibility Conditions:

> *A Relevant Athlete who does not meet the Eligibility Conditions (and any athlete who is asked by the IAAF Medical Manager to submit to assessment under these Regulations and fails or refuses to do so) will not be eligible to compete in the female classification in a Restricted Event at an International Competition (or to set a World Record in a Restricted Event at a competition that is not an International Competition). However, that athlete will be eligible to compete:*
>
> > *(a) in the female classification:*
> >
> > > *(i) at competitions that are not International Competitions: in all Track Events, Field Events, and Combined Events, including the Restricted Events; and*

> *(ii) at International Competitions: in all Track Events, Field Events, and Combined Events, other than the Restricted Events; or*
>
> *(b) in the male classification, at all competitions (whether International Competitions or otherwise), in all Track Events, Field Events, and Combined Events, including the Restricted Events; or*
>
> *(c) in any applicable intersex or similar classification that may be offered, at all competitions (whether International Competitions or otherwise), in all Track Events, Field Events, and Combined Events, including the Restricted Events.*

437. Regulation 3 contains provisions governing the "*Assessment of Cases*" that arise under the DSD Regulations. Regulation 3.1 provides that an athlete "*who is or believes that she may be a Relevant Athlete*" must advise the IAAF Medical Manager if she wishes to compete in the female classification in a Restricted Event at an International Competition. The same obligation applies to the athlete's National Federation. The Regulation further provides that:

> *She must do so as far in advance of the International Competition in question as possible (at least three months prior to the final entry date), and must provide the necessary information (or cooperate in the collection of the necessary information) and submit to the assessment described below to determine whether she is a Relevant Athlete and (if so) to demonstrate her satisfaction of the Eligibility Conditions.*

438. Regulations 3.2 and 3.3 provide that:

> *3.2 In addition, the IAAF Medical Manager may investigate at any time (including, without limitation, through analysis of blood and/or urine samples collected from athletes who are competing or entered to compete in the female classification in a Restricted Event at an International Competition) whether any athlete who has not advised the IAAF Medical Manager in accordance with clause 3.1 may be a Relevant Athlete whose case requires assessment under these Regulations. The Relevant Athlete agrees to provide samples for this purpose, and also agrees that any samples that she provides or has previously provided for anti-doping purposes and/or any anti-doping data relating to her may also be used for this purpose.*
>
> *3.3 Only the IAAF Medical Manager may initiate an investigation under clause 3.2, and he/she may only do so when acting in good faith and on reasonable grounds based on information derived from reliable sources, such as (for example, but without limitation) the athlete herself, the team doctor of the National Federation to which the athlete is affiliated, results from a routine pre- participation health examination, and/or information/data (including but not limited to blood testosterone levels) obtained from the collection and analysis of samples for anti-doping purposes.*

439. Regulation 3.4 states that, "*The dignity and privacy of every individual must be respected at all times*" and that all breaches of confidentiality and all forms of abuse or

harassment are prohibited. Any such conduct will constitute a serious breach of the IAAF Integrity Code of Conduct.

440. Regulation 3.5 states that cases will be investigated/assessed as quickly as reasonably practicable and that an athlete who is under investigation/assessment must cooperate in good faith including by "*providing blood and/or urine samples upon request for analysis, and if needed, by submitting to medical physical examination*".

441. Regulation 3.6 provides that the IAAF Medical Manager and an athlete whose case arises for investigation/assessment under the DSD Regulations may agree on the appointment of an independent ombudsman to assist the athlete in understanding and addressing the requirements of the Regulations.

442. Regulation 3.7 states that the IAAF Medical Manager will appoint a pool of independent medical experts from which a suitably qualified panel of experts may be drawn "*to review cases under these Regulations as they may arise*". Regulation 3.8 then summarises the standard procedure for conducting assessments under the DSD Regulations:

> *The case will be assessed in accordance with the guidelines set out in Appendix 3 to these Regulations. The standard procedure may be summarised as follows:*
>
> > *(a) There will be an initial assessment by a suitably qualified physician, involving an initial clinical examination of the athlete, and compilation of her clinical and anamnestic data, as well as a preliminary endocrine assessment.*
> >
> > *(b) If it appears the athlete may be a Relevant Athlete, the IAAF Medical Manager will then anonymise the file and send it to the chair, who will convene an Expert Panel to determine whether further assessment is warranted as to whether the athlete is a Relevant Athlete.*
> >
> > *(c) If the Expert Panel considers that further assessment is warranted, the athlete will then be referred to one of the specialist reference centres listed at Appendix 4 to these Regulations for further assessment, in order to reach a diagnosis of the cause of the athlete's elevated levels of blood testosterone, and to consider further the degree of the athlete's androgen insensitivity (if any).*
> >
> > *(d) The report of the specialist reference centre will then be sent back to the Expert Panel for consideration.*

443. Regulation 3.9 provides that the Expert Panel will review the report of the specialist reference centre together with the rest of the file and will then transmit a written recommendation to the IAAF Management. Sub-paragraph (a) provides that:

> *If the Expert Panel considers that the athlete is a Relevant Athlete but that she has not (yet) met the Eligibility Conditions, it must explain in writing the reasons for its view. It should also specify what else the athlete must do to satisfy the Eligibility Conditions, should she wish to do so. In such a case, it will recommend that the athlete not be declared eligible to compete in the female classification in Restricted*

Events at International Competitions unless and until the IAAF Medical Manager decides that she has done what the Expert Panel considered remained necessary to satisfy the Eligibility Conditions.

444. Regulation 3.11 states that a Relevant Athlete is "*solely responsible for continuing to comply with the Eligibility Conditions for as long as she wishes to compete in the female classification in a Restricted Event at International Competitions.*"

445. Under Regulation 3.14, if it is determined that a Relevant Athlete has competed in the female classification in one or more Restricted Events at an International Competition while having blood testosterone of 5 nmol/L or more then the IAAF "*may in its absolute discretion disqualify the individual results obtained by the athlete in such Restricted Events at that competition, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other rewards awarded to the athlete based on those results.*"

446. Regulation 3.15 (in its original unamended form) and Regulation 3.16 provide that the IAAF will bear the costs of assessment and diagnosis under the DSD Regulations, while the athlete must bear the costs of her personal physician(s) and of any treatment required to satisfy the Eligibility Conditions, as well as the costs of providing the evidence of continuing satisfaction of the Eligibility Conditions.

447. Regulation 3.18 provides that an athlete who wishes to participate in the female classification in a Restricted Event at an International Competition (or to be eligible to set a World Record in a Restricted Event outside an International Competition) must agree to comply fully with the DSD Regulations and to cooperate promptly and in good faith with the IAAF Medical Manager and Expert Panel including by:

(i) providing them with all of the information and evidence they request to determine whether she is a Relevant Athlete and (if so) to assess her compliance and to monitor her continuing compliance with the Eligibility Conditions, including (without limitation) submitting to testing in accordance with these Regulations;

(ii) ensuring that all information and evidence provided is accurate and complete, and that nothing relevant is withheld;

(iii) providing appropriate consents and waivers (in a form satisfactory to the IAAF Medical Manager) to enable her physician(s) to disclose to the IAAF Medical Manager and the Expert Panel any information that the Expert Panel deems necessary to its assessment

448. In addition, under Regulation 3.18(d) such an athlete is also required to follow the dispute resolution procedures set out in Regulation 4 (see below) and must "*not... bring any proceedings in any court or other forum that are inconsistent*" with that provision.

449. Regulation 4 concerns confidentiality. It provides that all cases, results of investigations and assessments conducted under the DSD Regulations will be dealt with in strict confidence at all times (Regulation 4.1) and that the IAAF will not comment publicly on the specific facts of a case arising under the DSD Regulations (save in response to public comments made by the athlete or their representatives) (Regulation 4.2).

450. Regulation 5 contains provisions concerning dispute resolution. Regulation 5.2 provides that any dispute in connection with the DSD Regulations arising between the IAAF and an affected athlete (and/or her member federation) shall be subject to the exclusive jurisdiction of the CAS. Regulation 5.3 also establishes a right for affected athletes to appeal to the CAS against certain decisions under the DSD Regulations:

> *The affected athlete may appeal the following decisions (and only the following decisions) made under these Regulations to the CAS, in accordance with this clause 5, by filing a Statement of Appeal with the CAS and with the IAAF within thirty days of the date of communication of the written reasons for the decision (and the IAAF will be the respondent to the appeal):*
>
> > *(a) a decision that an athlete is a Relevant Athlete who does not satisfy the Eligibility Conditions and so is not eligible to compete in the female classification in a Restricted Event at an International Competition or to set a World Record in a Restricted Event at a competition that is not an International Competition;*
> >
> > *(b) a decision that an athlete who is asked by the IAAF Medical Manager to submit to assessment under these Regulations and fails or refuses to do so (or fails to cooperate fully and in good faith the investigation/assessment under these Regulations) is not eligible to compete in the female classification in a Restricted Event at an International Competition or to set a World Record in a Restricted Event at a competition that is not an International Competition;*
> >
> > *(c) a decision that a Relevant Athlete has failed to continue to satisfy the Eligibility Conditions, with the consequences set out in clause 3.13; and*
> >
> > *(d) a decision to disqualify results further to clause 3.14.*

451. Appendix 2 to the DSD Regulations contains a list of 15 medical experts.

452. Appendix 3 then sets out a detailed "*Framework for Assessment of Cases*" which identifies three levels of assessment, namely Level 1 ("*initial clinical examination and compilation of data and preliminary endocrine assessment*"); Level 2 ("*assessment by an Expert Panel*"); and Level 3 ("*assessment by specialist reference centre*"). According to the Appendix:

- The Level 1 stage of the assessment begins with an initial clinical examination of the athlete, the compilation of her clinical an anamnestic data, and a preliminary endocrine assessment (which involves the collection of urine and blood samples for analysis by an IAAF-approved laboratory). The IAAF Medical Manager will then review whether there is sufficient information for the Expert Panel to conduct the Level 2 Assessment. To this end, the IAAF Manager may arrange for the collection of further blood or urine samples from the athlete and may seek "*an advisory opinion on a confidential basis from such person(s) as he/she considers appropriate*".

- At the Level 2 stage the Expert Panel will seek to determine whether the athlete has one of the specified DSD and, if so, whether she has blood testosterone of 5

nmol/L or above and "*has sufficient androgen sensitivity for those levels of testosterone to have a material androgenizing effect*". In respect of the latter, the Expert Panel "*will look at the results of the clinical examination and the data collected as part of the Level 1 Assessment in order to determine the nature and extent of the androgenising effect, with the benefit of any doubt on this issue being resolved in favour of the athlete.*" The Expert Panel "*may make such enquiries or investigations as it considers necessary to carry out the required assessment effectively, including (without limitation) requesting further data or information from the athlete or the athlete's physician and/or obtaining additional expert opinion(s)*", while the athlete and her personal physician "*must cooperate and assist with that process*".

- At the Level 3 stage a specialist reference centre "*will conduct a full examination on the athlete and will carry out a diagnosis of the athlete in accordance with best medical practice*". The Level 3 assessment "*will normally include the following different types of test: physical, laboratory (including urine and blood analysis and appropriate genetic testing for mutations in the genes involved in the conditions at issue), imaging, and psychological assessment.*"

453. The concluding paragraph of Appendix 3 provides that the Expert Panel "*will only recommend that the athlete be treated as a Relevant Athlete if it is satisfied that she meets all of the criteria set out at paragraph 12*" and that "*the benefit of any doubt shall be resolved in favour of the athlete.*"

IX. MERITS

A. Introduction

454. Ms. Semenya is a woman. At birth, it was determined that she was female, so she was born a woman. She has been raised as a woman. She has lived as a woman. She has run as a woman. She is – and always has been – recognised in law as a woman and has always identified as a woman.

455. As an athlete, she says that she was born to run. She has undoubtedly had outstanding success in her career as an elite middle-distance runner, winning multiple Olympic, World, Commonwealth and regional championship titles. She is, today, a strong and dignified woman and one of the most famous and accomplished female athletes in the history of the sport.

456. The IAAF is entrusted with enacting regulations to facilitate and ensure the fair and principled administration of the sport of athletics for the benefit of all athletes. To this end, the IAAF has for some years, if not decades, struggled to deal with a problem that the IAAF believes must be solved. While children manifest similar athletic ability pre-puberty, this changes significantly post-puberty. Later in this Award, some of those changes are discussed but, at this point, suffice to say that post-puberty, generally speaking, male athletes outperform female athletes and, at elite level, this difference is insurmountable. Accordingly, in order to enable women to compete at elite level, with all of the benefits that result from such competitions and success in such competitions,

it has been considered necessary to provide for what the IAAF calls "*a protected class*" of female athletes. Without the protection of restricted entry to that class, the IAAF says, women athletes would be at risk of being denied the right to compete and succeed at the highest levels. It would follow that women athletes would cease to compete in events where that protection is not available. Accordingly, the "protected class" must exist, and some workable and effective condition(s) must be established to regulate who may, and may not, participate within it.

457. The answer, at first, seems to be logical and straightforward: restrict entry to that "protected class" to female athletes and deny entry to male athletes, who have their own category in which to compete. In short, require like to compete against like. However, that straightforward answer assumes that sex is binary for all purposes, which it is not. It is not so simple. While elite competitive athletics has been divided into discrete binary categories of male and female, a neat and discrete boundary between male and female does not exist in nature. The male/female categorisation at the heart of competitive athletics thus does not map perfectly onto the diverse spectrum of sex characteristics that exists in natural human biology.

458. In recent years, a further complicating factor has begun to emerge. Laws governing the assignment of legal sex have begun to evolve in a number of jurisdictions around the world. In some jurisdictions legal sex is no longer exclusively confined to the statuses of "male" and "female". Other legal sex statuses – such as "intersex" – are now recognised in some countries. Moreover, in some jurisdictions, an individual born as one sex may change their legal sex in certain circumstances. The circumstances where this is possible vary across those jurisdictions that permit such changes to occur. The present case is not concerned with athletes who change their legal sex. Separate regulations cater specifically for such cases. The IAAF nonetheless points in this case to the growing divergence in the national rules governing legal sex as a further factor that means that the right to participate in the female class cannot simply depend on whether an athlete is recognised in national law as female.

459. The IAAF has tried to find a solution to this dilemma and has put forward a number of solutions, all of which have been deemed inappropriate. The DSD Regulations are the latest iteration of the IAAF's struggle to enact an effective and legally defensible means of reconciling the binary male/female classification in competitive athletics with the variegated spectrum of biological sex characteristics that exist in nature and the increasingly complex and diverse national laws governing legal sex.

460. This case therefore involves a collision of scientific, ethical and legal conundrums. It also involves incompatible, competing, rights. It is not possible to give effect to, or endorse, one set of rights without restricting the other set of rights. Put simply, on one hand is the right of every athlete to compete in sport, to have their legal sex and gender identity respected, and to be free from any form of discrimination. On the other hand, is the right of female athletes, who are relevantly biologically disadvantaged vis-à-vis male athletes, to be able to compete against other female athletes and not against male athletes and to achieve the benefits of athletic success, such as positions on the podium and consequential commercial advantages. This right of competition is often described (although not so easily defined) as the right to compete on a "level playing field".

461. In the present case it is not in dispute that it is necessary to have a "protected class" of female athletes. It is common ground that competitive athletics is (and should be) divided into separate male and female categories. No party has suggested that male athletes should generally be permitted to compete at international elite levels against female athletes (although the DSD Regulations would permit women XY 5-ARD athletes who do not wish to lower their testosterone levels to compete in the male category). However, the issue of how to regulate the right to participate in the "protected class" is complex. In strictly biological terms, not all individuals' bodies fit neatly and unambiguously into a single binary male/female classification. Complex questions of biology therefore arise, necessitating consideration of issues of genetics, endocrinology and gynaecology.

462. It is common ground that any rules regulating who may participate in the female category must be rational, objective and fair. The IAAF insists that it does not challenge or call into question the sex or gender of Ms. Semenya or DSD athletes in general. Rather, in a consideration of eligibility to compete in certain events as a female, it refers to what it terms the "sports sex" of women athletes, invoking the existence of certain DSD and the level of endogenous testosterone to introduce a further qualification or eligibility requirement for entry into certain events in the female category. It asserts that the DSD Regulations represent a progressive and fair compromise between the right of female athletes to have a separate category of competition from the men so that they have the same chances to excel, on the one hand, and the desire of "*certain biologically male athletes with female gender identities to compete in the female category of competition*" on the other. Ms. Semenya and ASA strenuously reject the characterisation of the DSD Regulations as fair and progressive. They also strongly object to the IAAF's invocation of the concept of "*biologically male athletes*", which they regard as offensive and tantamount to questioning [...] sex [...].

463. In considering the issues in this case, it is important to bear in mind that the labels "male" and "female" may mean different things in different contexts. For example, these words may refer to a person's legal sex (i.e. their sex in the eyes of the law), their subjective gender identity (i.e. how they identify themselves) or some specific aspect of their individual physiology (for example their gonadic characteristics or their hormonal profile). The different meanings that attach to the same words in different contexts explain, in part, why rules governing eligibility to participate and compete in the female category generate such controversy and strength of feeling. A rule that seeks to define "maleness" or "femaleness" for one purpose can easily be perceived (rightly or wrongly) as an attempt to define – or to challenge – a person's "maleness" or "femaleness" for other purposes or in other contexts.

464. As a result of this, it will be necessary in this Award to refer to matters, or use language, that some people may find insensitive or inappropriate. It is simply not possible to explain the arguments and evidence advanced by the parties without drawing on the distinctions and language so advanced. It is, therefore, important to stress that nothing in this Award is intended to question, determine or pass judgment upon any aspect of any person's sex or gender. Instead, this Award is solely concerned with deciding the specific legal issues that arise for determination of the lawfulness of the DSD Regulations as challenged by Ms. Semenya and ASA.

465. Before addressing those issues, the Panel wishes at the outset of its reasoning to record its deep appreciation for the assistance it has received throughout the proceeding from the parties and their legal representatives. While the issues in the case are complex and sensitive, the hearing before the Panel was conducted with conspicuous skill, diligence and courtesy.

466. The Panel also wishes to place on record its gratitude for the assistance provided by the various witnesses who testified in this proceeding. The arguments in this case span issues of great breadth and complexity. In seeking to comprehend and determine those issues, the Panel has derived significant assistance from the detailed written and oral evidence provided by an array of esteemed experts and other witnesses with relevant personal experience of these matters. Much of the expert evidence was discussed concurrently in a series of "hot tubs". The Panel expresses its gratitude to the expert witnesses for their conduct in this process and the helpful attempts made to explain where they had reached consensus and where and why they differed.

467. Most importantly, the Panel wishes to acknowledge the dignity displayed by Ms. Semenya throughout this proceeding. While the parties presented their evidence and submissions with due sensitivity, the Panel is conscious that the written and oral phases of the proceeding involved extensive and sensitive scrutiny of Ms. Semenya's personal health and physiology. The Panel pays tribute to Ms. Semenya's grace and fortitude throughout this difficult process and expresses its gratitude for her dignified personal participation and the exemplary manner in which she has conducted herself throughout the proceeding.

468. The Panel also wishes to stress that while much of the argument in this proceeding has centred around the "fairness" of permitting [...] women with [...] DSD conditions) to compete against other female athletes, there can be no suggestion that [...] female athletes with 46 XY DSD have done anything wrong. This is not a case about cheating or wrongdoing of any sort. Ms. Semenya is not accused of breaching any rule. Her participation and success in elite female athletics is entirely beyond reproach. She has done nothing to warrant any personal criticism and nothing in this Award should be taken to suggest otherwise.

469. The Panel freely admits that it has not found the issues in this case easy to decide. It is clear from the range of expert evidence presented in this proceeding that there are many scientific, ethical and regulatory issues on which reasonable and informed minds may legitimately differ. The Panel is mindful that, in considering these issues, it is not acting as a policy maker or regulator. It is neither necessary nor appropriate for the Panel to step into the shoes of the IAAF by deciding how it would have approached issues had it been charged with making policies or enacting rules itself. *See, e.g.* CAS 2016/O/4684 *ROC et al. v. IAAF*. Instead, its function is a purely judicial one. The Panel must adjudicate the disputed legal issues on the basis of the applicable legal tests and by reference to the arguments and admissible evidence on the record in these proceedings. While this inevitably requires consideration of arguments and evidence based on an array of policy and scientific matters, the Panel must be mindful of its judicial role and the limits of that role.

B. The *Chand* decision

470. The CAS previously considered some of the issues relevant to this procedure in CAS 2014/A/3759 *Chand v IAAF*. The parties have used some of the discussion in *Chand* as a starting point for the present case. This Panel will not revisit the analysis in *Chand* but will, as did the parties, assume that some of the findings in that case are apposite to this one. Nevertheless, there has been a large amount of expert evidence presented to this Panel that was not available in *Chand* and the Panel looks exclusively to the evidence presented in this case to make its determination regarding the validity of the DSD Regulations.

471. Given the parties' extensive references to *Chand* during their written and oral submissions, the present Panel considers it important to stress that the findings and decision in *Chand* are in no way binding on this Panel. In particular, it is necessary to emphasize that the *Chand* appeal concerned a challenge to the validity of a different regulation, which was brought by a different claimant, and which was heard and determined by a differently constituted CAS Panel on the basis of the evidence and submissions presented to it during the course of that proceeding. This Panel is not hearing an appeal from – and nor is it bound to follow – any aspect of the decision rendered in *Chand* almost four years ago. Instead, it is the duty of this Panel to determine the issues that arise in the present proceeding based solely on the evidence and arguments advanced by the parties in the context of this proceeding.

472. Nevertheless, since the parties used aspects of *Chand* as a framework for their submissions before this Panel, it is appropriate to highlight some of the features of the reasoning that the parties cited and relied upon. The matters in *Chand* that the parties drew to the Panel's attention include:

- Separate male and female categories in athletics are appropriate and justifiable in the interests of fair competition.
- There should be an objective criterion or criteria to regulate the divide between the male and female categories.
- The previous regulations, the IAAF's *Regulations Governing Eligibility of Females with Hyperandrogenism to Compete in Women's Competition* ("the Hyperandrogenism Regulations") were held to be discriminatory on the basis of requiring testing only of female, and not male, athletes and on the basis of natural physical characteristics.
- The higher-ranking rules of the Olympic Charter, the IAAF Constitution and the Laws of Monaco prevailed over the Hyperandrogenism Regulations unless the IAAF could establish that the Regulations were necessary, reasonable and proportionate for the purpose of establishing a level playing field in female athletics.
- Lean body mass, which is the result of the increased level of testosterone which begins in males at puberty, is of "*key importance*" in respect of the 10-12% difference in performance as between elite male and female athletes.

- In order to justify the existence of regulations restricting the right of hyperandrogenic female athletes to compete in the female category, it is necessary to demonstrate that such individuals enjoy a significant performance advantage by virtue of their enhanced testosterone levels over their non-hyperandrogenic female peers, which makes it necessary to exclude them from competing in the female category because otherwise the very basis for having a female category would be subverted and a level playing field would be prevented.

- In this regard, it is necessary to demonstrate that the performance advantage was of comparable significance, if not identical magnitude, to that enjoyed by male athletes over female athletes, and that there is a causal relationship between that performance advantage and levels of endogenous testosterone which are the subject of the regulations.

C. The factual and scientific issues in this case

473. A number of complex factual and scientific issues emerged during the proceeding. In light of those issues and the direct bearing that they have upon the legal tests that the Panel must apply, it is necessary to understand the factual matrix before addressing the legal issues confronting the Panel.

474. The factual and scientific issues can broadly be grouped by reference to the following questions:

- What is the role of testosterone in male/female sporting ability?

- What is the role of DHT in male/female sporting ability?

- What are the main characteristics of an athlete with a DSD such as 5-ARD?

- Can it be said, as advanced by the IAAF, that an athlete who has a female legal sex and a female gender identity nevertheless has a "male sports sex"?

- Did the athletes whose data were the subject of BG17 provide informed consent for those data to be used for the purposes of that study?

- Do women with a 46 XY DSD such as 5-ARD have an athletic advantage over other female athletes?

- If so, what is the magnitude of that advantage?

475. The evidence on these questions was provided by a number of eminent experts in an array of scientific disciplines. The challenges made to the independence of some of those experts are rejected. The Panel is satisfied that each expert used his or her best endeavours to express their own genuinely held views. Different weight can be, and is, afforded to some of those views where they were not shown to be based on evidence or on personal experience but were more in the nature of individual opinion or hypothesis, or related to matters beyond the specific expertise of the relevant witness. Many of the opinions expressed in the written expert reports were refined by the mechanism of a series of "hot tubs", where the experts gave concurrent oral evidence before the Panel.

476. Some matters were not ultimately in dispute as between the experts called by the parties; some matters remained in dispute. The following paragraphs seek to summarise the results of the hot tubs, which addressed different subjects as set out below. The Panel is mindful that the different experts addressing each subject did not necessarily have the same areas of expertise and experiences and therefore brought different perspectives to the topic. There was, nevertheless, a consensus on many aspects.

477. In respect of sex and DSD, the following points of agreement emerged during the first hot tub (in which Prof. Hirschberg, Prof. Spitaels, Prof. Auchus, Dr. Vilain and Dr. Gomez-Lobo participated):

- Biological sex is not binary. There is a range of different markers for sex including chromosomes, gonads and external genitalia.

- The process for determining natal sex in ambiguous cases has evolved over time as scientific understanding of the complexity of sex and DSD has evolved. The process is now one that should involve a "*shared decision*" between clinicians and the baby's family.

- 5-ARD is not a single genetic mutation. There are many different types of mutation in the same gene that may lead to 5-ARD. 5-ARD may occur in different degrees in different individuals; it is not an "all or nothing" condition.

- 5-ARD is a rare condition. The exact prevalence, however, is difficult to assess since mild cases may escape clinical attention. There are a multitude of factors that must be considered in determining whether someone actually has 5-ARD. When seeking to determine whether a person has 5-ARD, a clinician should obtain as much information as possible in order to make an informed diagnosis. It is not always possible to determine whether a particular individual has 5-ARD.

- Different individuals with 5-ARD may experience different degrees of virilisation.

- Some individuals with 5-ARD decide to change legal sex or gender at puberty. Estimates vary as to the proportion of 5-ARD individuals who do this.

- The clinical treatment provided to individuals with 5-ARD has changed over time as scientific understanding and practices have evolved.

- It is difficult to diagnose PAIS. It is often a diagnosis of exclusion (i.e. is the only remaining possibility after all other possibilities have been excluded). Diagnosing CAIS is easier.

478. The experts did not agree on whether, leaving aside hair, prostate development and genital appearance, all 5-ARD individuals present identically to males without 5-ARD. They also did not agree whether the evidence establishes that individuals with 5-ARD have the same muscle mass as males without 5-ARD. This was a point that was examined in further detail during a later hot tub (see below).

479. In respect of the role of testosterone in athletic performance, the following points of agreement emerged during the relevant hot tub (in which Prof. Holt, Prof. Hackney, Prof. Handelsman, Prof. Baggish and Prof. Tucker participated):

- Differences in testosterone levels are the primary, but not the exclusive, cause of the recorded gap in performance between males and females.
- The main physical attributes that contribute to elite athletic performance include power generation, aerobic power, body composition, fuel utilisation and economy of motion. They also include neuromuscular function, tendon function and innate immunity.
- 46 XY individuals generally have greater lean body mass, larger hearts, higher cardiac output, larger haemoglobin mass and larger VO2 max than 46 XX individuals. The single biggest reason for the sex differences in these physical attributes is exposure in 46 XY individuals with functional androgen receptors to much higher levels of testosterone during growth and development (puberty) and throughout the athletic career.

480. The experts did not reach agreement, however, regarding:

- the magnitude of the performance advantage that is derived by having endogenous testosterone in the normal male range of 7.7 to 29 nmol/L;
- the strength of the correlation between levels of endogenous testosterone and lean body mass in adult males;
- whether the fact that 46 XY DSD athletes are overrepresented only in some track events constitutes a paradox that suggests the IAAF's hypothesis concerning the relationship between high endogenous testosterone and athletic performance is incorrect; and
- whether differences in exposure to growth hormone may account for some of the differences in athletic performance between men and women.

481. In respect of PCOS, the experts (Dr. Gomez-Lobo, Prof. Auchus and Prof. Hirschberg) agreed that:

- Approximately 8% to 16% of the female population has PCOS.
- Some individuals with PCOS may have elevated endogenous testosterone. In those cases the level is normally under 5 nmol/L. There may, however, be rare cases in which the level is over 5 nmol/L. The published literature suggests that (a) there is approximately a 1 in 10,000 chance that a woman with PCOS will have testosterone over 4.8 nmol/L; and (b) there is an approximately 1 in 20,000 to 1 in 30,000 chance that a woman with PCOS will have testosterone over 5 nmol/L.
- If a woman with PCOS has testosterone over 5 nmol/L there is a serious risk that she has an adrenal tumour, which needs to be investigated.

- The Endocrine Society's published guidelines on treatment of PCOS identify oral contraceptives as the first choice of treatment for this condition.
- It is difficult to assess the extent of virilisation in a particular individual. A number of factors must be taken into account when assessing virilisation. There are certain scales that can be used to assess particular characteristics such as hair growth and breast development; however applying these scales is not straightforward and necessarily involves a degree of experience and judgement. Over time a clinician can develop a degree of expertise in performing this assessment.

482. In respect of 5 alpha-reductase and DHT, the following points of agreement emerged from the expert hot tub (which involved Prof. Hackney, Prof. Holt, Prof. Williams, Dr. Gomez-Lobo, Prof. Auchus, Prof. Handelsman, Prof. Hirschberg and Prof. Baggish):

- There are three types of 5 alpha-reductase enzymes. (Type 3 has no involvement with androgens and therefore requires no further discussion in this case.)
- The type 1 enzyme is expressed in a range of tissues. Its exact function is unknown.
- The type 2 enzyme is expressed predominantly in the urogenital sinus during fetal life. In adult life the type 2 enzyme is expressed in skin and hair follicles (there is also a residue of this enzyme in scrotal tissues).
- The type 2 enzyme converts testosterone to DHT. The type 2 enzyme has tissue-specific localisation that amplifies the effect of testosterone. It is made locally and acts locally.
- The ratio of circulating DHT to circulating testosterone is approximately 1:10 to 1:12.
- The activity of DHT on androgen receptors is three to five times more potent than the potency of testosterone.
- Exogenous DHT is on the WADA Prohibited List. It should remain on the Prohibited List since it has the potential to improve physical performance.
- There have been no adverse analytical findings for use of exogenous DHT.

483. The experts did not reach agreement, however, regarding:

- whether 5 alpha-reductase is expressed in skeletal muscle;
- whether levels of endogenous DHT affect physical performance;
- the conclusions concerning the performance enhancing effect of endogenous DHT that can be drawn from the lack of evidence that individuals actually use exogenous DHT to illicitly improve athletic performance; and
- whether the laboratory tests carried out by WADA accredited laboratories can actually distinguish between testosterone and DHT.

484. In respect of the impact of a DSD such as 5-ARD on sport performance, the relevant experts (Prof. Hackney, Prof. Holt, Prof. Tucker, Prof. Williams, Dr. Villain, Prof. Auchus, Prof. Handelsman, Prof. Hirschberg and Prof. Baggish) agreed that:

- All individuals with 5-ARD have serum testosterone levels in the normal male range. The proportion of that testosterone that is biologically active (i.e. free testosterone) is also on average the same as the proportion of biologically active free testosterone in normal healthy adult males.
- Individuals with 5-ARD would on average have a lower level of DHT than normal healthy adult males.
- Individuals with 5-ARD have a performance advantage over 46 XX female athletes.
- Individuals with 5-ARD have on average greater muscle mass and haemoglobin than 46 XX female athletes.
- At present there are no hard and fast data that enable the effect of DHT on muscle mass to be quantified.
- On average men have higher levels of haemoglobin than women. Higher levels of testosterone result in higher levels of haemoglobin.
- Individuals with CAIS have a mutation in the androgen receptor gene which does not respond at all to androgens. Such individuals are phenotypically female in all respects other than with respect to their internal organs.
- CAH may occur in XY and XX individuals. However men with CAH tend to have the same level of testosterone as normal healthy adult males. In theory, it might be possible for an XX individual with CAH to have testosterone above 5 nmol/L while also having enough cortisol to enable them to compete without undergoing testosterone-reducing cortisol treatment.

485. However, those experts did not agree:

- whether individuals with 5-ARD are different to normal males in any way that impacts on sport performance (in particular, whether individuals with 5-ARD would have the same body composition and muscle mass as normal healthy adult males);
- whether pharmacological studies concerning the use of 5 alpha-reductase inhibitors by males without 5-ARD enable a reliable conclusion to be drawn that individuals with 5-ARD have the same/comparable muscle mass as those males;
- whether individuals with 5-ARD have the same/comparable levels of haemoglobin as normal healthy adult males;
- whether individuals with 5-ARD have the same/comparable VO2 max as normal healthy adult males; and

- whether the differences in haemoglobin levels between males and females are solely due to differences in testosterone levels.

486. In respect of the impact of treatments to lower testosterone, the relevant experts (Prof. Hirschberg, Prof. Spitaels, Prof. Auchus, Dr. Vilain, Dr. Gomez-Lobo, Prof. Blockman and Prof. Dave) agreed that:

- Oral contraceptives, GNRH agonists and gonadectomy all result in a reduction in the testosterone levels of individuals with 46 XY DSD.
- Oral contraceptives are generally milder and have less significant side effects than GNRH agonists.
- Gonadectomy is an irreversible treatment. Birth control pills and GNRH are generally fully reversible (although if feminisation occurs that may be partially irreversible).
- Athletes who use oral contraceptives to lower their testosterone and women in the general population who use oral contraceptives to avoid pregnancy will experience the same *types* of side effects from the use of such contraceptives.
- A person who undergoes a reduction in endogenous testosterone from a high level to a low level will usually experience withdrawal symptoms.
- Some 46 XY DSD individuals with 5-ARD choose to undergo a treatment that either lowers their testosterone and/or increases their oestrogen levels in order to achieve a physiological outcome that is more consistent with how they perceive themselves.
- There is not a single established protocol for how to lower the testosterone levels of DSD athletes to below 5 nmol/L.

487. The experts were unable, however, to reach agreement in respect of the following matters:

- whether the withdrawal symptoms caused by a reduction in testosterone levels are nearly always temporary;
- whether the risks of deep vein thrombosis (DVT) and other side effects of oral contraceptives are dose-dependent (i.e. the higher the dose, the greater the risks);
- whether the size of the dose required to reduce testosterone to below 5 nmol/L in individuals with 46 XY DSD is the same as the size of the dose that is administered for normal contraceptive use (e.g. one contraceptive pill per day);
- whether, in the context of the DSD Regulations, reducing the testosterone levels of 46 XY DSD athletes is beneficial to those athletes;
- the extent to which oral contraceptives can cause athletes with 46 XY DSD to have a reduced level of testosterone that is stable;

- whether the use of oral contraceptives to reduce the testosterone levels of XY DSD athletes has any impact on their athletic performance above and beyond the impact caused by testosterone withdrawal symptoms; and

- whether oral contraceptives have any effect on the athletic performance of healthy XX female athletes.

D. What is the role of testosterone in male/female sporting ability?

488. The role of testosterone in determining sporting ability was a major focus of each party's submissions and evidence. A fundamental feature of the Claimants' case is that there is no single determinant in defining sex as male or female and no single determinant for sporting ability. In respect of the latter, the Claimants contend that natural genetic variation can provide many examples of enhanced athletic ability that has led to outstanding success for particular individual athletes or groups of athletes.

489. It is accepted by all parties that circulating testosterone has an effect from puberty, in increasing bone and muscle size and strength and the levels of haemoglobin in the blood. After puberty, the male testes produce (on average) 7 mg of testosterone per day, while the female testosterone production level stays at about 0.25 mg per day. The normal female range of serum testosterone (excluding cases of PCOS), produced mainly in the ovaries and adrenal glands, is 0.06 to 1.68 nmol/L. The normal male range of serum testosterone concentration, produced mainly in the testes, is 7.7 to 29.4 nmol/L.

490. The DSD Regulations require athletes with 5-ARD and athletes with other 46 XY DSD who wish to compete in the female category to reduce their testosterone levels to within the normal female range and to maintain those levels within that range. It is not in dispute that 5 nmol/L represents a level that no 46 XX woman would exceed (save for rare cases involving CAH, which the IAAF intends to remove from the scope of the DSD Regulations, and potentially a small fraction of women with PCOS, who may occasionally have levels of testosterone marginally above that level).

491. Testosterone may not be the only factor that results in an increase in lean body mass, higher levels of haemoglobin and increased sporting ability, but the expert evidence explains that it is the primary factor. The IAAF cited the view, endorsed by some 42 leading international experts in sports science and sports medicine, that:

> *"Based on our collective expertise and experience, the undersigned specialists in the sports science and sports medicine communities consider the following to be indisputable scientific facts:*
>
> *1.* ***The main physical attributes that contribute to elite athletic performance are:***
> - ***power generation*** *(speed and strength), which is based on muscle mass, muscle fiber type, and biomechanics;*
> - ***aerobic power*** *(VO2 max), which is based on hemoglobin concentration, total blood volume, maximal stroke volume, cardiac size/mass/compliance, skeletal muscle blood flow, capillary density, and mitochondrial content;*
> - ***body composition****, i.e. lean body mass and fat mass;*

- ***fuel utilization**, i.e. glycogen and anaerobic capacity; and*
- ***economy of motion**.*

*2. **Biological males and biological females are materially different with respect to these attributes**.*
Compared to biological females, biological males have greater lean body mass (more skeletal muscle and less fat), larger hearts (both in absolute terms and scaled to lean body mass), higher cardiac outputs, larger hemoglobin mass, larger VO2 max (also both in absolute terms and scaled to lean body mass), greater glycogen utilization, higher anaerobic capacity, and different economy of motion.

*3. **The primary reason for these sex differences in the physical attributes that contribute to elite (>99th percentile) athletic performance is exposure in gonadal males with functional androgen receptors to much higher levels of testosterone during growth and development (puberty), and throughout the athletic career.***
No other endogenous physical or physiological factors have been identified as contributing substantially and predominantly to these differences. As a policy matter, the exogenous factors that influence elite athletic performance – nutrition, training, sports psychology, environmental manipulation, sports medicine techniques, etc. – should be equally accessible to biological male and biological female athletes.

*4. **Therefore, the primary driver of the sex difference in elite athletic performance is exposure in biological males to much higher levels of testosterone during growth, development, and throughout the athletic career.**"*

492. There was ultimately no dispute among the parties' expert witnesses that testosterone was *at least* a primary factor, although Prof. Tucker maintained his rejection of some of the other contributing attributes cited in that statement. Nevertheless, the overwhelming majority view was that testosterone is the primary driver of the physical advantages and, therefore, of the sex difference in sports performance, between males and females.

493. Having considered all of the scientific evidence adduced by the parties, the Panel accepts this conclusion.

E. What is the role of DHT in male/female sporting ability?

494. This question arose in the context of the scientific evidence concerning the effects of 5-ARD. Individuals with 5-ARD have the same levels of testosterone as normal adult males. They do not, however, have the same levels of DHT. The question, therefore, is what role (if any) DHT has on sporting ability and physical performance. As noted above, while there was a degree of agreement among the experts regarding certain DHT-related issues, they could not reach agreement concerning whether levels of endogenous DHT affect physical performance (and, if they do, what the magnitude of that effect may be).

495. The Panel has carefully considered the evidence adduced by the parties' experts on this point, which only came into focus at a relatively late stage in the proceedings. On the basis of that evidence, the Panel is unable to exclude the possibility that DHT may have some effect on physical performance and sporting ability. The Panel is satisfied, however, that such an effect (if it exists at all) is at most modest compared to the effect of testosterone. In reaching this conclusion, the Panel considers that while DHT is included in the WADA Prohibited List, the weight that can be attached to this factor is small in light of paucity of examples of exogenous DHT actually being used for performance enhancing purposes.

496. The majority of the Panel also found the evidence of Prof. Baggish, who described the absence of any discernible impact on athletic performance in males taking 5-alpha reductase inhibitors, to be persuasive. In particular, the Panel noted Prof. Baggish's evidence that in tests carried out on approximately 150 men taking 5-alpha reductase inhibitors there was no discernible impact on the athletic performance of any of those individuals. The evidence of Prof. Handelsman, who testified that to his knowledge there was no evidence that DHT had an effect on athletic performance separate to testosterone, was also persuasive. While the Panel gave careful consideration to the countervailing evidence of the Claimants' experts, including in particular Prof. Hackney, the majority of the Panel are satisfied that endogenous DHT has either no effect on athletic performance or, at most, has a modest effect, of a different order of magnitude to the effect of endogenous testosterone.

F. What are the main characteristics of an athlete with a 46 XY DSD (in particular 5-ARD)?

497. [...] all 46 XY DSD such as 5-ARD are forms of genetic mutation that can affect testosterone levels. Individuals with 5-ARD have what is commonly identified as the male chromosomal sex (XY and not XX), male gonads (testes not ovaries) and levels of circulating testosterone in the male range (7.7-29.4 nmol/L), which are significantly higher than the female range (0.06-1.68 nmol/L).

498. In individuals with 5-ARD, the deficiency in 5-alpha reductase affects the conversion of the male foetus's testosterone into DHT, with the result that the external genital tissues do not develop normally. At birth, depending on physical examination of external genitalia and often in consultation with the parents and other experts, such a person may be assigned the female sex or the male sex. While the enzyme deficiency affects the development of male gonads in utero, following the onset of puberty circulating testosterone has the same virilising effect on the body of an individual with 5-ARD as it does on males without 5-ARD. The testes produce normal male levels of testosterone. According to the IAAF's expert evidence, a reported 58-63% of 5-ARD persons who were assigned the female sex at birth change to the male sex when these secondary sex characteristics develop at puberty.

499. 5-ARD has tissue-specific effects (e.g. in respect of genital formation) and not general effects. The virilising effects of circulating testosterone after puberty on muscle size and strength, bone size and strength and serum haemoglobin concentration are not affected. Individuals with 5-ARD are all fully androgen sensitive. Therefore, all individuals with 5-ARD experience the virilising effect of their circulating testosterone. That is, for these

athletes, the question of partial or complete androgen insensitivity is not relevant, although it is relevant to other 46 XY DSD athletes with high levels of circulating testosterone.

500. It is not disputed that a person, whether a man or a woman, with 5-ARD is a person who is XY, with testes and not ovaries and levels of endogenous circulating testosterone in the male range. What is in dispute is whether these differences, and particularly testosterone levels, do in fact affect body composition, muscle mass and haemoglobin levels to the same or similar extent as in the male adult population and whether such differences have an impact on sports performance. The Panel addresses these disputed issues further below.

G. Can it be said, as advanced by the IAAF, that a woman can have a "male sports sex"?

501. For the reasons explained above, it is difficult in this area concerning sex and gender to describe matters in a way that is not offensive to some and still explain some of the arguments advanced before the Panel. The terminology used by the IAAF in its submissions may fall into this category. To explain the parties' submissions, it is necessary to repeat some of the terminology used by the parties. In doing so, the Panel reiterates that it is not the purpose or effect of this Award to question or pass judgement upon any person's sex or gender.

502. As explained above, the sport of athletics is divided in a binary fashion: male and female. The existence and legitimacy of that division is not challenged. The IAAF emphasises, however, that the division cannot be a matter of legal sex and/or gender identity alone. This current area of dispute is, says the IAAF, one of perhaps only two situations where using legal sex as a proxy for the simple male-female binary does not work. The other situation concerns transgender athletes. In such cases, the IAAF submits that "*biology has to trump identity*" – just as it does in medicine where anatomical reality drives treatment, such as treatment of testes or ovaries for testicular or ovarian cancer. The IAAF accepts that using legal sex as the proxy for the male-female binary works well in most cases. However, the IAAF does not accept that female legal sex or self-identifying as a woman necessarily equates with female biology or female sex traits, or that biological sex traits are irrelevant considerations in the present context. To the contrary. In that manner, the IAAF refers to a "*male sports sex*". It uses that expression as shorthand for the biological sex characteristics that, on its submission, are causative of the performance advantage that male athletes enjoy over female athletes.

503. The IAAF contends that, for sporting purposes, individuals with 5-ARD are biologically indistinguishable from males without a DSD and have been shown to dominate in sport over "biological females" who, the IAAF asserts, have no chance to win when competing against such "biologically male" athletes. This is because, it says, from a biological perspective 5-ARD athletes are the same in every material respect to male athletes without DSD. They have the same biological and physiological features that confer the same ergogenic effect. The only material physical difference is the size and shape of external genitalia which, the IAAF emphasises, has no impact on sport performance.

504. The IAAF submits that it is a matter of unfairness to "biological females" – using that term to encompass XX women born with female gonads and low levels of circulating testosterone from puberty – to require them to compete against "biological males" with a female legal sex and gender identity. The IAAF does not deny the right of "biological males" with a female legal sex/female gender identity to compete in the female category but, it says, such an athlete must do the minimum necessary to ensure that their participation does not defeat the purpose of the category. If there is to be a female category the purpose of which is to protect "biological females" against unfair competition, then the IAAF submits that eligibility to compete in that category must be based on the relevant differences between "biological males" and "biological females".

505. The IAAF distinguishes the issue in this case from that examined in *Chand*, where the question was raised as to the effect of elevated endogenous testosterone on "biological females". Here, it submits, the case is about "biological males" with 5-ARD and other 46 XY DSD, how their bodies respond to testosterone and the extent of any consequential performance advantage.

506. The Claimants strongly reject the IAAF's characterisation of women with 5-ARD and other 46 XY DSD as "biological males". They submit that the expert evidence adduced by the IAAF in support of that characterisation is fundamentally flawed and is inconsistent with the mainstream scientific consensus that no single biological parameter transcends all others when it comes to defining whether a person is male or female.

507. While the parties' submissions concerning the validity of the concepts of "biological males" and "male sport sex" provide important context to the arguments for and against the DSD Regulations, the Panel notes that the validity of these concepts and the appropriateness of the IAAF's terminology do not themselves require determination as matters of fact. The Panel, therefore, does not consider it necessary specifically to determine whether the IAAF's invocation of the concept of a "male sport sex" possessed by "biological males" and a "female sport sex" possessed by "biological females" is valid and/or proper. Instead, the Panel considers it appropriate to focus on whether women with 46 XY DSD such as 5-ARD have an athletic advantage over other female athletes and, if so, whether the magnitude of that advantage is capable of subverting fair competition in certain athletic events.

H. Did the athletes whose data were the subject of BG17 provide informed consent for those data to be used by the IAAF for the purposes they are now relied on?

508. Before addressing the existence and magnitude of any such advantage, however, it is necessary to address an issue concerning the question of informed consent raised by ASA. No evidence was adduced in support of this submission, including from athletes whose data was used and who did give evidence to the Panel, although the IAAF declined to produce documents sought by ASA in respect of this question. This raises the inference that no documents would assist the IAAF. ASA contends that, for the purposes of the law of Monaco, there was no informed consent on the part of the athletes for their biological material and data that are the subject of BG17 to be used for the purpose of such a study. ASA submits that this "*may have violated applicable national laws on biomedical research if proper informed consent was not obtained*". It submits

that, as a consequence, the IAAF evidence and results, which it asserts were based on "*research*" as referred to in various statutes, in the absence of informed consent, should be rejected as inadmissible in this proceeding. Accordingly, ASA argues that the questions concerning the existence and degree of any performance advantage enjoyed by 46 XY DSD athletes must be considered without reference to BG17. The Panel notes that this ground is pressed by ASA on a theoretical basis; none of the athletes whose samples were used in this way gave evidence to this effect before the Panel.

509. In support of this argument, ASA refers to and relies upon Monegasque legislation on the protection of individuals in "*biomedical research*". However, it does not support that assertion by providing, by statute or otherwise, a definition of "*biomedical research*" or explain how or whether, under Monegasque law, this legal term includes analysis of pre-existing data arising from collection with the consent of the athletes concerned.

510. The IAAF relies on the initial consent provided for doping control purposes and says that the data have been used for those purposes, *inter alia*, in establishing normal serum androgen values in elite female athletes and establishing correlations between those levels and performance, which helps to assess the justification for inclusion on the WADA Prohibited List of substances which block the conversion of endogenous testosterone to oestrogen.

511. ASA's response to this is based on the characterisation of the study as "*research*" in its own right and ASA raises a number of hypotheticals, as to which it demands a response from the IAAF. ASA points to different forms of consent, such as consent for single use, consent to storage for future use, sample and data sharing and consent for research purposes, possibly involving research ethics committees. As ASA points out, the issue of whether fresh consent is necessary in any case is complex and multi-factorial.

512. In support of its submissions on this point, ASA repeatedly asked the IAAF to disclose copies of the signed consent forms provided by the athletes whose samples and data form the basis of the analysis in BG17. The IAAF has declined to do so. The Panel considers that it can therefore be inferred that no such forms exist, or that if they do exist they do not assist the IAAF on this issue.

513. The core submission advanced by ASA equates the study in BG17 – which was an analysis of previously obtained data – with a research project or research proposal and as constituting biomedical research under the laws of Monaco. However, no sufficient explanation has been advanced by ASA as to whether this analysis equates to the kind of research encompassed by the relevant provisions of Monegasque legislation cited by ASA. The results in BG17 represented an analysis of data that had been collected in the ordinary course in previous competitions in Daegu and Moscow. On the basis of the available material, it is not clear to the Panel that the subsequent analysis of data collected in that way would fall within the purview of the Monegasque statutes governing "*biomedical research*" invoked by ASA.

514. ASA also relies upon Monegasque law said to relate to "*the protection of nominative information*" which "*prohibits any conduct which directly or indirectly reveal, inter alia, health data, personal data and genetics*" without consent. ASA relies on a prohibition on the use of blood samples for research without consent. ASA does not

assist in establishing what amounts to "*reveal*", or whether the information was required to reveal the identity of a person, or that blood samples were used for "*research*".

515. In addition, ASA relies on laws of the Republic of Korea and the Russian Federation and on the European Convention on Human Rights and Biomedicine (the "Oviedo Convention") that prohibit use of human material in "*research*" without consent, noting that the Russian provision is in terms of "*medical intervention*" which, ASA says, includes "*research*". Again, no explanation is provided as to the extent of "*research*" encompassed by the relevant legislation. Further, there is no evidence that the Oviedo Convention has been adopted into Monegasque law (in contrast to other international treaties relied in this proceeding, as to which there is such evidence). Indeed, ASA states that Monaco has not ratified the Oviedo Convention, although it asserts that the convention will find "*indirect application*" in Monegasque law, in the context of a submission concerning the right to respect for private life in Article 8 of the European Convention of Human Rights. It is not for this Panel to accept that assertion, nor to speculate upon the extent of such possible future "*indirect application*" under the law of Monaco.

516. In short, the Panel concludes that ASA has failed to establish that the analysis undertaken in BG17 constitutes "*research*" or "*biomedical research*" for the purposes of any of the national laws invoked by ASA. Furthermore, even accepting *ex hypothesi* that the athletes did not provide specific consent to such further analysis, informed consent is a complex question of fact and law, which may differ between jurisdictions. ASA did not provide sufficient analysis or support of its submission to enable the Panel to rule that the evidence is inadmissible by virtue of any breach of applicable national or international laws. Accordingly, the Panel concludes that the IAAF's evidence based on its analysis of the Daegu and Moscow data is admissible in these proceedings.

I. Do women with a 46 XY DSD such as 5-ARD have an athletic advantage over other female athletes? If so, what is the magnitude of that advantage?

517. The role of evidence and scientific assessment to support regulatory decision-making is obviously of great importance. This has resulted in detailed focus on the evidence relied upon by the IAAF to support the DSD Regulations, in particular the evidence concerning the existence and extent of the alleged athletic advantage that female athletes with 46 XY DSD enjoy over other female athletes without such DSD. The evidence adduced by the IAAF in respect of this issue comes from a variety of sources. It includes scientific evidence regarding the physiological effects of conditions such as 5-ARD and the relationship between endogenous testosterone, DHT and athletic performance; observational data regarding the correlation between endogenous testosterone levels and athletic performance in two World Championships; and statistical evidence contrasting the incidence of certain 46 XY DSD in the general adult population with the markedly more prevalent incidence of those conditions amongst elite female athletes in certain athletic disciplines. The reliability, meaning and effect of much of this evidence is strongly contested by the Claimants, whose experts provided detailed counter-evidence in response.

518. Both Ms. Semenya and ASA strongly attack the evidence relied upon by the IAAF. They point to matters such as an asserted lack of transparency, bias, flawed processes

and arbitrariness. They direct much of the attack to BG17, which they say is the only empirical evidence put forward by the IAAF concerning performance differences in elite female athletes based on endogenous testosterone. The Claimants assert that it is clear that BG17, although published in a peer-reviewed journal, contains significant errors and that it falls well short of a statistically valid assessment or a controlled clinical trial or of a basis for regulation. Further, on review of some of the data, Prof. Pielke has identified "*anomalies and errors*" in a sub-set of the underlying data for the four events cited, namely, duplicated athletes (more than one time for the same athlete), duplicated times (the same time repeated for an individual athlete), phantom times (no athlete in the reported time) and times included for athletes disqualified for doping. The basis for challenge to the data is not limited to these matters. Ms. Semenya points to statistical flaws and to testosterone data in respect of non-Restricted Events and for male athletes which, she says, do not support a relationship between athletic ability and higher levels of testosterone.

519. ASA adduced evidence of a systematic review of current best evidence for the role of hyperandrogenism in improving athletic performance, employing a "*detailed search strategy*" and found two studies, one of which was BG17. ASA's experts supported the submission that the heterogeneity in study design and methodological concerns rendered both studies unsuitable for meta-analysis. ASA's evidence and submissions detailed the perceived flaws, including hypothetical confounding factors such as state of health, excitement, menstruation and time of day and season which, they said, need to be standardised. For the purposes of the Daegu study reported in BG17, the athletes were required to go to the doping station at any time during their stay, provided that it was at least 24 hours after arrival (to limit effects of jet lag) and no less than two hours after intense exercise. ASA contends these two conditions, even if complied with, were insufficient to ensure that the samples provided by those athletes generated reliable data concerning testosterone levels. ASA also seems to reject any assay that does not comply with what it describes as the "*gold standard*" and rejects the measurements used as not having been validated in everyday clinical practice or in elite athletes of varying ethnicities and ages.

520. The Claimants rely on a number of published studies that have failed to identify or specify the degree of enhancement in physical performance said to be exerted by elevated levels of testosterone. ASA in particular relies upon a series of possible factors arising from an individual's genetic makeup that may contribute to competitive advantage. However, it concedes that the degree of advantage conferred by these attributes is unquantified and, in many cases, theoretical. It also points to other factors that have been shown to enhance performance in various sports, such as caffeine and other nutrition modalities and sport specific training, such as altitude training. This does not, however, answer the question posed as to the performance enhancing effect of testosterone which, as found in *Chand* and not disputed here, is a male marker and acts to increase lean body mass at puberty, thereby, at least in theory, providing some degree of enhanced athletic performance. The effect of exogenous testosterone in enhancing athletic performance is not disputed and was not disputed in *Chand*. The question that remained was the magnitude of the effect of endogenous testosterone in DSD athletes.

521. The fact that other factors, such as altitude training and nutrition, can affect athletic performance has not been in dispute. It does not, however, answer the scientific question

that is the focus of the present inquiry, namely whether (and, if so, to what extent) women with 46 XY DSD such as 5-ARD enjoy a significant performance advantage over other elite female athletes.

522. Dr. Bermon and his co-authors subsequently released a follow-up analysis of the data reported in BG17, published in the British Journal of Sports Medicine, which referenced certain errors, including double counting, and contained a modified analysis of the data examined in BG17. Importantly, the latter publication reported a difference between the high testosterone tertile and the low testosterone tertile as 1.6% (reduced from 2.0% in BG17, a reduction of one fifth). This is, of course, very different to the 10-12% performance advantage said to be enjoyed by the best male athletes over female athletes. (The Panel also notes that it is substantially lower than the 3% to 4% margin posited – albeit without having had the opportunity to test that hypothesis at the time – by Dr. Bermon in *Chand.*)

523. Importantly, however, it should be noted that at no time have Dr. Bermon or the IAAF contended that the studies reported in BG17 and in the amending paper constituted, or could be equated to, a double-blind clinical trial. Such a trial could not be carried out, not the least because such a study would be unethical (a point which was not contested by the Claimants). Dr. Bermon conceded that the study design cannot provide evidence for causality between androgen levels and athletic performance, but said that it can indicate associations between them which may support the existence of a causal relationship when viewed in conjunction with other evidence. The IAAF does not say that these studies withstand the kind of application of statistical principles in design and analysis demanded by the Claimants. That was not, the IAAF experts say, the purpose, or basis of the interpretation, of BG17, which represented an observational study. Accordingly, they say, the criticisms advanced by the Claimants' experts are simply not relevant.

524. As an observational study, BG17 cannot alone establish a causal relationship between testosterone levels and athletic performance. Prof. Handelsman relies on this to rebut observations made in other studies relied upon by the Claimants' experts, many of them observational studies, that reach different conclusions to the ones he reaches based on the papers in his review. The relevance of an observational study with the aim of collecting real-life data was also supported by Dr. Kowalski, who explains that statistical measures are different from those used in, for example, confirmatory trials such as randomised controlled trials. He observes that observational studies, as here, still provide an important contribution to the total picture of the correlation between testosterone levels and physical performance in athletes and says that the results in BG17 show an association between athletic performance and the highest levels of testosterone in certain events.

525. The IAAF also places substantial reliance on the Handelsman Paper, published in Endocrine Reviews, which is a peer-reviewed journal. This paper contains a review of the available literature up to 2018. The authors concluded, in effect, that the available evidence supports the link between circulating testosterone of adults and the sex differences in sports performance in most sports, that is, that testosterone was a causative factor. The main physiological factors affected were muscle size and strength,

bone size and strength, and haemoglobin, each of which, alone, were said to increase athletic ability.

526. Ms. Semenya attacks the lack of independence on the part of some of the authors of BG17 and the Handelsman Paper. She refers to comments and observations made outside of the papers themselves, at conferences and in private communications. The Panel does not propose to deal with such evidence and assertions because it does not consider this relevant to the decision it is required to reach. The Panel has the publications which provide the data and has seen the witnesses in the hot tubs, where the data were discussed and analysed by witnesses from all sides. That evidence provides the basis for the Panel's consideration of the specific factual issues concerning the existence and magnitude of the performance advantage enjoyed by female athletes with 46 XY DSD over female athletes without such DSD.

527. Ms. Semenya does not accept the validity of the review or the conclusions in the Handelsman Paper. She says that the review fails to include contrary reported studies, published before and after the *Chand* decision, that it overstates the significance of the evidence that it reviews and that it fails to consider other endocrine factors. She also says that the paper does not reflect the effect of a high level of testosterone on a female athlete with a DSD and either partial or complete androgen resistance. The degree of androgenisation is also complex and female athletes with DSDs would have significantly different phenotypes, depending for example on different chromosomal, gonadal and hormonal traits. There is also variability of indicia of virilisation across different populations and ethnic groups, leading, she submits, to findings that are inherently subjective and lead different experts to reach different conclusions as to the degree of androgenic effect in the same female.

528. The Panel has taken careful note of all of these criticisms and arguments. The Panel nonetheless considers it useful to highlight some of the matters set out in the Handelsman Paper and Prof. Handelsman's expert evidence. Prof. Handelsman draws the following conclusions (with cited supporting data) arising from his review, regarding the role of testosterone on athletic performance:

- Post-puberty, male testosterone production increases such that the average circulating levels are 15-fold higher in adult males than in adult females.
- There is no evidence that the Y chromosome *per se* provides an advantage in sports performance.
- There is no overlap between adult male and adult female testosterone levels.
- The level of 5 nmol/L of testosterone represents the maximum level that occurs in females without 46 XY DSD (taking account of the increased levels for XX women with PCOS). For 46 XX women without PCOS, the range is 0.06 to 1.68 nmol/L.
- The effect of testosterone is the same on males and females. There is no evidence that "muscles know their sex" when responding to testosterone. The physiological response is the same irrespective of the sex of the individual.

- The effect of testosterone on the human body is the same, whether the source is exogenous or endogenous.

- Testosterone binds to the androgen receptors in androgen-sensitive target tissues, including muscle, skin, bone and bone marrow tissues, thereby stimulating synthesis of muscle, bone and haemoglobin.

- There are data which show rising increases in circulating haemoglobin with increased testosterone that result in an 8.9% increase at 10 nmol/L in women with adrenal hyperplasia – an effect similarly generated with exogenous testosterone, which is linked to enhanced aerobic capacity.

- While numerous genes and environmental factors may contribute, testosterone is the key determinant of muscle mass/lean body mass and strength in males. There are data which demonstrate that increased testosterone causes material increases in muscle mass and strength.

- Although, for ethical and logistical reasons, where objective interventional studies are not feasible (which is not in dispute) there is limited evidence available for the effect of testosterone on muscle mass and strength in women, there is evidence which indicates the same dose-response relationship as exists in men and that increased testosterone, even from 0.9 to 4.3 nmol/L, correlated with improved aerobic and anaerobic performance and increased lean body mass and decreased body fat.

- In 46 XY athletes with CAIS, circulating testosterone has no virilising effect. In 46 XY athletes with PAIS, the degree of virilisation will depend on the degree of impairment of the function of androgen receptors.

- An androgen-sensitive individual with circulating testosterone between 5 and 10 nmol/L will have an ergogenic advantage both in terms of muscle mass and strength and in terms of levels of circulating haemoglobin over an individual with circulating testosterone below 5 nmol/L.

- There is no biological explanation to explain the observed correlation between increased circulating testosterone and enhanced sporting ability other than to conclude that there is a causative relationship, although there is no cross-sectional analysis which proves it.

529. From the studies cited in the Handelsman Paper, Prof. Handelsman concludes that there is an unequivocal dose-response relationship in males between levels of serum testosterone on the one hand and muscle mass and strength and serum haemoglobin concentration on the other. The dose-response is not supported at low levels of testosterone (including in the XX female range below levels for women with PCOS) but is supported when testosterone is increased into and above the male range.

530. While Prof. Handelsman holds and expresses his views strongly, the majority of the Panel considers that his evidence provides a cogent basis, on a review of the available literature and published studies, to support his conclusions regarding the effect of

testosterone on athletic performance. He also provides a reasoned explanation to counter the criticisms of his conclusions raised by the Claimants' experts. In some cases, the potential confounding factors raised by the Claimants' experts are conceded as possibilities that may, in theory, have some effect, but not the quantitative effect sufficient to displace the conclusions Prof. Handelsman has reached, which incorporate many of such factors into the analysis or are otherwise factors that are available to both men and women and therefore do not explain the differences in performances between the sexes. The Panel considers that Prof. Handelsman's response to the evidence adduced by the Claimants' experts is credible and persuasive.

531. The IAAF also relies on the results obtained when the testosterone levels of a small group of 46 XY DSD athletes were suppressed and the haemoglobin concentrations fell accordingly. To the extent that the IAAF relies upon data purporting to demonstrate a period of deteriorated performance coinciding with suppression of testosterone levels in three DSD athletes, Ms. Semenya contends that such data do not demonstrate a link between performance and testosterone levels as the decline in performance could not be said to be caused by the testosterone level. She relies on the small sample size and expert evidence as to other confounding factors, as well as her evidence and that of other DSD athletes as to the side effects of taking testosterone-lowering medication.

532. The Panel takes careful note of this criticism and does not find that these results are, of themselves, conclusive. On the basis of the material before the Panel, it is not possible to allocate the degree of deterioration in performance as between the lowered testosterone levels and the athletes' evidence as to the adverse side effects of the testosterone-suppressing treatment. Nevertheless, the Panel considers that these results provide some evidence that the suppression of testosterone had some negative effect on the haemoglobin levels and athletic performance in athletes with 46 XY DSD.

533. The IAAF also relies on a simple evaluation of available numbers concerning the striking over-representation of 46 XY DSD athletes at various levels in elite female athletics. According to the evidence put forward by the IAAF, in the general population the incidence of XY athletes with DSD is 1 in 20,000; in elite women's competition, it is 7 in 1,000 (140 times greater). The population incidence of 5-ARD is less than 1 in 100,000 (<0.001%). [...]. The IAAF submits that these statistics make it clear that women with normal levels of testosterone have not been able to compete on a level-playing field.

534. The Panel also notes the Claimants' submission that the degree of advantage enjoyed by 5-ARD athletes does not equate to that of the best elite male athletes. In this respect, the Panel considers the evidence supporting that submission, which cited the very large numbers of male athletes, not all at elite level, who beat the times of the best female athletes.

535. The Panel has carefully considered all of the scientific evidence adduced by the parties in these proceedings. On the basis of that analysis, the majority of the Panel accepts that the preponderance of the evidence is that female athletes with 5-ARD and other 46 XY DSD have high levels of circulating testosterone in the male range and that this does result in a significantly enhanced sport performance ability, for example, by action in the body to increase muscle mass and size and levels of circulating haemoglobin.

536. The majority of the Panel further concludes that that enhanced performance ability translates in practice to a significant performance advantage in certain athletics events covered by the DSD Regulations. In reaching this conclusion, the majority of the Panel notes that while BG17 cannot, alone, establish a causal relationship and has a number of shortcomings identified by the Claimants' experts, this does not disprove the IAAF's case concerning the connection between 46 XY DSD, testosterone and athletic performance. Rather, BG17 (even as an observational study) provides empirical data which demonstrate that the IAAF's scientific evidence concerning the physiological effects of increased testosterone levels translates, in a real world competitive context, to a significant and often determinative performance advantage.

537. In reaching this conclusion, the majority of the Panel highlights in particular the notable statistical over-representation of female athletes with 5-ARD [...]. In the majority of the Panel's view, those statistics provide compelling evidence that the physical characteristics associated with 5-ARD give female athletes with that condition a significant and frequently determinative performance advantage over other female athletes who do not have a 46 XY DSD. The contrast between the rare incidence of 5-ARD in the general population and the overwhelming success that women with 5-ARD have achieved [...] provides powerful evidential support for the conclusion that female athletes with 5-ARD have a significant performance advantage.

538. In reaching this conclusion, the majority of the Panel does not purport to quantify precisely the exact percentage of the performance advantage that elite female athletes with 46 XY DSD have over other female athletes. The Panel's task is to examine the evidence before it and to consider whether the totality of that evidence provides adequate support for the IAAF's claim that female athletes with a 46 XY DSD enjoy a significant performance advantage over other female athletes, which is of such magnitude as to be capable of subverting fair competition within the female category. Having examined and considered the totality of the evidence, the majority of the Panel concludes that the evidence supports that proposition. The Panel addresses the issue of the magnitude of that performance advantage, and its effect on the necessity, reasonableness and proportionality of the DSD Regulations, further below.

J. The legal issues regarding the validity of the DSD Regulations

539. Having addressed the factual and scientific issues and the specific challenge based on the issue of informed consent, the Panel now turns to the legal issues that arise for determination in this case. A number of issues fall to be determined as to the validity of the DSD Regulations, which can be considered under the following headings:

- Where does the burden of proof lie?
- Do the DSD Regulations constitute discrimination?
- Are the DSD Regulations necessary?
- Are the DSD Regulations reasonable and proportionate?

(i) Where does the burden of proof lie?

540. It is common ground that the Claimants bear the legal burden of establishing that the DSD Regulations discriminate on the basis of a protected ground. It is not in issue that if there is discrimination, then the burden of proof shifts to the IAAF to demonstrate, on the evidence, that the DSD Regulations are necessary, reasonable and proportionate.

541. In *Chand*, discrimination was not disputed and the IAAF was therefore held to have the burden of proof, there described as the onus "*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*". Ms. Semenya has brought that test to this Panel's attention; the IAAF has not really disputed that it bears that burden, if it is found that the DSD Regulations are discriminatory.

(ii) Do the DSD Regulations constitute discrimination?

542. In *Chand*, it was common ground that the Hyperandrogenism Regulations were prima facie discriminatory and therefore that the onus was on the IAAF to establish that they were necessary, reasonable and proportionate. In the present case, however, the IAAF does not accept that the DSD Regulations are prima facie discriminatory. Instead, it submits that the onus is on the Claimants to establish that the DSD Regulations are prima facie discriminatory and that they have failed to discharge that onus.

543. The IOC's Fundamental Principles of Olympism provide that the enjoyment of the rights and freedoms set forth in the Olympic Charter "*shall be secured without discrimination of any kind, such as race, colour, sex, sexual orientation, language, religion, political or other opinion, natural or social origin, property, birth or other status*". Article 4(4) of the IAAF Constitution similarly provides that the IAAF's objects include "*striv[ing] 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.*"

544. Ms. Semenya maintains that the DSD Regulations unfairly discriminate on the basis of at least five grounds: natural physical, genetic or biological traits, sex, gender, physical appearance and what events a woman competes in. She submits that this violates the IAAF Constitution, the Olympic Charter, international human rights laws including those that apply in Monaco (the governing law of the IAAF) and the domestic laws of many countries in which the IAAF has members and holds international competitions. It is not necessary to set out the detailed principles of those documents or of the United Nations Convention on the Elimination of All Forms of Discrimination against Women, which is part of the laws of Monaco. Pursuant to the above, the DSD Regulations do, subject to an argument raised by the IAAF and set out below, discriminate on a number of bases, including natural biological or genetic characteristics, sex and gender.

545. The IAAF submits that the DSD Regulations are not prima facie discriminatory, since their purpose and effect is to ensure that like cases are treated alike, while different cases

are treated differently. This, the IAAF submits, is the antithesis of discrimination. Accordingly, the Claimants' case falls at the first hurdle, and no assessment of the necessity, reasonableness and proportionality of the DSD Regulations is required.

546. The IAAF submits that preventing "biologically male" athletes from participating in the female category on the ground that their biological advantages make their inclusion unfair is not discrimination. On the contrary, the IAAF is treating different cases differently. The IAAF contends that treating athletes with 5-ARD and other 46 XY DSD the same as 46 XX athletes for competition purposes solely because they have the same legal sex/gender identity, which has no effect on sport performance, in circumstances where they have such substantial differences leading to enhanced sports performance is "*arbitrary and irrational*", in particular in circumstances where non-binary legal sex and the ability to change legal sex at will are, or are becoming, a reality.

547. The Panel has carefully considered the IAAF's submission and the Claimants' response thereto. The Panel concludes that the Claimants have discharged their onus of establishing prima facie differential treatment based on protected characteristics, which the IAAF must therefore establish is necessary, reasonable and proportionate. The Panel's reasons for this conclusion may be summarised as follows:

(a) It is not disputed that the DSD Regulations only apply to athletes who are recognised at law either as female or intersex (*see* Regulation 2.3(a)). Athletes with a male legal sex are therefore not affected by the DSD Regulations (save to the limited and indirect extent that the DSD Regulations provide that Relevant Athletes may compete in the male category in Restricted Events, and therefore the pool of athletes eligible to compete in the male category is theoretically marginally wider than it was before the DSD Regulations were enacted).

(b) It is similarly not disputed that within the class of individuals who are legally recognised as female or intersex, the DSD Regulations impose certain eligibility restrictions and conditions on a subset of individuals on the basis of certain biological characteristics possessed by those individuals (namely having one of the DSDs listed in Regulation 2.2(a)(i), having circulating blood testosterone level over 5 nmol/L, and having a sufficient degree of androgen sensitivity for those levels of testosterone to have a material androgenising effect).

(c) Accordingly, the DSD Regulations are expressly intended to, and do in fact, impose conditions and restrictions on a particular group of individuals on the basis that those individuals (i) are not legal males; and (ii) all possess certain natural biological characteristics that other females and intersex individuals do not possess. Conversely, the DSD Regulations do not impose any conditions or restrictions on individuals who have a male legal sex, or who have a female or intersex legal sex and who do not possess the biological characteristics enumerated in Regulation 2.2(a).

(d) Since the DSD Regulations establish conditions and restrictions that are targeted at a subset of the female/intersex athlete population, and do not impose any equivalent conditions or restrictions on male athletes, the Panel considers that the Regulations are prima facie discriminatory on grounds of legal sex. Similarly, since the DSD Regulations create conditions and restrictions that are targeted at a

group of individuals who have certain immutable biological characteristics (namely a 46 XY DSD coupled with a material androgenising effect arising from that condition), and which do not apply to individuals who do not have those characteristics (e.g. 46 XX individuals with or without DSDs) it follows that the DSD Regulations are prima facie discriminatory on grounds of innate biological characteristics.

548. The conclusion that the DSD Regulations are prima facie discriminatory is merely the starting point, and not the end, of the Panel's legal analysis. In particular, it is common ground that a rule that imposes differential treatment on the basis of a particular protected characteristic is valid and lawful if it is a necessary, reasonable and proportionate means of attaining a legitimate objective. It is to these questions that the Panel must therefore now turn.

(a) The arguments concerning the validity of the process by which the DSD Regulations were created

549. Before turning to address these questions, the Panel notes that some of the Claimants' expert opinion evidence questioned the validity of the process by which the DSD Regulations were devised by the IAAF. Ms. Semenya relies upon the evidence of Prof. Pielke, who describes the correct basis for the making of policy and regulations. He says that there are four key criteria, all of which must be present to support the making of regulations. In summary, these criteria are that the judgments be scientific and not of policy; that the scientific advice is and is seen to be free from conflict of interest; that the studies relied upon are transparent; and that the research used be peer-reviewed. Prof. Pielke says that, to him, there are serious concerns about the extent to which the DSD Regulations fail to meet each of these criteria.

550. Ms. Semenya says that all four criteria are absent, not least because Dr. Bermon, Prof. Handelsman and Prof. Hirschberg are all members of either the IOC or IAAF (or both) working groups responsible for the DSD Regulations and other earlier regulations concerning DSD athletes. She also points to the lack of diversity of participants in the meetings where the regulations concerning DSD athletes were discussed and the lack of transparency in the opinions there expressed and their outcomes. These points were supported by Dr. Vilain, who challenges the way in which the IAAF supported and promulgated the DSD Regulations, speaking as a person who participated in various meetings at which this was discussed. The arguments were also endorsed and amplified by ASA.

551. It is undoubtedly true that the process by which any rules governing participation in competitive sport are created is important. In this respect, the criteria for sound regulatory policy making identified by Prof. Pielke are undoubtedly laudable objectives. However, the question whether the IAAF's creation and promulgation of the DSD Regulations meets those criteria is not a matter which the Panel considers it is required to determine in this case. Indeed, there is no sufficient evidence enabling it to do so. The Panel's role is not to evaluate the adequacy of the IAAF's general policy making process or to re-write its rules. As the CAS panel noted in CAS 2016/O/4684 *ROC et al. v. IAAF*, "[t]*he rule-making power, and the balance to be struck in its exercise between the competing interests involved, is conferred on the competent bodies of the*

sport entity, which shall exercise it taking into account also the overall legislative framework. The duty of this Panel is to ensure that such an exercise does not conflict with the rules that govern it and not to alter the content (whether by way of interpretation or other form of "manipulation") of existing rules transforming them into something different." See also Sheikh Hazza bin Sultan Bin Zayed Al Nahyan v. FEI, CAS 2014/A/3591.

552. Put simply, the responsibility of this Panel is to determine whether the DSD Regulations are necessary, reasonable and proportionate. While arguments concerning the manner in which the DSD Regulations were devised may cast light on those legal issues, the Panel is not required to – nor does it consider it has sufficient evidence to enable it to – appraise the adequacy of the IAAF's policy-making process.

(b) The arguments concerning the compatibility of the DSD Regulations with various domestic and international human rights laws

553. Another question that has been raised by the Claimants concerns whether the DSD Regulations violate domestic and international human rights laws. The Panel received an *amicus curiae* submission from the United Nations to that effect, as well as expert opinion evidence on the likelihood that the DSD Regulations would be found to breach the national laws of several specific jurisdictions.

554. While the Panel is grateful for the contributions of those experts and the *amicus curiae* submission from the United Nations, it has not found the opinions expressed to be particularly useful in resolving the specific legal issues that the Panel must decide in this case. Much of the legal opinion evidence and submissions focused on the issue of discrimination. It can, of course, be accepted that there are important rights to equality and freedom from discrimination, including in sport, and that those rights find reflection in an array of domestic and international human rights instruments. However, as has been stated above, the Panel is faced with conflicting rights concerning the rights of female athletes who do, and do not, have DSD. Resolving that difficult conflict requires a careful analysis of questions of necessity, reasonableness and proportionality. The *amicus curiae* submission and much of the expert opinion evidence did not descend to an examination of the conflicting rights and the resolution of that conflict.

555. Further, while the Panel appreciates the different legal opinions from experts in a number of jurisdictions, it cannot come to a conclusion on whether or not the DSD Regulations would be found to be unenforceable in, or contrary to the domestic law of, different national jurisdictions. That is not the task before it. The Panel accepts that such possibilities may well exist but that is a matter for the IAAF in promulgating the DSD Regulations and, if they are upheld by this Panel, it will ultimately be a matter for the courts of the various jurisdictions in question to determine.

(iii) Are the DSD Regulations necessary?

556. There is no dispute that ensuring fair competition in the female category of elite competitive athletics is a legitimate objective for the IAAF to pursue. This point was common ground in *Chand* and is common ground in the present case. The Panel accepts that this is an important and legitimate objective. The more difficult (and disputed) question is whether the DSD Regulations are necessary for this purpose.

557. The Panel begins its consideration of this question by observing that once it is recognised that it is legitimate to have separate categories of male and female competition, it inevitably follows that it is necessary to devise an objective, fair and effective means of determining which individuals may, and which may not, participate in those categories. The Panel understands this point to be common ground.

558. The Panel accepts the IAAF's submission that reference to a person's legal sex alone may not always constitute a fair and effective means of making that determination. This is because, as explained above, the reason for the separation between male and female categories in competitive athletics is ultimately founded on biology rather than legal status. The purpose of having separate categories is to protect a class of individuals who lack certain insuperable performance advantages from having to compete against individuals who possess those insuperable advantages. In this regard, the fact that a person is recognised in law as a woman and identifies as a woman does not necessarily mean that they lack those insuperable performance advantages associated with certain biological traits that predominate in individuals who are generally (but not always) recognised in law as males and self-identify as males. It is human biology, not legal status or gender identity, that ultimately determines which individuals possess the physical traits which give rise to that insuperable advantage and which do not.

559. On true analysis, therefore, the purpose of the male-female divide in competitive athletics is not to protect athletes with a female legal sex from having to compete against athletes with a male legal sex. Nor is it to protect athletes with a female gender identity from having to compete against athletes with a male gender identity. Rather, it is to protect individuals whose bodies have developed in a certain way following puberty from having to compete against individuals who, by virtue of their bodies having developed in a different way following puberty, possess certain physical traits that create such a significant performance advantage that fair competition between the two groups is not possible. In most cases, the former group comprises individuals with a female legal sex and a female gender identity, while the latter group comprises individuals with a male legal sex and male gender identity. However, this is not true of all cases. Natural human biology does not map perfectly onto legal status and gender identity. The imperfect alignment between nature, law and identity is what gives rise to the conundrum at the heart of this case.

560. Once it is recognised that the reason for organising competitive athletics into separate male and female categories rests on the need to protect one group of individuals against having to compete against individuals who possess certain insuperable performance advantages derived from biology rather than legal status, it follows that it may be legitimate to regulate the right to participate in the female category by reference to those biological factors rather than legal status alone. Since those biological factors do not correspond perfectly with legal sex in every case, the Panel accepts the IAAF's submission that it is sometimes necessary to devise eligibility conditions that are not exclusively based on legal sex. The Panel stresses, however, that the necessity criterion can only be established where the evidence establishes to the requisite degree of proof that the biological factor which is the subject of the regulation confers a sufficiently significant performance advantage in each athletic discipline that is covered by the regulation. In other words, if a certain biological factor is shown to confer a substantial performance advantage in Event A but is not shown to confer a substantial performance

advantage in Event B, then a regulation that purported to regulate eligibility to participate in Event B by reference to that biological factor would not be necessary.

561. Ms. Semenya argues that genetic difference and outstanding success is by no means uncommon in elite sport. Indeed, it is generally and rightly celebrated. Her evidence supports the submission that a 46 XY DSD is a form of genetic mutation that is not qualitatively different form other genetic differences that are accepted in sport and which in many instances may be determinative of athletic success. She submits that human diversity should be celebrated through inclusiveness and points to her own success in overcoming adversity through strength and perseverance.

562. The Panel points out that there is no challenge whatsoever to Ms. Semenya's character or her outstanding achievements throughout her career. Rather, the IAAF's position is that the evidence demonstrates that the performance advantage that 5-ARD athletes enjoy by virtue of their elevated endogenous testosterone is the same as the performance advantage that the hormone confers on all male athletes. Accordingly, the IAAF says, female athletes who enjoy that male performance advantage must reduce their levels of testosterone so that the IAAF can meet its commitment to equal treatment of the sexes, including enabling them to compete in equal number in finals, on podiums and in winning championship medals. The IAAF submits that this is why the female category was designed and exists. It is to the benefit of the female athletes, the sport and the stakeholders, as well as the wider society.

563. The IAAF says that all but one of the many different factors that contribute to sport performance - including training, coaching, nutrition and medical support, as well as many genetic variations - are equally available to men and women. It submits that the sole factor that is available only to men is exposure to adult male testosterone levels and that it is this exposure that produces the physical advantages that males have over females in sport performance. The IAAF submits that if the purpose of the female category is to prevent athletes who lack that testosterone-derived advantage from having to compete against athletes who possess that testosterone-derived advantage, then it is necessarily "category defeating" to permit any individuals who possess that testosterone-derived advantage to compete in that category.

564. The majority of the Panel accepts the logic of the IAAF's submission, subject to the IAAF demonstrating that the degree of the performance advantage caused by elevated testosterone levels is so great as to require athletes who lack that advantage to be protected against having to compete against athletes who possess it. For the reasons explained above, the Panel accepts that the criteria that regulate who may compete in the "protected" female category must align with the reason for establishing that "protected" category in the first place. If the "protected" category's existence is founded on the significant impact of particular performance-related biological characteristics, in specific events, then it is legitimate to regulate participation in the "protected" category in those events by reference to those characteristics.

565. In *Chand*, the IAAF failed at the hurdle of establishing that the Hyperandrogenism Regulations were necessary because the Panel there was unable, on the evidence before it, to conclude that female athletes with hyperandrogenism enjoyed such a significant

performance advantage from their elevated testosterone levels that it was necessary to exclude them from competing in the female category.

566. The Claimants in the present case submit that it is incumbent on the IAAF to satisfy the criteria set out in *Chand*: to quantify the effect of elevated testosterone on actual performance, to establish a causative connection and to demonstrate that this is equivalent to the male advantage (which was there said to be of the order of 10-12%). They submit that the evidence adduced by the IAAF in support of its defence of the DSD Regulations fails to meet those criteria. In support of that submission, Ms. Semenya and ASA contended that, from a statistical perspective, the data presented in BG17 is not reliable, is not rigorous, does not establish that higher testosterone leads to increased performance and does not provide a proper basis or procedure to support these regulations.

567. Ms. Semenya points out that her fastest time in her best event, the 800 metres, has been beaten by almost 3,000 men and that she is consistently between 9% and 14% slower than the comparable men's performances. The evidence also demonstrates that the margin by which she finishes ahead of the second place is, on average, just 1.03% - a margin that is not a statistical outlier in comparison with the history of track events analysed in the same timeframe. This does not, she submits, accord with the criterion in *Chand* of an advantage comparable to that of male athletes, such as to make it necessary to exclude women athletes with DSD from the female category.

568. Ms. Semenya further submits that the lack of accuracy or reliability in determining the degree of virilisation in a woman with a DSD compounds the difficulties with the requirements in the DSD Regulations. In particular, she says that, as there is significant variability in the degree of androgenic effect such that, depending on that degree of effect, the corresponding increase in performance would be between zero and a fraction of 10% to 12%. As in *Chand*, she submits that the DSD Regulations are premised on an assumption that an endogenous testosterone level within the male range + virilisation = a degree of competitive advantage of commensurate significance to the competitive advantage that male athletes enjoy over female athletes. Ms. Semenya submits that the IAAF has not discharged the burden of establishing that that assumption is valid.

569. The Panel takes note of all of these submissions. In the Panel's view, the necessity of the DSD Regulations turns on the question identified in *Chand*, namely whether the degree of the performance advantage that Relevant Athletes enjoy by virtue of their elevated testosterone levels is so significant as to require the imposition of restrictions on their eligibility to compete against other female athletes who do not enjoy that testosterone-based advantage. The answer to this question turns on a disputed issue of science (*viz.* the existence of and magnitude of the performance advantage) and an evaluative assessment (*viz.* whether that magnitude is so great as to warrant the imposition of restrictions on the ability of such athletes to compete in the female category).

570. In respect of the first issue, matters have moved on in the four years since the hearing in *Chand* took place. The Panel in *Chand* did not have BG17 or the Handelsman Paper, which were published subsequently, nor the totality of the evidence adduced in this proceeding.

571. The present Panel has taken careful note of the evidence and the opinions advanced by the various experts. In particular, the Panel has noted the criticisms of the basis for the use of testosterone levels and the conclusions of the IAAF's experts as to the effects of those levels on athletic performance. After reading the evidence and hearing the experts give concurrent evidence, which greatly assisted the Panel, and taking account of the submissions of the parties, the majority of the Panel concludes that it is satisfied that:

- Testosterone levels are significantly higher in male athletes than in female athletes, after puberty;
- Testosterone impacts and enhances athletic performance by acting on muscle strength and size and on circulating haemoglobin levels;
- Circulating testosterone has its effect in the human body whether the source is exogenous or endogenous;
- The target of testosterone action is sex neutral; its mechanism of action is the same in male and female bodies;
- The different levels of circulating testosterone in the male and female population give rise to an advantage in athletic performance which means that male athletes significantly outperform female athletes;
- 46 XY 5-ARD athletes have levels of circulating testosterone at the level of the male 46 XY population and not at the level of the female 46 XX population;
- This gives 46 XY 5-ARD athletes a significant sporting advantage over 46 XX female athletes.

572. The Panel observes that the Handelsman Paper provided the theoretical basis of the role of testosterone and the results from a number of studies that supported not only the link but also a causative connection between serum levels of testosterone, on the one hand, and on the other hand, muscle strength and size and circulating haemoglobin levels. In addition, Prof. Hirschberg provided evidence of a double-blind, randomised, placebo-controlled study in which 48 healthy, physically active women aged 18-35 years were randomised to 10 weeks of treatment with 10 mg of testosterone cream daily or placebo. The serum testosterone levels in the treated group increased from a mean value of 0.9 to 4.3 nmol/L. This corresponded with an increase of 8.5% in aerobic performance, 3.2% increase in anaerobic performance and increases in lean body mass and muscle mass. Prof. Hirschberg concluded that this demonstrated the same effect of testosterone on females as on males. In the Panel's view, this provides clear support for the proposition that androgen-sensitive women with elevated testosterone levels enjoy a significant performance advantage over other female athletes.

573. Furthermore, BG17, as amended, reported data that supported (although were not capable in themselves of establishing) a causative connection between testosterone and performance in 46 XY 5-ARD athletes. The Panel takes note of the limitation on the conclusions in BG17 and the methodological and statistical criticisms advanced by the Claimants in respect of that study. The majority of the Panel nevertheless considers that BG17 provides a degree of further evidential support for the IAAF's position.

574. The statistics [...] supports the existence of a performance advantage for which no other explanation has been established. That performance advantage may not be of the order of 10-12% but it is sufficient to enable those athletes consistently to beat women who do not have 46 XY DSD. In the majority Panel's opinion, it is not a performance advantage that could fairly be characterised as marginal or minimal.

575. The majority of the Panel, therefore, concludes that it is satisfied that androgen sensitive female athletes with 46 XY DSD enjoy a significant performance advantage over other female athletes without such DSD, and that this advantage is attributable to their exposure to levels of circulating testosterone in the adult male range.

576. In respect of the second issue (*viz.* whether that magnitude is so great as to warrant the imposition of restrictions on the ability of such athletes to compete in the female category), there was some discussion by the parties of the asserted 10-12% male advantage referred to in *Chand* and the fact that BG17 (as amended) showed a much lower advantage. The IAAF responds to the low measure of advantage recorded in BG17 by saying that this demonstrates that a male athlete not of elite level can still beat an elite biological female athlete, although by a smaller margin but still enough to win gold.

577. In *Chand,* the evidence, and the basis for the Panel's observations, was that the difference between elite male athletic ability and elite female athletic ability is of the order of 10-12%. In the present case, the IAAF emphasised that, while this may be so, there is still a difference and a performance advantage between "second tier" male athletes and elite female athletes. The magnitude of that difference would not be of the order of 10-12% but would still be relevant and sufficient to deny female athletes the fair opportunities to win. That is, male athletes do not have to be elite to surpass even the very best female athletes. Dr Bermon pointed out that, in a race such as the 800m, a 1.6% advantage, as calculated in BG 17, was sufficient to determine first place by in the region of nine metres.

578. Thus, with the benefit of further evidence and submissions, it can be accepted that the relevant male performance advantage should not be limited to one of 10-12%. Rather, a lower percentage advantage may still be sufficiently significant as to render competition meaningless.

579. In considering whether the degree of the performance advantage is so great as to require the imposition of restrictions on the ability of athletes with 46 XY DSD to compete against other female athletes, the majority of the Panel pays particular regard to the extent to which [...] demonstrates that the elevated testosterone levels that such athletes possess can create an insuperable advantage over other female athletes who do not have a 46 XY DSD condition.

580. On this basis, the majority of the Panel accepts that the IAAF has discharged its burden of establishing that regulations governing the ability of female athletes with 46XY DSD to participate in certain events are necessary to maintain fair competition in female athletics by ensuring that female athletes who do not enjoy the significant performance advantage caused by exposure to levels of circulating testosterone in the adult male range do not have to compete against female athletes who do enjoy that performance advantage.

581. The next question, therefore, is whether the IAAF has discharged its burden of establishing that the DSD Regulations are both reasonable and proportionate.

(iv) Are the DSD Regulations reasonable and proportionate?

582. The Panel freely acknowledges that the issues of this case are of significant scientific complexity. It is also highly relevant that the parties' experts differ as to many of the relevant factors and that there is a paucity of evidence regarding certain matters concerning the effect of enhanced testosterone levels, largely because of the impossibility of ethically conducting full clinical trials. Nevertheless, the Panel has to make determinations based on the evidence available, and taking account of the burden of proof.

583. As framed by Ms. Semenya, the criterion for reasonableness is whether the restrictions imposed by the DSD Regulations are rationally connected to their objective of ensuring fair competition for female athletes in elite athletics. It is relevant to note that the Regulations do not apply to all events but only to those Restricted Events for which evidence is relied on to demonstrate a practical performance advantage. The answer to this specific question – namely whether there is a reasoned basis for the DSD Regulations – is therefore in the affirmative for the same reasons that the majority of the Panel outlined in determining that they are necessary.

584. The majority of the Panel therefore concludes that the DSD Regulations are necessary and reasonable. The area that has given rise to the greatest difficulty is that of proportionality. The IAAF contends that its evidence leads to the conclusion that they are proportionate, in that they allow for the minimum treatment invasion, using a commonly prescribed treatment used by women around the world to avoid pregnancy, to reduce the level of testosterone to a concentration well above the female range.

585. The Claimants seek to establish that the DSD Regulations are disproportionate. They rely on a number of matters that, they submit, will affect athletes complying with the Regulations such that, in weighing these effects with the claimed benefit of the Regulations, they are disproportionate. The varying factors that have been raised are, in the main, either hypothetical, or supported by challenged or inconclusive data, or are not relevant to the facts of the present case.

586. The IAAF Council has made amendments to the DSD Regulations following the hearing in this case. The Claimants strongly submit that they would be prejudiced by any consideration of those amendments without further evidence and submissions. The Panel agrees with the Claimants and moreover highlights the untimely nature of such amendments and therefore does not include those amendments in its consideration of the validity of the DSD Regulations. To the extent that the proposed amendments relate to or respond to criticisms raised by the parties or by the Panel in this proceeding, the Panel is not precluded from coming to its own conclusions as to the proportionality of the version of the DSD Regulations that was in force prior to those newly foreshadowed amendments. And finally, the parties shall note that even if the Panel were to consider the post-hearing amendments to the Regulations, such amendments would not affect the Panel's ultimate conclusion in this procedure.

a. The effect of the DSD Regulations on society generally

587. Ms. Semenya submits that there is a disproportionate effect in the consequences of the DSD Regulations in broader society. On the one hand, she points out, they affect only a relatively small number of vulnerable athletes; on the other, they interfere with fundamental human rights in a manner that is likely to have significant implications for the treatment of women in society generally.

588. The Panel does not consider that it is able to undertake an assessment of the likely impact of the DSD Regulations on wider society, which would require an analysis of multifaceted sociological issues which are not amenable to judicial resolution by an arbitral tribunal that is tasked with determining the validity of rules that govern eligibility to participate in sporting competitions.

589. The IAAF is charged, *inter alia*, with supervision of athletics in accordance with its own Constitution and overarching principles. The majority of the Panel have accepted that, within the relevant segment of society governed by IAAF regulations, these DSD Regulations are necessary and reflect a rational resolution of conflicting human rights. In light of this conclusion and the constraints on the Panel's competence and role, the majority of the Panel does not consider it necessary or appropriate to seek to make any assessment of the possible wider impact of the DSD Regulations outside of that sphere.

b. The effects of testosterone-suppressing medical treatment

590. The Claimants submit that, in order to be eligible to compete in a Restricted Event, Relevant Athletes must undergo testosterone-suppressing treatment that is both medically unnecessary and has serious and potentially dangerous side effects. The Claimants argue that this is a factor of very great significance when it comes to an assessment of the reasonableness and proportionality of the impugned Regulations.

591. In response, the IAAF emphasises that the DSD Regulations do not require any athlete to undergo any surgery in order to comply with the requirements in the Regulations. Further, the IAAF submits that hormonal treatment is a recognised standard of care for athletes with various 46 XY DSD conditions (such as 5-ARD patients with a female gender identity) and for male-to-female transgender patients. The side effects of such treatment are generally limited and the effects of the treatment are quickly reversible when the treatment ends.

592. The Panel proceeds, as did the parties, on the basis that the DSD Regulations can be evaluated in the context of hormonal treatment using contraceptive pills, recognising that such treatment is not as efficient in inhibiting testosterone as the use of GnRH agonists, while withdrawal of the latter is likely to have greater side effects. If oral contraceptives were not capable of achieving the result of maintaining the level of testosterone below 5 nmol/L – thus requiring an athlete to turn to GnRH agonists or gonadectomy in order to compete – a different analysis of proportionality would need to be undertaken.

593. The evidence from those experienced in treating individuals with DSD is that ordinary doses of oral contraceptives are efficient in reducing testosterone to normal female levels. Prof. Gomez-Lobo spoke of her clinical experiences generally rather than with

athletes, while Prof. Hirschberg spoke of her experience in reducing testosterone from 20 to 1 nmol/L. However, the evidence of such treatment on elite athletes is extremely limited; it consists principally of evidence concerning Ms. Semenya's use of oral contraceptives to reduce her testosterone levels. There are no current guidelines to instruct how a clinician would use oral contraceptives to reduce testosterone levels in a woman with a 46 XY DSD to less than 5 nmol/L and keep it at that level, but there are expert clinicians who have done so (such as Prof. Hirschberg, who says that she treats each person on an individual basis). Further, Prof. Auchus says that the standard of care and treatment would not be different than for a 46 XY male with gender dysphoria.

594. Ms. Semenya does not only rely upon the significant detriment to and violation of the equality rights of the women to whom the DSD Regulations apply. She also relies upon her own evidence, and that from and concerning other DSD athletes, as to the side effects – both mental and physical – of being having to reduce the level of endogenous testosterone with hormonal treatment. While taking oral contraceptives, Ms. Semenya suffered a range of side effects including weight gain, feverish symptoms and consistent abdominal pain. As a result, she felt constantly unwell and was unable to focus mentally, which impeded her training and performance.

595. The Panel accepts the Claimants' evidence that the use of oral contraceptives to reduce testosterone levels can cause a range of unwanted side effects. Those side effects potentially affect all of the women who take them, both XX and XY DSD women. The Panel notes that expert evidence adduced by the Claimants describes different adverse effects that may result from the various pharmacological and surgical methods to reduce testosterone, including decreased bone density, significant weight gain, hypotension, renal dysfunction, electrolyte abnormalities and venous thromboembolism, as well as the social, mental and psychological problems encountered by women with DSDs. Thus, the expert evidence supports Ms. Semenya's evidence as to the side effects that she says that she experienced.

596. The evidence of the side effects experienced by [...] athletes with 46 XY DSD concerned reactions experienced when bringing their testosterone levels down to below 10 nmol/L. There was no (or no sufficient) evidence before the Panel to enable any conclusion to be drawn as to whether those side effects would increase if the maximum permitted level were further decreased to 5 nmol/L. The Panel proceeds on the assumption that, at the very least, the side effects would be as strong as those experienced by Ms. Semenya and others.

597. The evidence of Ms. Semenya was, of its nature, anecdotal but real. However, it is not possible for the Panel to conclude that all of the symptoms that she encountered while attempting to reduce her levels of testosterone were due to the medication, or that they could not otherwise be controlled, or that they would continue, or that other athletes [...] would experience exactly the same side effects (different women react differently to different forms of oral contraceptive), or that another form of oral contraceptive, if prescribed, would result in the same side effects.

598. In any event, there is also the evidence of clinicians who say that the side effects are not different in nature to those experienced by the many thousands, if not millions, of other XX women, who take oral contraceptives. Those clinicians also say that care would be

taken to individualise treatment to minimise side effects when using such oral contraceptive treatment to manage the testosterone levels of women with 46 XY DSD. As to the social, mental and psychological problems, these have not been shown to be attributable simply and exclusively to the use of oral contraceptives. Further, the evidence did not establish the length of time that the symptoms occurred and whether they could all be attributed directly to the taking of the medication.

599. In the majority of the Panel's view, requiring 46 XY DSD athletes to take oral contraceptives to lower testosterone in order to compete in the female category in Restricted Events at International Competitions is not, of itself, disproportionate. In the circumstances, the majority of the Panel is of the view that, on the present evidence, the side effects that may be experienced by such athletes [...] as a result of taking an oral contraceptive do not outweigh the need to give effect to the DSD Regulations in order to attain the legitimate objective of protecting and facilitating fair competition in the female category.

c. The effect of requiring Relevant Athletes to undergo intimate medical examinations and assessments of virilisation

600. The Claimants submit that the requirement to undergo intimate personal examination to determine the extent of virilisation if an athlete does have high levels of testosterone is another form of sex or gender testing and is both subjective and inappropriate. It can also be highly intrusive and is an infringement of bodily integrity that can result in psychological harm. This harm would be repeated were an athlete to appeal to the CAS, where further examination may be required, and further detailed discussion of her body would take place. The Claimants also submit that psychological harm may arise from an athlete being labelled as having a DSD and from learning that they have such a condition.

601. The Panel acknowledges the potential consequences described and notes that being subjected to an examination of virilisation may be unwelcome and distressing even when conducted with due care and sensitivity. At the same time, the Panel also notes that all athletes are tested for testosterone for doping control purposes, which include identifying whether athletes have taken exogenous testosterone. If the results of those tests show a high level of testosterone in a sample provided by a female athlete with a 46 XY DSD who is unaware of that condition, further investigation to establish that the athlete has a DSD is likely to be necessary in order to exonerate her of doping. This investigation of itself will likely inform the athlete of her DSD condition, whether or not the DSD Regulations are in place. Accordingly, in assessing the proportionality of the DSD Regulations the Panel has regard both to the likelihood that Relevant Athletes will undergo undesired examinations and to the possibility that such examinations may in some cases yield the discovery of medical information that is capable of assisting athletes to reach informed decisions about possible necessary medical treatments and of exonerating them from any erroneous finding that they have taken exogenous testosterone.

602. In addition, Ms. Semenya submits that the requirement for an assessment of virilisation to be carried out introduces an unacceptable element of arbitrariness into the process for determining whether an athlete is required to reduce their testosterone levels as a

condition of being allowed to compete in Restricted Events. In particular, she says, there is no objective test for virilisation that is capable of being applied in a consistent manner across all cases covered by the DSD Regulations. Instead, the process of assessing virilisation necessarily depends upon the subjective views of the clinician tasked with carrying out the assessment. Accordingly, she submits it is inevitable that the DSD Regulations will be applied in an arbitrary and inconsistent manner.

603. The Panel notes that the eligibility restrictions established under the DSD Regulations only apply where an athlete has a testosterone level over 5 nmol/L and experiences a material androgenising effect from that enhanced testosterone level. The determination whether such material androgenising effect exists is entrusted to the IAAF medical manager and an Expert Panel comprised of suitably qualified independent medical experts who are experienced in such assessments. There is a recognised scale of degree of virilisation. Prof. Auchus and Prof. Hirschberg have given evidence that, for an expert, the assessment of the degree of androgen sensitivity is not difficult to evaluate, using physical examination and laboratory evaluation. Further, and importantly, the DSD Regulations provide that the benefit of any doubt will be resolved in favour of the athlete.

604. Having regard to all these factors, the majority of the Panel therefore concludes that the provisions in the DSD Regulations dealing with the assessment of virilisation do not render the DSD Regulations disproportionate.

d. The risk that the confidentiality of Relevant Athletes will be compromised

605. The Panel does accept that the IAAF has been successful in preserving the confidentiality of DSD athletes covered by the predecessor to the DSD Regulations. Nevertheless, the exclusion of athletes from Restricted Events in International Competitions where, for example, the athlete has qualified in National Competitions would be likely to render confidentiality meaningless in some cases. In those situations, it would not be difficult for an informed observer to infer from the absence of that athlete at subsequent International Competitions that the athlete has a relevant 46 XY DSD and has declined (or been unable) to reduce their endogenous testosterone to within the prescribed level. The Panel considers this is likely to be an inevitable detrimental effect of the DSD Regulations as they are currently framed. The Panel does not consider that this factor of itself renders the DSD Regulations disproportionate having regard to the countervailing legitimate interests pursued by the Regulations. It nevertheless has regard to the likelihood of some harm arising from the inferential disclosure of confidential medical information in reaching its overall conclusion as to the proportionality of the Regulations.

e. The application of the DSD Regulations to only the Restricted Events

606. The IAAF says that it accepted the observations in *Chand* that it should apply restrictions only where the evidence of a significant performance advantage arising from enhanced testosterone levels in athletes with 46 XY DSD was clear and compelling. Much of the IAAF case, and the evidence in support, centered around one event, the 800m. The Claimants submit that the Restricted Events were selected arbitrarily. They point out that events for which there was evidence of advantage in

BG17 (such as the hammer throw and pole vault) were not included within the category of Restricted Events, while the 1500m and 1 mile events – where the evidence of advantage was less significant – were included. Nevertheless, the Claimants also focused their evidence and submissions on the 800m and there was no specific and targeted focus on the empirical basis for the inclusion of other events within the definition of Restricted Events. This is understandable, as the focus was the event most pertinent to Ms. Semenya.

607. The IAAF did provide some evidence relating to all of the events included within the category of Restricted Events. It says that of the [...] identified DSD athletes, [...] competed in track events over distances between 400m and one mile. The IAAF explains that the decision not to include other events was based on the fact that the available evidence indicated that the number of 46 XY DSD athletes competing at elite international level in those events was currently not sufficient to warrant their inclusion in the category of Restricted Events. The IAAF contended that this cautious and conservative approach to the Restricted Events was intended to ensure that the DSD Regulations imposed the minimum possible restrictions necessary to ensure a level playing field within the female category. According to the IAAF, this reflects the IAAF's conscientious attempt to ensure that the DSD Regulations do not impose any greater restrictions than are necessary and proportionate.

608. On the basis of the evidence presented to the Panel, the IAAF's decision to include the 1500m and 1 mile events within the list of Restricted Events seems to be based, at least in part, on speculation that athletes who compete in the 800m also compete successfully in the 1500m and 1 mile. However, there were no submissions by the Claimants directed specifically to the inclusion of these two events within the category of Restricted Events.

609. The Panel has some concern about the inclusion of two events within the category of Restricted Events on the basis (at least in part) of a speculative assumption that since female athletes who compete successfully in the 800m often also compete successfully in those longer events, it must follow that 46 XY DSD athletes are likely to enjoy a significant performance advantage over other female athletes in those two events. Nevertheless, the majority of the Panel considers that the IAAF has provided a rational overall explanation for how the category of Restricted Events has been defined. The scope of the Restricted Events therefore cannot be described as arbitrary. While the Panel has concerns about the adequacy of the evidentiary basis for including the 1500m and one mile events within the list of Restricted Events, it is mindful that it does not have the power to rewrite the DSD Regulations or to amend the list of events covered by the Regulations. Instead, it is required to make an assessment of the overall proportionality of the DSD Regulations. Having regard to the evidence adduced by the parties, the majority of the Panel does not consider that the scope of the Restricted Events *in toto* is disproportionate.

f. The rationale and effect of the 5 nmol/L threshold

610. A further issue of concern relates to the level of endogenous testosterone permitted under the DSD Regulations. The upper level of testosterone permitted in the Hyperandrogenism Regulations, as considered in *Chand*, was 10 nmol/L. The rationale

for that former limit was that 10 nmol/L is at the lower end of the normal male range. The upper level in the DSD Regulations has been lowered to 5 nmol/L. The IAAF's explanation for the change is that it has determined a level by reference to XX female levels of testosterone. Thus, this lower threshold represents a level that is significantly higher than the upper limit of the normal range for the female XX population (0.06 to 1.68 nmol/L), adjusted upwards to allow for increased levels of testosterone in female XX athletes with PCOS. The IAAF points out that individuals with levels above 5 nmol/L will either have a testosterone-secreting tumour in the adrenal glands or ovaries, be taking exogenous testosterone, or be a male-to-female transgender athlete or a 46 XY DSD individual who is not suppressing their testosterone levels. The IAAF has not provided any further concrete explanation for why the level was lowered or why it is not, for example, 7.7 nmol/L (which is the accepted lower limit of the normal male range).

611. There are statements in the IAAF's evidence as to a performance advantage when the level of an individual's endogenous testosterone increases from 5 nmol/L to 10 nmol/L. There is some evidence that exogenous doses to increase women's circulating testosterone to 7.3 nmol/L resulted in 4.4% increased muscle mass and 12-26% increased muscle strength and that increasing endogenous testosterone from 0.9 to 5, 7 and 10 nmol/L increased circulating haemoglobin by 6.5%, 7.5% and 8.9% respectively. The Panel is therefore satisfied that the decision to reduce the testosterone threshold from 10 nmol/L to 5 nmol/L was not arbitrary.

g. The ability of the athlete to maintain a level of testosterone below 5 nmol/L

612. There is, however, another issue that was really only given prominence in the parties' final submissions, after the completion of the evidence and hot tubs. The issue concerns the question of unintentional fluctuations in the levels of endogenous testosterone when Ms. Semenya was taking hormonal medication to bring her testosterone levels to below 10 nmol/L. There was evidence that heavy training causes a reduction in testosterone levels, leading to further reductions in the level of testosterone than the reduction caused by treatment alone. However, the level and extent of training is not constant and the common practice of "tapering" training prior to a major competition could lead to fluctuations and an unintentional increase in the level of endogenous testosterone despite full compliance with the prescribed medication. Spikes in Ms. Semenya's testosterone level were recorded while she was taking the treatment consistently. In particular, there was evidence that during the period that Ms. Semenya consistently took oral contraceptives to lower her testosterone levels to below 10 nmol/L in accordance with the agreed treatment regime, her testosterone levels (which included tests during periods of training) showed significant fluctuation, ranging from 0.5 to 7.85 nmol/L, although still below 10 nmol/L (as was then required).

613. Ms. Semenya suggested that such spikes could result in an athlete inadvertently breaching the 5 nmol/L maximum level under the DSD Regulations even if the treatment regime of oral contraceptives designed to reduce the level of testosterone sufficiently was followed diligently. A number of theoretical scenarios were advanced. They included the difficulty in keeping the level consistently below 5 nmol/L, even when medication was taken regularly, because of the possibility of temporary,

inadvertent and unavoidable spikes above that level. Another scenario was the accepted propensity of some women to forget to take the medication on a given day and the possibility of unintentional fluctuation for that reason. Another was the difficulty for an athlete to monitor their testosterone levels when the results of a test, which may record a fluctuation or uncontrolled spike, would not be available to them until some days later. Further, individual metabolism and other gastro-intestinal issues could, as suggested by Professors Dave and Blockman, affect testosterone levels, as could what were described as potential pharmacokinetic effects on the absorption or metabolisation of oral contraceptives if taken with supplements or other medications.

614. The IAAF's response is that, even with fluctuations, Ms. Semenya's level of testosterone consistently remained below 10 nmol/L (the maximum limit at the time) during the period when she was fully complying with the prescribed treatment. In the Panel's view, this nevertheless raises a very important question for the issue of proportionality, having regard to the new maximum level of 5 nmol/L. If a Relevant Athlete takes the medication as prescribed to lower testosterone and fully complies with that treatment and still has fluctuations over the maximum permitted level, that would, under the DSD Regulations in force at the time of the hearing, still disqualify her from competing in a Restricted Event. It would be an impossible burden for the athlete to demonstrate that such unintentional fluctuations did not impact her performance. Further, in order to monitor for fluctuations, the athlete would have to monitor herself continuously, during training and during rest periods, presumably at her own cost. It seems inevitable that the athlete would not know the results of that testing until some days after each test. As a result, it is likely that she would take part in competitions without being able to know for certain whether her testosterone level is below the prescribed threshold on the day of the competition. A delay between testing and notification of the results of that testing would inevitably mean that the athlete could not respond to any fluctuations (such as a spike in testosterone caused by pre-competition tapering) that occur immediately before competitions. There is therefore a real risk that an athlete may suffer disqualification – and all of the detrimental consequences this entails – despite using her best endeavours to comply conscientiously with the DSD Regulations.

615. For the purposes of the proportionality assessment, a balance must be struck between countervailing factors. On one hand is the imposition of a new maximum threshold of 5 nmol/L which was rationally selected because it represents the highest level well above the normal female range (allowing for athletes with PCOS). On the other hand, there are the side effects of using medication to lower testosterone levels coupled with the risk of inadvertent fluctuations above the 5 nmol/L threshold and, potentially, the difficulty for an elite athlete in competition to keep their testosterone consistently below 5 nmol/L, to monitor that level adequately in real time and to pay for that monitoring.

616. The matters of compliance are clearly very important. If the DSD Regulations cannot be implemented fairly in practice, that could render them disproportionate at a later stage, since a regulation which is impossible or excessively difficult to apply fairly cannot be characterised as a proportionate interference with the rights of those who are subjected to it.

617. The Panel does not, of course, have direct evidence of compliance with the DSD Regulations, which have not yet been implemented. Nevertheless, the Panel does have concerns as to the maximum level of 5 nmol/L and the practical ability of female athletes with 46 XY DSD to ensure that their levels of testosterone do not exceed that level. These matters will necessarily require oversight by the IAAF to ensure that this requirement is workable in practice.

618. As to implementation by the IAAF, the Panel only has what is set out in the DSD Regulations and the evidence of the experts, some of whom would be examples of those of relevant expertise who would be called upon to make relevant assessments. The IAAF has identified a worldwide pool of experts for this purpose. These are medical experts who have to determine androgen sensitivity as part of their regular clinical medicine practices. Some of those gave evidence before the Panel which demonstrated a high level of care and sympathetic approach to the treatment of 46XY DSD women. The bona fides of that approach and the fact that the benefit of the doubt is given to the athlete, as well as a practical approach in monitoring compliance with respect to the maintenance of a level of 5 nmol/L, are of crucial relevance to the Panel in weighing the factors for the consideration of proportionality.

619. However, the matters raised concerning potential difficulties in complying with the DSD Regulations were speculative (apart from agreement as to the possible difficulty with absorption of the hormone if the athlete had a gastro-intestinal infection) and without evidence or evidentiary support with respect to compliance with the 5 nmol/L requirement. That level chosen by the IAAF did have evidentiary support and explanation. The task for the Panel is to consider the DSD Regulations as promulgated and not yet implemented. Hypothetical consequences of the way in which the DSD Regulations might be implemented do not provide an evidentiary basis for a conclusion that they are presently and on their face disproportionate.

h. Conclusion on reasonableness and proportionality

620. The majority of the Panel concludes that, on the evidence before it, the IAAF has shown that the DSD Regulations are reasonable and proportionate on their face. Nevertheless, the Panel has some grave concerns as to the future practical application of the DSD Regulations. While the evidence has not established that those concerns are justified, or that they negate the conclusion of *ex facie* proportionality, this may change in the future unless constant attention is paid to the fairness of how they are implemented. In this regard, reference is made to the matters discussed above.

621. Ms. Semenya has raised matters regarding the difficulty of complying with the requirements imposed under the DSD Regulations that, if established, could lead to a different conclusion as to the proportionality of the DSD Regulations. However, as the case stands, those matters have not been established on the evidence and the majority of the Panel considers that the side effects of hormonal treatment, while significant for each athlete who suffers from them, are not sufficient to outweigh the matters identified by the IAAF in support of the DSD Regulations. The IAAF should, however, take notice of the Panel's concerns.

622. The matters of particular concern to the Panel which prompted it to inquire whether the parties would consent to the application of Article R45 included the matters discussed

above regarding difficulties of implementation of the DSD Regulations and the significance of those difficulties in the context of a maximum permitted level of testosterone of 5 nmol/L rather than 10 nmol/L. The Panel notes the strict liability aspect of the DSD Regulations and repeats its concern as to an athlete's potential inability to remain in compliance with the DSD Regulations in periods of full compliance with treatment protocols, and, more specifically, the resulting consequences of unintentional and unavoidable non-compliance.

623. In addition, the evidence of actual (in contrast to theoretical) significant athletic advantage by a sufficient number of 46 XY DSD athletes in the 1500m and 1 mile events could be described as sparse. The IAAF may consider deferring the application of the DSD Regulations to these events until more evidence is available.

624. The Panel is precluded by reason of the lack of authorisation by the parties from making a decision *ex aequo et bono*. It nevertheless considers it appropriate to highlight its concerns with aspects of the DSD Regulations which arose from the submissions and evidence adduced by the parties in these proceedings. The Panel strongly encourages the IAAF to address the Panel's concerns in its implementation of the DSD Regulations. In that regard, the Panel notes the assertion by the IAAF that the DSD Regulations are a "living document". At the same time, the majority of the Panel observes that it may be that, on implementation and with experience, certain factors, supported by evidence, may be shown to affect the overall proportionality of the DSD Regulations, either by indicating that amendments are required in order to ensure that the Regulations are capable of being applied proportionately, or by providing further support for or against the inclusion of particular events within the category of Restricted Events.

K. Conclusion on validity of the DSD Regulations

625. The Panel is faced with regulations that are dealing with an agreed binary division of athletes for competition, namely male and female, in a world that is not so neatly divided. It is not the role of the Panel to decide whether or not to implement regulations such as the DSD Regulations. That is a matter for the IAAF. The Panel's task is to determine whether the DSD Regulations, which are discriminatory, are necessary, reasonable and proportionate. That decision must be made on the basis of the case as advanced by the parties, that is, on the basis of the evidence adduced and the submissions made. The Panel appreciates the difficulties for all parties that much of the evidence that the parties might have wished to adduce was unfortunately, as of today, simply not available. The Panel is also mindful of the principles of natural justice and procedural fairness, which means that the Panel cannot make findings on matters which the parties have not addressed, or not had an opportunity to address.

626. For the reasons explained above, the majority of the Panel finds that the DSD Regulations are discriminatory but that on the evidence currently before the Panel such discrimination is a necessary, reasonable and proportionate means of achieving the aim of what is described as the integrity of female athletics and the upholding of the "protected class" of female athletes in certain events.

X. COSTS

627. In respect of costs, the IAAF and Ms. Semenya agreed that irrespective of the outcome of the proceeding, neither party would seek an award of costs against the other. In light of that agreement, the Panel is not required to make any decision in respect of the IAAF and Ms. Semenya's respective costs liabilities *inter se*.

628. No equivalent agreement on costs, however, was reached in respect of ASA. ASA seeks an award of costs against the IAAF but does not seek any award of costs against Ms. Semenya. The IAAF, for its part, seeks an award of costs against ASA. The Panel must therefore determine what costs award (if any) it should make in respect of this.

629. Article R64.5 of the Code states:

> *In the arbitral award, the Panel shall determine which party shall bear the arbitration costs or in which proportion the parties shall share them. As a general rule and without any specific request from the parties, the Panel has discretion to grant the prevailing party a contribution towards its legal fees and other expenses incurred in connection with the proceedings and, in particular, the costs of witnesses and interpreters. When granting such contribution, the Panel shall take into account the complexity and outcome of the proceedings, as well as the conduct and the financial resources of the parties.*

630. The Panel, therefore, has a broad discretion in respect of the making of any costs award, which shall be exercised by reference to all the circumstances of the case including the complexity and outcome of the proceedings and the conduct and financial resources of the parties.

631. The majority of the Panel notes, first, that it has upheld the DSD Regulations and dismissed ASA's challenge to the DSD Regulations. While the outcome of the proceedings might ordinarily militate in favour of an award of costs against ASA, the Panel notes that the proceedings have served an important purpose in evaluating the legality of important and controversial rules which are a matter of significant and legitimate interest to all stakeholders in the sport of athletics. The Panel also notes that while ASA's involvement in the proceeding did lengthen the duration of the hearing, its evidence and submissions were of some assistance to the Panel in resolving the important issues that arose for determination. The Panel also notes that the majority of the evidential and legal issues canvassed in the submissions of Ms. Semenya and the IAAF would need to have been addressed by the parties and the Panel in any event even if ASA had not been a party to this proceeding. In these circumstances, the Panel considers that, in the exercise of its discretion under Article R64.5, it is appropriate to make no award of costs either against or in favour of ASA. Therefore, the costs of the procedure, to be determined by the CAS Court Office, shall be shared equally by the parties.

632. This conclusion is subject to one exception. The Panel considers that ASA's unsuccessful challenge to the appointment of two of the three members of the Panel were wholly without merit and should not have been made. Accordingly, the Panel considers it appropriate to require ASA to make a contribution to the legal costs incurred

by the IAAF and Ms. Semenya in responding to those unnecessary and unmeritorious challenges. In the circumstances, the Panel therefore determines that ASA should pay CHF 1,500 to Ms. Semenya and CHF 1,500 to the IAAF in respect of their legal and other costs associated with this interlocutory matter.

ON THESE GROUNDS

The Court of Arbitration for Sport rules that:

1. The requests of arbitration filed by Ms. Mokgadi Caster Semenya on 18 June 2018 and Athletics South Africa dated 25 June 2018 against the International Association of Athletics Federations seeking to declare unlawful the Eligibility Regulations for the Female Classification (Athletes with Differences of Sex Development) are dismissed.

2. The costs of the arbitration, to be determined and served to the parties by the CAS Court Office, shall be shared equally by Ms. Mokgadi Caster Semenya, Athletics South Africa, and the International Association of Athletics Federations.

3. Athletics South Africa is ordered to pay CHF one thousand five hundred (CHF 1,500) to each of Ms. Mokgadi Caster Semenya and the International Association of Athletics Federations as contribution towards their legal and other expenses incurred in connection with these arbitration proceedings.

4. All other motions or prayers for relief are dismissed.

Seat of arbitration: Lausanne, Switzerland
Date: 30 April 2019

THE COURT OF ARBITRATION FOR SPORT

The Hon. Dr. Annabelle Bennett AO SC
President of the Panel

The Hon. Hugh L. Fraser
Arbitrator

Dr. Hans Nater
Arbitrator

Edward Craven
Ad hoc Clerk