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IN THE COURT OF ARBITRATION FOR SPORT

IN THE MATTER OF FLOYD LANDIS,

CAS 2007/A/1394

FLOYD LANDIS V. UNITED STATES ANTI-DOPING AGENCY

APPELLANT'S CLOSING BRIEF

I.

INTRODUCTION

This case should be about a search for the truth. Mr. Landis's defense has consistently attacked the many fundamental flaws in the methods and procedures of the Laboratorie National de Depistage et Dopage ("LNDD"), including its failure to use properly validated methodology, and the many deviations from the applicable International Standard for Laboratories and sound laboratory practice. As a scientific case, Mr. Landis' issues have remained the same as when they were presented in the AAA proceedings and its CAS briefs and declarations. This closing brief will not repeat these arguments, but focuses on the evidence introduced at the CAS hearing as it relates to those issues, which are:

1. LNDD failed to use an accredited or validated method to identify testosterone compounds when it conducted the Carbon Isotope Ratio test ("CIR") of Mr. Landis' Stage 17 samples. USADA did not prove that the method was reliable and cannot do so, given that USADA failed to even establish what method the LNDD staff used. Because USADA cannot establish what method of CIR analysis LNDD used and that it was reliable, this case must end. Even if this Panel concludes that USADA somehow established what method LNDD used to analyze Mr. Landis' sample, and has further established that this method was either accredited or otherwise reliable, Mr. Landis should prevail because he has proved that LNDD repeatedly failed to comply with the ISL when performing that analysis;
2. LNDD failed to validate its positivity criteria in violation of the ISL;
3. LNDD had no effective or appropriate quality controls in violation of the ISL;
4. The Isoprime1 was not linear;
5. LNDD's chromatography was poor in violation of the ISL and LNDD improperly manually processed IRMS test results;
6. LNDD failed to use the same column in the CIR test as required by its SOP;
7. LNDD failed to properly train and supervise its laboratory technicians;
8. LNDD failed to comply with the ISL when it deleted data;

9. LNDD failed to maintain chain of custody pursuant to the ISL and the WADA technical documents;

10. LNDD failed to comply with the ISL regarding laboratory documentation;

11. The reprocessing and retesting process does not constitute a waiver of Mr. Landis' claims on appeal;

12. Dr. DeBoer's attendance at the Sample B testing does not constitute a waiver of Mr. Landis' claims on appeal;

13. The total picture of LNDD's laboratory test results in this case are inconsistent with the known science on testosterone metabolism;

14. The presence and importance of fraudulent documents, bias, false statements, cover-up and witness credibility and,

15. Sanctions

Altogether, these issues paint a cohesive picture that shows that for the testing of Sample 995474 and the other tests from the other stages of the 2006 Tour de France ("Tour"), numerous errors were committed that render the test results unreliable and of no evidentiary value. In order to focus on citation references, the format of this brief will be an expanded outline with citations to the critical points.[1]

This brief will primarily focus on the discussion of the critical issues and responding to USADA's evidence, and not repeating the testimony of Mr. Landis' experts or the arguments already contain his Opening Brief, all of which are incorporated here by reference.[2] In order to

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1 The AAA hearing transcript is cited as "AAA Tr. Page:Line." The CAS hearing transcript is cited as "CAS Tr. Page: Line." The exhibits are cited by exhibit number. The pleadings and correspondence are cited by descriptive name (if they have no assigned exhibit number).

2 The scientific conclusions of Mr. Landis' IRMS experts were largely unchallenged on cross-examination, and Dr. Amory's conclusions were adequately addressed in his redirect testimony and cross-examination, and little time will be devoted here to repeating those conclusions.

understand the absurdity of USADA's current arguments in this appeal, it is critical to understand the context of the history of the arguments USADA has made in connection with this case. Many of the arguments USADA tried to defeat during this appeal were actually arguments that they presented in earlier discovery responses, briefs and testimony at the AAA proceeding. Three glaring examples, among others, include: (1) USADA and LNDD first contended that the internal standard was added to each sample as a quality control, and an assurance of excellent laboratory procedure; (2) USADA and LNDD contended that they identified peaks in the IRMS chromatograms by matching the retention times of the peaks with the retention times of the peaks in the GC/MS chromatograms; and (3) USADA and LNDD contended that chain of custody was complete and easy to determine from the documents. It was only after Mr. Landis established that these assertions were incorrect that USADA changed their story. During the CAS hearing, USADA spent considerable time trying to establish that these previous points are wrong or scientifically insignificant, while ascribing their genesis to Mr. Landis. In order to shift their stories in order to win at any cost, USADA and LNDD have argued against the plain meaning of the documents, apparently abandoned the assertion that all of the alleged positives are scientifically supported and have seen their witnesses contradict each other.

Most troublingly, Mr. Landis' search for the truth in this case has been obstructed – often with devastating results – by the presence of bias, inconsistent and false statements and fraudulent documents. When he identifies an error with the column, a witness magically appears to clear up the error, but the documents are fraudulent. When the AAA Panel notes that LNDD failed to monitor linearity in compliance with its SOP, a new linearity testing document magically appears to help repair the damage. These incidents are not the hallmarks of a search for the truth, but of a desire to win at all costs. The decision to include these arguments was not

made lightly and only after deliberation and careful analysis of the record. Much of this evidence went completely unanswered at the CAS hearing. The search for truth should end with the vindication of Mr. Landis, not the affirmation of a litany of bad lab practices and poor oversight.

II.

BURDEN AND STANDARD OF PROOF

A. The Burden of Proof

1. USADA bears the significant burden of "establishing that an anti-doping violation has occurred." WADA Code, Art. 3.1; UCI Anti-Doping Rules, Art. 16. There are three elements to USADA's case: method reliability, compliance with mandatory laboratory standards, and absence of causation.

2. USADA benefits from certain presumptions as to the first two of these elements if the method used by the LNDD was accredited by the national accreditation entity; in this case, COFRAC. WADA Code, Art. 3.2.1, 3.2.2; UCI Anti-Doping Rules, Art. 18; *Hamilton v. USADA*, CAS 2005/A/884, Paragraphs 50 and 52.

3. Method reliability. If USADA has established that the method actually used by the LNDD to analyze Mr. Landis's Stage 17 sample was, in fact, accredited by COFRAC, that method used will be presumed to have been a reliable one, and it will be presumed that the lab performed the method in compliance with the ISL (the "compliance" element). WADA Code, Art. 3.2.1; UCI Anti-Doping Rules, Art. 18; *Hamilton* at Paragraph 50. However, in order to be entitled to the Code's presumptions, USADA must establish to the comfortable satisfaction of the Panel that the Carbon Isotope Ratio test actually used by LNDD was an accredited method.

4. If USADA fails to establish that the CIR method actually used by LNDD was accredited by COFRAC, it loses the benefit of the presumption in Section 3.2.1, and must prove that the method was reliable. This is mandated by Article 3.2 of the WADA Code, which dictates that the anti-doping agency must establish the facts related to the anti-doping violation– in this case, the Adverse Analytical Finding (AAF)-- "through any reliable means." WADA Code, Art. 3.2; Hamilton at Paragraph 48; UCI Anti-Doping Rules, Art. 17; USADA's Response Brief at 18, quoting WADA Prohibited List, S1.1b, at 3 (proof that a Prohibited Substance is of exogenous nature may be established by using a "reliable analytical method").

5. Where the AAF relies upon an unaccredited analytical test as the "means" of proof, Art. 3.2 of the Code and Hamilton mandate that the anti-doping agency first establish what the lab's method was, and then prove that the lab's method was a "reliable" means. The agency does so by proving to the comfortable satisfaction of the Panel that a) the method conformed to the "scientific community's practices and procedures," and b) the lab "satisfied

itself as to the validity of the method before using it." *IAAF v. Boulami*, CAS/2003/A/452, Section 5.49, quoting *Muehlegg v. IOC*, CAS 2004/A/374 at Section 7.1.8; *Hamilton*, CAS 2005/A/884, Paragraphs 48, 52-53. In the absence of accreditation, then, USADA bears the burden of establishing to the comfortable satisfaction of the Panel what method LNDD used to perform the CIR analysis of Mr. Landis's Stage 17 sample, that the method used by LNDD "conformed to the "scientific community's practices and procedures" and that LNDD validated the method before using it. Failing that, USADA cannot prevail, and the Panel need not reach the other elements of the case.

6. The burden of proving reliability in the absence of accreditation is a heavy one. Nevertheless, the Tyler Hamilton case provides useful guidance about the types of proof that should be proffered if USADA is to prevail. In that case, USADA used an unaccredited HBT method, but carried its burden of establishing that the method was reliable by producing substantial persuasive evidence including proof that: (1) the positivity criteria it used were more conservative than would usually be required (Para. 61); (2) practitioners and researchers had concluded that the method used was valid (Para. 62); (3) a lab-specific validation study had been performed (Para. 62); (4) the scientific rigor of the test had been confirmed by outside experts (Para. 62); (5) the methodology used had been published in the peer-reviewed literature (Para. 64); (6) experts for both sides agreed that those peer-reviewed articles provided "proof of principle" (Para. 64); and (7) the actual method used had been previously validated in at least three WADA labs (Para. 64).

7. Compliance. If USADA establishes that the laboratory used a validated and reliable method--either through proof of accreditation or proof of reliability–USADA will benefit from Article 3.2.1's presumption that the method used by LNDD was indeed performed in conformance with the International Standard for Laboratories (ISL), ISO 17025 (ISO), and the relevant WADA Technical Documents at the time it was used to analyze Mr. Landis's sample, #995474. *Hamilton*, Para. 54; UCI Anti-Doping Rules, Art. 18; WADA Code, Art. 3.2.1, 3.2.2.

8. Mr. Landis may rebut the presumption of compliance with proof (that he establishes by a balance of the probabilities), that the laboratory did not in fact comply with the ISL or other relevant standards when it analyzed his sample. WADA Code, Art. 3.2.1, 3.2.2. If he does so, the burden shifts back to USADA to establish to the comfortable satisfaction of the Panel that the deviation from the standards did not cause the alleged AAF.

9. Absence of Causation: If the athlete rebuts the presumption of compliance, the burden shifts back to USADA to establish to the comfortable satisfaction of the Panel that the alleged AAF was not caused by the deviation from the ISL and other relevant standards. WADA Code, Art. 3.2.2; UCI Anti-Doping Rules, Art 18. Simply put, USADA must present sufficient evidence that had the deviation not occurred, the analytical testing method still would have resulted in the alleged AAF. As was noted in Landaluce case, this burden is significant because proving the negative is difficult.

B. Standard of Proof

1. USADA must carry the burdens described above to the comfortable satisfaction of the Panel. The amount of comfort required by the Panel is different in every case because the

standard is dependent on the "seriousness of the allegation which is made." WADA Code, Art. 3.1, 3.2.1, comment. The WADA Code states that the standard of comfortable satisfaction is more than a balance of the probabilities, but less than beyond a reasonable doubt. Therefore, the "more serious the allegation the higher the degree of probability, or 'comfort,' required." *USADA v. Montgomery*, Paragraph 36, GDC 00134-00160 at 00148-50. Or, put differently, the more serious the allegation, the closer the standard shifts to the "beyond a reasonable doubt" standard. *Montgomery*, Paragraph 36, GDC 00134-00160 at 00148-50.

2. The seriousness of the allegations in this case cannot be understated. For the first time in the history of the race, the winner of the Tour de France has been charged with a doping violation. USADA's burden should therefore be close to the "beyond a reasonable doubt" standard.

3. Mr. Landis's burden is lighter. If necessary, he satisfies his burden by producing evidence tipping the "mere balance of probabilities" in his favor. WADA Code, Art. 3.1, emphasis added; *Montgomery*, GDC 00149, Para. 36. To satisfy his burden, Mr. Landis must present evidence that establishes that it is "more likely than not" that the burden is satisfied. WADA Code, Comment, Art. 3.2.1 (using the term "preponderance of the evidence" in place of "balance of probabilities"); *Montgomery*, GDC 00149, Para. 36.

III.

LNDD DID NOT PERFORM THE CARBON ISOTOPE RATIO TEST IN ACCORDANCE WITH THE ISL, ISO, ITS OWN SOPS AND SCIENTIFIC PRINCIPLES AND METHODS

A. LNDD's Carbon Isotope Ratio Test Was Not Accredited

1. The accreditation must be of the *same CIR test method that was in fact used to test the samples at issue*. In other words, neither accreditation of the laboratory as whole, *nor accreditation of a different CIR test method* is sufficient. This is clearly conceded by USADA's counsel to the AAA Panel below:

> "I'm a laboratory and I want to use the IRMS method to detect testosterone...And so I have to – we know that the IRMS method works generally. But I have to demonstrate that I can make it work on my machine in my lab. And so I do validation studies on samples...The next thing that happens in this process is that the international standard says that for me to be using this method, I need to get it ISO certified. *And they don't just ISO certify the lab – I mean, they do ISO certify the lab – but they also ISO certify* particular methods *that are employed by the lab."*

USADA v. Floyd Landis, AAA No. 30 190 00847 06, Tr. of Proceedings, February 23, 2007, Vol. II at 100:6-7, 14-18; 101:4-9, emphasis added.

2. USADA has consistently and incorrectly maintained throughout this case that LNDD used an accredited method when it conducted the GC/C/IRMS testing of Mr. Landis's

sample. This is false. According to the accreditation documents themselves, Exhibit 26, at LNDD 0086, the method used by LNDD was not an accredited method in July 2006:

a. The COFRAC accreditation document lists the CIR test assay as EC31 and notes that the components of the assay are EC31-VA1, I-CONF-31, M-Ex-24 and M-An-41. *See* Exhibit 26, LNDD 0086. However, M-An-52, which is the method LNDD used to perform the GC/MS portion of the CIR test, is not listed on the accreditation documents. *See* Exhibit 24, USADA 0124-26, Exhibit 25, USADA 0303-05; Goldberger Decl. at ¶ 81.

b. The COFRAC accreditation document lists the measurement of uncertainty for the EC31 method as 20%. Indeed, this 20% measurement of uncertainty is listed in no fewer than three documents by COFRAC. *See* Exhibit 26, LNDD 0086, LNDD 0414, LNDD 0429. This is contrary to LNDD's purported measurement of uncertainty for the CIR test used by LNDD in testing Appellant's sample, which was 0.8‰.[3]

c. In an attempt to overcome these direct contradictions, USADA has argued that the failure of the GC/MS portion of the CIR test to be listed in the component section of the May 2006 accreditation document is meaningless. The evidence presented to support this argument is not sufficient to give this Panel a comfortable satisfaction that the CIR test used to analyze Appellant's sample was accredited:

i. Dr. Ayotte asserts that the inclusion of a statement referring to the GC/MS portion of the CIR test method in quality document M-EX 24 on January 1, 2006, somehow establishes that COFRAC evaluated the SOP M-An-52 but failed to include it in the accreditation document. Ayotte Rebuttal Decl. at ¶ 45. This is simply nonsensical. Dr. Ayotte wants this Panel to assume that because the COFRAC auditor may have seen a document referring to GC/MS in relation to the CIR test, the auditor must have given careful consideration to the GC/MS portion of the test and simply failed to include M-An-52 in the component section of the May 2006 accreditation. Not a shred of evidence supports this assumption. Furthermore, Dr. Ayotte is not competent to tesify on this topic. She does not work for COFRAC, has never been regulated by COFRAC, and did not in any way participate in the particular COFRAC review of the LNDD's IRMS method. Her testimony is completely speculative.

ii. Mr. LeGuy testifies that the COFRAC auditor had all of the relevant SOPs and documents and would not have accredited the method without approving the M-An-52 SOP. This testimony presumes that the auditor in fact had and knew that the CIR test

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3 LNDD also failed to use an accredited method for the T/E ratio test performed on Appellant's sample. The assay method EC24D was the T/E test method used by LNDD to test Appellant's sample, but the only accredited method was EC24C. Additionally, despite LNDD in fact using an unaccredited testing method, USADA, and in particular Dr. Ayotte, as led in questioning by USADA's counsel, was willing to testify at the AAA hearing that LNDD used the accredited method, EC24C. *See* AAA Tr. at 831:12-23. Such statements are simply incorrect and were false statements made to the Panel.

method used by LNDD should include a GC/MS portion and also presumes that, if the auditor was aware of M-An-52, he would not have accredited it unless he approved of the SOP. *See* LeGuy Letter. However, Mr. LeGuy was not the COFRAC auditor and has provided no foundation for his statements. *See* Exhibit 26, LNDD0393 (listing Bruno le Bizec as the auditor present on February 10, 2006). It is telling that USADA made no attempt to provide the testimony of the actual auditor and subject that auditor to cross-examination.

d. USADA next argues that the December 2006 accreditation document was actually an erratum, which corrected an error in the May 2006 document. But the evidence proffered in support of this assertion is equally unpersuasive and does not satisfy its burden:

i. While it is undisputed that the December 2006 accreditation document lists for the first time a measurement of uncertainty level of 0.8‰ for LNDD's CIR method, the cover letter of this new accreditation document – drafted by Mr. Robin LeGuy of COFRAC – does not state that the accreditation document should be back-dated to the May 2006 accreditation document. Exhibit 26, LNDD0447.

ii. Dr. Ayotte also purports to testify that the 20% uncertainty figure was a "mistake." But this testimony should not cause this Panel any concern and must be disregarded because taken at face value, the testimony does not establish that the December 2006 document should be back-dated to the May 2006 accreditation document. Rebuttal Declaration of Dr. Ayotte at ¶ 44. Further, there is no support for the proposition that the laboratory has *always* had a measurement of uncertainty of 0.8‰ or that the purported undated validation study provided during discovery was in fact completed or submitted to COFRAC before the May 2006 accreditation was issued at any time prior to December 14, 2006. Rebuttal Declaration of Dr. Ayotte at ¶ 44, Exhibit 26, LNDD0477. Finally, as stated above, Dr. Ayotte does not work for COFRAC and is in no position to interpret its documents. In sum, Dr. Ayotte's testimony on this issue is mere speculation.

iii. This purported correction of COFRAC's mistake came only after Mr. Landis pointed out this deficiency in an early pleading. The alleged correction came at the request of an LNDD staff member who sent an email to COFRAC asking it to correct this "mistake." *See* Exhibit 26, LNDD0477. Neither the actual email was produced to Appellant, nor was any supporting documentation that may have been sent to COFRAC, was provided in this litigation. All that has been provided by LNDD is an unsigned and undated study asserted to establish that LNDD's CIR test measurement of uncertainty was 0.8‰. Exhibit 26, LNDD 0451-0457. This should be contrasted with the documentation provided to support the T/E measurement of uncertainty for method EC24C (Exhibit 26, LNDD 0461-0471). Note that LNDD 0462 provides dates for each step of the validation of the measurement of uncertainty for T/E, signed and dated contemporaneously with the completion of each such step. No such similar form exists for the purported validation of the measure of uncertainty for EC31 (the CIR test). Exhibit 26, LNDD0451-0457.

e. The March 2008 letter provided by Mr. LeGuy should be given no evidentiary weight as it was written almost one and one-half years after the December 2006 accreditation document and provides no details for why the December 2006 accreditation document was in fact an erratum. *See* LeGuy Letter.

f. A further deficiency in USADA's accreditation argument is that USADA did not and can not even identify the method used by LNDD to identify testosterone metabolites as part of the CIR test. *See* III.B., infra. USADA cannot prevail on the argument that its CIR test method was accredited because it cannot establish *what* method was used to analyze sample 995474.

g. In addition to the above arguments, USADA made a wholesale argument that the CIR testing method used by LNDD must have been the CIR test method accredited because the COFRAC auditor observed the LNDD technicians performing the same CIR test method used on Appellant's sample during the COFRAC audit. This argument has no evidentiary support:

i. USADA presented no evidence from the COFRAC auditor, Bruno LeBizec, who observed the CIR test method during the audit. *See, e.g.*, Exhibit 26, LNDD0400.

ii. Mongongu indicated that Mr. Le Bizec was not informed that LNDD manually processed quality control samples and does not recall whether Mr. Le Bizec observed the manual processing of quality controls. CAS Tr 693:11-24.

iii. No information or documentation (if any such documentation exists) about the identification of peaks in the blank urine pool 4 was provided to the COFRAC auditor. CAS Tr. 699:16-19.

h. Lastly, USADA's accreditation argument should be rejected because:

i. At the time Ms. Frelat supposedly performed the CIR test method during the COFRAC audit, she was not validated by LNDD and was not permitted to work on actual samples. CAS Tr. at 870:14-19.

ii. Ms. Frelat admitted that she was not fully trained on the CIR test method at the time she performed the CIR for purposes of the COFRAC accreditation. *See* CAS Tr. at 870:14-19. Frelat Decl. at pp. 1, 2.

iii. The manual processing SOP is not listed in the component section and there is no credible evidence that the auditor actually observed manual processing being performed during the audit. Ms. Mongongu suggests that the auditor "did indeed" witness manual processing, but when asked, she "[does not] know" details. CAS. Tr. at 693:11-24. Also, while Ms. Mongongu was present at the accreditation, she was not the operator witnessed by the auditor. CAS Tr. 679:13-20. Frelat, whom the auditor did witness, speculated that the auditor would have seen her manually integrate "when necessary," but gave no testimony about what the auditor did or did not actually witness. Frelat Decl. at pp. 2, 3.

3. While LNDD was accredited to conduct *some CIR test method* in July 2006, USADA should not be given the benefit of the Code's presumptions because it cannot establish *that the method LNDD actually used* was the method allegedly accredited by COFRAC. Accordingly, LNDD was not properly accredited to conduct CIR test method and is not entitled to a presumption.

B. USADA Did Not, and Cannot, Prove That LNDD Had a Documented and Validated Method for Identification of Testosterone's Target Compounds, All in Violation of the ISL and TD2003IDCR

1. A critical component of the CIR test in testing for testosterone is the proper identification of the testosterone metabolites.[4] This requirement is embodied in the ISL 5.4.4.3.1, which requires that LNDD "establish criteria for identification of a compound at least as strict as those stated in any relevant Technical Document." WADA TD2003IDCR requires that "*the appropriate analytical characteristics must be documented for a particular assay. The Laboratory must establish criteria for identification of a compound.*" WADA TD2003IDCR continues that an example of a proper identification criteria is for the retention time of an analyte to match by (1) percent or ± 0.2 minutes (whichever is smaller) from that of the same substance in a spiked urine sample, reference collection, or reference material. LNDD is in violation of both the ISL and TD2003IDCR because USADA has failed to set forth any documented method for identification of target analytes, and, even worse, did not and cannot identify what method LNDD actually used to identify the target analytes in Sample 995474.

2. LNDD's technicians admitted that there is no SOP or documented validation study that describes LNDD's method for identifying compounds in the CIR test. CAS Tr. at 660:5-661:20, 838:15-22. This demonstrates the falsity of USADA's repeated statement that the COFRAC auditor examined all relevant documents for compliance with the ISL and related technical documents, and if those documents were missing, would have created a "deficiency report." *See e.g.* Tr. 193:3–194:15. COFRAC did not create any deficiency report, and no COFRAC documents exist for the absence of any documentation for the critical and required (by the ISL 5.4.4.3.1 and TD2003IDCR) step of compound identification.

3. USADA and LNDD have presented multiple and different stories describing the method used to identify the testosterone metabolites in this case. The sheer number of stories, the "development" of these stories over time, the lack of documentation of any of these stories and the after the fact nature of these stories all strongly demonstrate that LNDD cannot prove what method was used on the day that Sample A and Sample B of Sample 99547 were analyzed.

a. <u>The Discovery Response</u>

i. On January 22, 2007, Mr. Landis served his request for production of documents on USADA requesting: "All DOCUMENTS that relate to the identification of each of the peaks in the IRMS analysis for any sample tested by LNDD from Floyd Landis during the 2006 Tour de France." *See* Jan. 22, 2007 Discovery Served on USADA, at 7. On February 7, USADA and LNDD replied with the following response: "LNDD is providing full GC-MS scans for each of the six peaks used in the IRMS analysis of the A and B sample, as well as for the standards." *See* Feb. 7, 2007, USADA Discovery Response, at Exhibit B (LNDD

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[4] The absence of any documented or validated method stands in stark contrast to the fact that documentation exists for such things as the IRMS parameters and an extraction method.

Response to Second Request for Documents) at 10. *Nowhere in this discovery response did USADA and LNDD state that LNDD identified testosterone metabolites using (1) peak matching or peak pattern matching, (2) Mix Cal Acetate or (3) Blank Urine, as later testified to by USADA's experts at the CAS hearing.* In the discovery responses, USADA and LNDD solely referenced Mix Cal Acetate and Blank Urine as quality control measures. *See id.* at 7-9.

ii. The discovery responses were consistent with statements by Mr. Young to the AAA panel, when he explained how testosterone metabolites are identified in the CIR test. *See* Transcript of Proceedings, February 2007, 101:21-22 ("The way you identify the substance is using GC/MS link to the IRMA (sic)."

b. USADA's AAA Briefs

USADA's Pre-Hearing Brief states that compound identification is "achieved by matching GC retention times and MS ion patterns (ion ratios) between the compound in the sample and a reference standard." *See* USADA Pre-Hearing Brief, at 41. Nowhere does USADA's Pretrial Hearing Brief refer to Mix Cal Acetate or Blank Urine as part of the identification method. Nowhere does USADA refer to any peak matching or peak pattern matching of any kind.

c. AAA Hearing: Testimony of Dr. Brenna

At the AAA Hearing, Dr. Brenna was the second witness to testify, and in response to the question of how peak identification was conducted, he stated: "Well, they have retention times that match on the previous, with the previous GC/MS, and the GC/MS delivers structural information, like aliquots and so forth, that tell us which is which. *See* AAA Tr. 255:16-22. When Dr. Brenna was cross-examined and learned that GC/MS retention times do not match, the story changed.

d. USADA's CAS Brief

i. In its CAS Brief, USADA asserts that the AAA Panel correctly identified LNDD's method for identifying the testosterone metabolites: "Specifically to identify the substances in question, one would compare the pattern of peak heights and retention times in the GC/C/IRMS chromatograms, anchored by the internal standard with a known RT, with the pattern of peak heights and RTs in the GC/MS chromatograms . . . ." USADA CAS Brief, at 50. USADA goes on to say that the 5 beta from the Mix Cal Acetate also acts as a retention time marker. *Id.*

ii. Again, this description is contained nowhere in USADA's discovery responses and the testimony of Dr. Brenna before cross-examination. Moreover, this description of method is different than the method described by the LNDD technicians at the CAS hearing.

e. USADA's Expert Testimony at CAS

i. First and foremost, the testimony of USADA's expert witnesses should be given no weight when it comes to establishing *what* LNDD actually did. While

experts may be competent to testify about the scientific reliability of LNDD's method, they are *not* competent to testify about what LNDD *actually used for a method*, because they were not present. What happened is a matter for fact witnesses, not expert witnesses, so the testimony of experts purporting to testify about facts should be disregarded. Moreover, in at least one instance, USADA simply told one of its experts, Dr. Matthews, what LNDD's laboratory practices were – in contradiction to USADA's own discovery response. *See* CAS Tr. 1102:11-24. Lastly, and most importantly, even these experts cannot agree upon LNDD's precise method.

ii. Dr. Brenna testified (in his current version of testimony on this subject) that "[LNDD] acquires GC/MS data for their test steroids in the samples and in their urine pools that are comparable to standard GC/MS data, thereby establishing the major peaks and their order of elution . . . [i]njection of a steroid mixture on the GC-C-IRMS therefore produces a pattern that reveals the identity of the peaks. *See* Decl of Dr. Brenna, at 13.

iii. Dr. Matthews testified that LNDD used retention time of the 5 Beta P-Diol to "find the 5a-Adiol, and Pdiol from the peak elution patterns." *See* Decl. of Dr. Matthews, at 8.

iv. Dr. Jumeau testified that LNDD used a two step method. First, LNDD used a peak pattern matching analysis, followed by the use of Mix Cal Acetate to apply a retention time analysis between the internal standard and the etio, 5 beta diol and 11-keto-etio. *See* Decl. of Dr. Jumeau, at 8-11.

f. When the LNDD technicians testified at the CAS Hearing on cross-examination, they described different methods for identifying the testosterone metabolites:

i. Ms. Frelat testified on cross-examination that the method for identification of testosterone metabolites was as follows. The first step was peak matching between the GC/MS chromatogram and the GC/C/IRMS chromatogram for the sample. CAS Tr. 832:5-838:3. Step two involved matching relative retention times between blank urine in the GC/C/IRMS with studied blank urine values. CAS Tr. 838:15-842:17. Nowhere in the discovery responses or USADA's AAA brief or USADA's CAS brief is Blank Urine or peak pattern matching described as a method of identification.

ii. Cynthia Mongongu testified on cross-examination that the method for identification of testosterone metabolites was as follows. The first step was a pattern matching step between the GC/MS Blank Urine and the GC/C/IRMS. The second step was a retention time/relative retention time analysis between the GC/C/IRMS Blank Urine and the GC/C/IRMS sample fraction. *See* CAS Tr. 669:20-683:11; 734:21-748:19. Nowhere in the discovery responses or USADA's AAA brief or USADA's CAS brief is Blank Urine or peak pattern matching described as a method of identification.

iii. Dr. Buisson did not testify on cross-examination, but in her declaration, she states that the method involves a two step method of pattern peak matching and comparison of relative retention times to the blank urine. *See* Decl. of Buisson, at 8-9. Nowhere

in the discovery responses or USADA's AAA brief or USADA's CAS brief is Blank Urine or peak pattern matching described as a method of identification.

g. Additionally, in neither their declarations nor on cross-examination do the LNDD technicians suggest that they use retention times or relative retention times in GC/C/IRMS of substances in the Mix Cal Acetate to assist them to identify peaks in the sample. Only after being prompted by leading questions from Mr. Young on re-examination do the technicians discuss it and even then they do not say that they in fact do use Mix Cal Acetate for their identification method, but instead only indicated that the peaks in the Mix Cal Acetate also match. *See* CAS Tr. 770: 7-17. Finally, there is no document that compares retention time or relative retention times of the GC/C/IRMS peaks in the Cal Mix Acetate to retention time or relative retention times of GC/C/IRMS peaks in the samples. In short, contrary to the suggestion of some of USADA's IRMS experts, this is simply not a procedure used at LNDD.

h. Moreover, the use of the Blank Urine values at LNDD 309 and LNDD 310 is irrelevant in the relative retention analysis because those documents contain no information related to how those peaks *were initially* identified; these documents simply provide the isotopic value of the peaks in the blank urine. *See* Exhibit 26, LNDD 309, 310; CAS Tr. 698:6-699:24, 1083:6-1084:8.

i. To the extent that USADA now hopes to comply with the requirements of TD2003IDCR by contending that LNDD 309 and 310 constitutes a reference collection pursuant to ISL 5.4.6.2, USADA is in error.

i. ISL 5.4.4.2.1 states that "Reference standards should be used for identification, if available." In the discovery, it is clear that LNDD possessed reference standards for the metabolites 5 alpha androstandiol (Exhibit 26, LNDD 287), 5 beta pregnandiol (Exhibit 26, LNDD 278) and Androsterone (Exhibit 26, LNDD 284). First of all, because a reference standard is available, LNDD should have used reference standards for identification pursuant to the ISL.

ii. Second, WADA TD2003IDCR requires that "the Laboratory must establish criteria for identification of a compound," an example of proper criteria for capillary gas chromatography is that "the retention time (RT) of the analyte shall not differ by more than one (1) percent or ±0.2 minutes (whichever is smaller) from that of the same substance in a **spiked urine sample, Reference Collection sample, or Reference Material analyzed contemporaneously.**" (emphasis added). The Blank Urine Pool 4 does not qualify as any one of these.

iii. Blank urine is obviously not a "spiked sample."

iv. Blank urine is not a Reference Collection under the ISL:

> *5.4.6.2 Reference Collections*
> A collection of samples or isolates may be obtained from a biological matrix *following an authentic and verifiable administration of a Prohibited Substance or Method, providing that the analytical data are sufficient to justify the identity of the relevant chromatographic peak* or

isolate as a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Method.

v. These criteria are not met. Firstly, the sample must come from an "authentic and verifiable administration." That has not been established here: (1) no evidence was provided as to the origin of the sample Blank Urine 4, (2) no administration of the substances of interest was conducted, and (3) no evidence exists that the sample is from a pooled urine of several LNDD technicians and specifically not that of a single individual made the subject of an administration study.

vi. Secondly, the "analytical data [must be] sufficient to justify the identity of the relevant chromatographic peak." In this case, no evidence has been provided that the metabolites/substances in Blanc Urine pool 4 are the substances LNDD claim them to be. We have only LNDD's unsupported assertion that 5 Alph-Diol IRMS peak in the Blanc Urine is in fact 5 Alpha-Diol. The studies Ms. Mongongu claims to have performed on the Blu Pool 4 were not provided. Ms. Mongongu asserted, when asked if peak patterning matching absent a comparison to blank urine is sufficient to identify IRMS peaks, she replied "No. Not peak matching alone." See CAS Tr. 669:23-670:2. She also unequivocally states that it is impossible to use retention time and relative retention time comparison between GC/MS and GC/C/IRMS to identify peaks in GC/C/IRMS. CAS Tr. 680:17-20. Thus, there is no method identified by the LNDD technicians – including Ms. Mongongu (the technician who claimed to have done the validation on Blu Pool 4) to identify the peaks in the initial GC/C/IRMS run of Blu Pool 4. Finally, the only documents provided regarding Blu Pool 4 are LNDD0309 and LNDD0310 (SOP E-P-32) and there is no information on these pages that could provide identification of the peaks in Blu Pool 4. *See* CAS Tr. 698:6-699:24, 1083:6-1084:8.

vii. Lastly, Blank Urine is not a Reference Material, pursuant to the ISL 3.2, which defines it as a "material or substance one or more of whose properties are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method or for assigning values to materials."

j. Also, peak pattern matching is not a consistent scientific method. Dr. Goodman and Dr. Simon Davis testified that peak pattern matching is not appropriate and USADA never challenged them on this topic in cross-examination. *See* Declaration of Dr. Goodman ¶¶ 84-87, Declaration of Dr. Davis at ¶ 48. Ms. Mongongu testified that it would be "difficult" for her to identify the peaks in GC/C/IRMS chromatogram at Exhibit 91, LNDD 1362, with the GC/MS chromatogram at Exhibit 91, LNDD 1339. *See* CAS Tr. 752:18–753:3. Ms. Frelat had difficulty in matching the peaks during her cross-examination. *See* CAS Tr. at 831:4-834:12.

k. This history, which describes USADA's and LNDD's attempts to explain and prove just what method the LNDD staff used for testosterone identification, illustrates that the effort should not have been what it clearly was: a shifting, *post hoc* attempt to justify a result. A scientific method should not require repeated and conflicting attempts at explanation. The lack of clarity alone, and the struggle that USADA has undergone to prove the method that LNDD used to perform the CIR analysis on Mr. Landis' sample, is evidence itself that no documented, accredited and validated method existed.