BEFORE THE AMERICAN ARBITRATION ASSOCIATION

North American Court of Arbitration for Sport Panel

United States Anti-Doping Agency,

Claimant,

AAA No. 30 190 01107 03

John McEwen

v.

Respondent,

OPINION

WE, THE UNDERSIGNED ARBITRATIORS, having been designated by the above named parties, and having been duly sworn and having duly heard the proofs and allegations of the parties, FIND AND AWARD as follows:

ľ. HISTORY

On April 19 & 20, 2004 the above matter was heard before a panel of three -Arbitrators selected pursuant to the American Arbitration Association Procedures for Arbitration initiated by the United States Anti-Doping Agency (USADA) at the request of John McEwen (Respondent).

The Claimant, USADA, was represented by Richard Young, attorney and Travis T. Tygart, attorney. The Claimant represented the interest of USA Track and Field (USATF), and the International Association of Athletics Federation (IAAF), the International Federation responsible for upholding the Anti-Doping Rules of the IAAF.

Respondent, John McEwen, appeared and was represented by Howard L. Jacobs, attorney.

II BACKGROUND

This case, along with the matter of <u>USADA v Mellisa Price</u>, AAA No. 30 190 01126 03, present as cases of first impression in some respects. Both cases were presented individually to the parties chosen arbitration panels, which happened to have the same three members. Both cases involved track and field athletes, who are subject to the identical IAAF doping rules. The attorneys for both parties in each case were the same. Both cases rely upon the same background and testing issues, and evidentiary stipulations, in addition the parties to this matter have stipulated that all evidence submitted in <u>USADA v Price</u> are part of this record. The cases will differ in respect to their determinations of the athletes eligibility for continued competition in IAAF sanctioned events, and each will be judged on the individual facts unique to each athlete presented in each case.

Both arose out of a series of events which led to the discovery of a new anabolic steroid designed to be undetectable with the then state of testing. It was argued and alleged the newly designed anabolic steroid was intended to be used by athletes in a variety of sports to enhance performance. While there was no evidence submitted on that point, beyond= argument, it did alarm USADA and IAAF and caused follow-up investigation. Hence, the same background information as set out in the <u>USADA v. Price</u>, and the same legal discussion will also be repeated here as appropriate.

In very early June 2003, an employee of the United States Anti-Doping Agency (USADA) received a telephone call from a newspaper reporter well known to him. That reporter indicated that one of his sources had information about the production and distribution of an undetectable steroid within some persons involved in the sport of track and field. The reporter further advised that USADA would hear directly from this source.

On June 5, 2003, that same employee of USADA was contacted by telephone by an anonymous caller identifying himself as the source about which USADA had been told. The source stated that some athletes were then taking a new and undetectable steroid similar to genabol. In a second call that same day, the source indicated that he had in his possession a syringe containing this alleged steroid compound, and that he would send it to USADA.

On June 6, through the same employee, USADA received an overnight delivery package within which was a syringe containing an unknown clear liquid substance. The syringe was sent by overnight delivery to Richard L. Hilderbrand, Ph.D., the Director of Scientific Programs at USADA, and received by him on June 12, 2003

The Director of Scientific Programs transferred the unknown liquid substance into two clean test tubes. One of those tubes was then sent by overnight delivery to the IOC Certified Testing Laboratory at UCLA (the "Laboratory.")

During the ensuing week of June 16, 2003, the Laboratory prepared the unknown liquid substance for screening by the standard methodology used to test for the general presence of anabolic steroids. By the middle of that week, the Laboratory had confirmed

the presence of some form of compound which appeared to have some relation to known anabolic steroids, and reported this fact to USADA. This unknown substance was dubbed "Compound X."

Also reported by the Laboratory, was the difficulty experienced in attempting to identify the compound using the standardized screening methodology. It appeared that the compound broke down during the test and lost any coherent "signature," although the results of the test indicated that there was some complex compound present. Consequently, more research would have to be conducted to learn how to test the substance in a valid, repeatable fashion.

USADA then instructed the Laboratory to continue its efforts to identify this substance, as well as to develop scientifically valid tests both to screen for and to confirm its presence in urine samples ("specimens"). Specifically, USADA instructed the Laboratory to test all specimens received from the upcoming National Championships in Track and Field, to be held on June 19-21, 2003, (the "Nationals") for the presence of Compound X, and not to report any samples as free of prohibited substances (a "negative"), until those tests could be conducted. USADA did not apparently place any time limit on its instructions to the Laboratory in this respect, other than to urge that it be done as soon as possible.

On June 20, 2003, after being the runner-up at the USA Outdoor National Championship in the hammer throw event, John McEwen provided an in-competition urine sample at the request of USADA. His sample was received by the Laboratory on

-4

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Friday, June 20, 2003. On June 21, 2003 it was screened for all the then known prohibited substances, but not for the unknown Compound X. His specimen was negative on those screening tests. The sample was then held by the Laboratory, along with all other specimens received from athletes competing in the Nationals, pending development of information as to the nature of Compound X and scientifically valid tests to determine its presence, or its metabolites, in urine. No specimen of any athlete was reported as negative at that time.

Shortly after the Nationals were completed, the anonymous source again contacted USADA through the same employee with whom he had held his previous communications. In that communication, the source stated that a specific individual he claimed was distributing Compound X, had attended the Nationals, that he had the unknown compound in his possession, and that athletes were taking it at the Nationals.

In July of 2003, concerned over the possible introduction of a new and potentially dangerous doping compound, USADA decided to obtain urine samples from all top Track and Field athletes, as well as athletes in other some other sports, specifically for the purpose of determining the prevalence of this unknown compound.

During the remainder of June and through July and into August, the Laboratory carried out its instructions from USADA to identify the compound and its nature, and to develop reliable tests. By early July 2003, the Laboratory first identified what it believed the compound to be, including its molecular structure. It then synthesized the compound at another facility at UCLA. This supply of the compound was necessary both for testing and as a reference standard against which specimens could be tested.¹

¹ The nature of the tests conducted to determine the presence of a prohibited substance required a known sample of the product to be tested against a specimen, sometimes called a "calibrator."

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The Laboratory also requested that the Australian National Analytical Reference Laboratory ("NARL") synthesize the compound so as to have an independent reference to compare to that synthesized by the Laboratory. The UCLA synthesized compound was subjected to Nuclear Magnetic Resonance Imaging ("NMR") at a facility at UCLA, and the resulting data was also sent for independent analysis at the University of Minnesota. The NARL reference compound was subjected to NMR in Australia. All three organizations confirmed the structure of Compound X, which was discovered to be TetraHydroGestrinone ("THG"), shown below.,



Tetrahydrogestrinone

The compound has a molecular structure similar to gestrinone and trenbolone and other known, prohibited anabolic steroids, which was a good predictor that it would also have similar properties.

Also during this time, the synthesized product was subjected to testing in tissue cultures to confirm the predicted anabolic actions. The results indicated a powerful anabolic substance. Indeed, there was no question raised on this subject, and the athlete stipulated that THG was pharmacologically similar to gestrinone and trenbolone, known, prohibited substances.²

6

² See Stipulation 8, USADA Exhibit 1,

-2-

A reliable screening method was developed by the Laboratory using liquid chromatography with a series of mass spectrometers ("LC/MS/MS"). This differed from the original screening method in that it used liquid chromatography, rather than a gas chromatogram. This apparently avoided the breakdown of the THG which occurred in conjunction with the preparation used to make the sample sufficiently volatile to go into a gas ("derivatization"), and being subjected to the heat which render it into a gaseous state. While this screen was not as sensitive as a gas chromatogram linked to a mass spectrometer ("GC/MS"), it was a well known and scientifically acceptable technique which was sufficiently reliable so as to cause a more definitive confirmation test to be conducted.³

The NARL THG compound, which was used as the independent reference for purposes of screening and confirmation testing, arrived at the Laboratory in mid-August.

Meanwhile, the Laboratory was conducting extensive validation tests on the newly developed confirmation test for THG, which involved using different compounds to derivatize the specimen, methyl-oxime (MOX) and trimethylsilyl (TMS). The MOX-TMS combination is a well known and scientifically acceptable method used frequently by other laboratories to derivatize compounds for use in a GC/MS. Nevertheless, the Laboratory did extensive work to confirm its reliability, stability and repeatability in testing urine specimens for THG.

Finally, the confirmation test on the athlete's "A" sample, for THG, took place on September 16, 2003, and the positive THG results were reported to USADA pursuant to the Guidelines on September 23, 2003. The "A" sample additionally showed the

³ The confirmation test was also developed, but it was sufficiently complex that the Laboratory could only conduct about 5 tests per day, while it had a need to screen potentially hundreds of specimens.

presence of Modafinil on September 24^{th} and 25^{th} , 2003, as reported to USADA on September 26, 2003. (USADA Exhibits 3 & 4).

On September 29, 2003, the remaining specimens from the Nationals, which were negative on all tests including those for THG, were reported to USADA by the Laboratory.

On October 21, 2003, a confirmation test was done on the athlete's "B" specimen, in the presence of his appointed representative, Dr. David L. Black. That test confirmed the presence of Modafinil, and THG, using GC/MS, pursuant to the newly developed and validated procedure.

III STIPULATED FACTS

The parties have stipulated to a number of $facts^4$ and, in so far as those stipulations are relevant to the deliberations of the Panel, the parties specifically agreed that:

> The specimen collection and handling were appropriate and the urine samples which were reported as positive for the presence of THG were given by John McEwen;

> The laboratory handling of the bottles and aliquots was appropriate and the UCLA laboratory maintained the integrity of the samples; THG is pharmacologically related to the specifically listed substances gestrinone and trenbolone on the IAAF prohibited substances list, therefore there is no question but that THG is a prohibited substance;

The laboratory conducted of the test developed to detect the substance in question, THG, properly in accordance with the procedures developed by the UCLA laboratory for THG;

John McEwen had been tested ten times prior to June 2003, all of which were reported as negative for prohibited substances.

IV CONTESTED FACTUAL ISSUES

Therefore, the only factual issues presented to the Panel for decision were:

Whether the test itself is sufficiently reliable in the detection of THG so that it may be relied upon as a basis for concluding that THG is present in the athlete tested⁵; and

Whether USADA had presented sufficient evidence to support the level of penalty is seeks to have this Panel impose on the athlete, should it ultimately determine that the evidence supports a finding that doping had occurred.

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CONTESTED LEGAL ISSUES v

The athlete, through his counsel, argued that:

See, USADA Exhibits 1 and 2, herein and exhibits 13 and 47 in Price.

⁵ A related issue was whether USADA's burden included a requirement to determine if THG or its metabolites were an endogenous compounds such that there might be the necessity to conduct a

USADA acted improperly in instructing the Laboratory to hold the specimens until they could be tested for THG, and not to report any as negative until such time;

The Laboratory violated its own rules, as well as the rules of the Olympic Movement Anti-Doping Code by failing to report the specimens as negative immediately upon completion of all tests available at the time of the initial screen.

VI DECISION

While counsel for John McEwen argued ably, as in <u>USADA v Price</u>, that it is not and should not be permissible to hold specimens for testing at a later time, on direct interrogation, he conceded that in this case his argument did not rely on the length of time taken to conduct the screening tests. Moreover, the IAAF Rules are not rigid as to time, and only provide that the tests should be carried out "as soon as *reasonably practicable*" after arrival at the laboratory. (Rule 2.43, *emphasis added*). In addition, that Rule goes on to state that a fixed time limit "may be imposed on any analysis at the request of the IAAF." (Id.) Therefore, the IAAF Rules permit individual circumstances to govern the requirements for timely testing, within the boundary of reason. There is no hard cut off, absent a specific instruction from the IAAF.⁶

Rather, the crux of the athlete's case, here as in <u>Price</u>, was that all available, accurate screens were completed with negative results and, therefore, were required by

quantitative analysis to determine if the THG detected exceeded some, unknown, threshold level, such as is presently required for substances such as testosterone and nandrolone;

the applicable rules to be reported as "negative." Thereafter, it was argued, testing for any substance was a "retest" which, it was argued, is not permitted by the Rules, nor would it be equitable to do so.

This argument is based on three prongs:

- The OMADC, Appendix D, Rule 1.2, requires that "sensitive and comprehensive screening methods to eliminate "true negative" specimens from further consideration must be used;"
- The USADA Protocol limits "retesting" to anonymous testing⁷; and
- It would be inequitable to do so, since athletes "have a right to know what" the rules are."

For the reasons that follow, we believe that these arguments are misplaced.

The Laboratory Had the Authority to Conduct the Tests

The IAAF Rules are not silent on the question of the when tests can be conducted, and the language cited from the OMADC would not compel the result sought here by Mr. McEwen. The IAAF specifically recognizes that either a retest, or a different test may be conducted on a specimen as to which there may be a "question." (IAAF Rule 2.46)

Counsel for Mr. McEwen argued that there was no "question or issue" as to the specimens arising from the initial screens, and Dr. Catlin, the director of the Laboratory confirmed that during his testimony. However, the argument is misplaced. The Rule does not specify that the issue or question must arise from and be related to the results of

⁶ Indeed, even had the IAAF requested a strict time limit, it has not been demonstrated how the athlete would be prejudiced, or have any standing to rely on a laboratory failure to meet such a demand, as that would appear to be a contractual matter between the laboratory and its customer.

⁷ USADA Protocol, Rule 10.

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the screening test. Rather the IAAF Rule provides that if "any question or issue" arises "at any stage," then the laboratory "may conduct any further or other tests necessary"

There is no question that USADA raised a question about the possible presence of what was then call simply Compound X at the time that the initial screening tests were conducted, or that USADA gave strict instructions to conduct such test as might be "necessary to clarify the question or issue so raised" The athlete's specimen was not reported to anyone as "negative" for prohibited substances, as it had not as yet been tested for THG.[§]

The Panel also rejects the attempt by counsel to argue that the general proposition that an athlete has a right to certainty as to the rules under which he/she must compete, compels a rejection of the use of a newly developed test. While it is true as a general proposition that the rules or competition should be known, there is no lack of certainty in this case. At all relevant times, the class of anabolic steroids, of which the athlete concedes THG is a member, has been prohibited. The IAAF Rules are not limited to named compounds, but specifically include any other substance of similar efficacy. Rather, the argument here presented is that the athlete has right to know the nature of the screening tests being conducted for what the athlete is thoroughly on notice are prohibited substances. This is akin to saying that the athlete has a right to know when he or she will be tested, so that a positive result can be avoided.

Finally, the requirement that "sensitive and comprehensive screening methods" be used by the IOC laboratories to "eliminate 'true negatives," does not support, but cuts against the arguments of counsel for Mr. McEwen. It is clear to the Panel that the

Laboratory, and USADA, became aware of the existence of a new and previously unknown anabolic steroid compound prior to the testing of the specimens from the Nationals. Consequently, they would be under an affirmative obligation to develop whatever tests would be required to determine whether it might be present in the specimens received. The Laboratory, at the direction of USADA did just that and fulfilled their obligations under this Rule.

The Evidence Established That the Tests were Valid

Under IAAF Rule 59.3 and IAAF Guideline 2.60, the Hearing Protocols of USADA apply. Under that protocol, it must be presumed that the Laboratory conducted a valid test. (USADA Protocols for Olympic Testing, Annex D., Rule -33). However, that presumption may be challenged by a responding athlete, in which case the burden will shift to USADA to establish the validity of the test. Under IAAF Rules, which apply in this instance, that burden is the high standard that it must be proved "beyond a reasonable doubt." (IAAF Rule 59.6)

The shifting of the burden of proof to USADA to establish the validity of the test, is not done merely by an allegation of error. The USADA Rules of Evidence clearly state:

"This presumption can be rebutted by evidence to the contrary, but the accredited laboratory shall have no onus in the first instance to show that it conducted the procedures other than in accordance with its standard practices conforming to any applicable IOC requirements...."

^a Since that is the case, then we conclude that we need not reach the issue as to whether a specimen tested and actually reported as negative could have been retested at a later date, and any action taken against an In the present case, the athlete presented no evidence in support of his challenge to the validity of the test for THG, merely argument of counsel⁹. Hence, USADA argued, it had no obligation to present affirmative evidence.

However, given the circumstances of these companion cases, in which a new substance, THG, was the basis of the eligibility hearing, USADA did submit substantial evidence, including extensive blind testing with different substances and imposition of environmental stresses on the equipment, to assure that under all conditions the test results remained valid. This Panel finds that the evidence was uncontradicted that both the screening test using LC/MS/MS and the confirmation test using GC/MS, derivatized with MOX-TMS, were valid, scientifically acceptable, and correctly identified the presence of THG.

While counsel for the athlete conducted extensive cross-examination of the scientific witnesses presented by USADA and dissected the documentation packages while doing so, in the end the athlete did not present evidence that could overcome either the presumption, or the independent proofs made by USADA as to validity of the results. The mere raising of a question by counsel, unaccompanied by evidence, was insufficient to do either.

Counsel for the athlete also asserted that the Laboratory testing procedures were not followed in some instances. Those arguments related to certain ranges of variation which are permitted between result of *quantification* tests used to establish absolute levels of a substance in the athlete, such as would be conducted following a positive testosterone test. However, there is no *quantification* test required for THG in order for

athlete testing positive for a substance at a future date.

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a positive result to be reported, in the IAAF or OMADC Rules. A finding of any quantity of THG in the specimen is adequate to sustain the alleged violation of IAAF Doping Rules.

Nevertheless, USADA once again presented uncontradicted evidence, both (1) that THG is not and could not be an endogenous substance; and (2) that the kinds of test done merely to detect the presence of a substance, like THG, are sufficiently different from those which would be used to measure quantities, that no quantitative conclusions can, or should be reached from data resulting from a *qualitative* analysis.

VII AWARD

The Panel finds that USADA has met its burden to establish the presence of THG and Modafinil in the sample provided by John McEwen, and that he has committed a doping violation.

As noted THG is not endogenous to the human body. The use of THG by the athlete can be for no other purpose than to enhance his performance in violation of the spirit and absolute proscriptions of the IAAF doping rules. This is not a supplement contamination issue, nor a case of negligence, it is a willful act by the athlete. Therefore, pursuant to IAAF Rule 60.2(a)(i), John McEwen shall be ineligible to compete for a period of two (2) years from the date of the commencement of the hearing, to and including April 19, 2006.

⁹ The Panel notes that, while Dr. Black attended the "B" specimen testing on behalf of Mr. McEwen, no expert testimony was tendered at the hearing.

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In addition, pursuant to IAAF Rule 60.5, John McEwen shall also be ineligible and shall not be entitled to any award or addition to his trust fund for which he qualified as a result of his performance at the Nationals, or thereafter.

The parties shall bear their own costs and Attorneys fees.

The administrative fees and expenses of the American Arbitration Association and the compensation and expenses of the arbitrators shall be borne entirely by Claimant United States Anti-Doping Agency.

This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. All claims not expressly granted herein are hereby, denied.

THE COURT OF ARBITRATION FOR SPORT

Chairman of the Panel Peter Lindberg H

April 29, 2004

Arbitrator

April 29, 2004

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Christopher L., Campbell

Edward T. Colbert, Esq.

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Arbitrator Chis Colum April 29, 2004

Christopher L. Campbell

Arbitrator

April 29, 2004

Edward T. Colbert, Esq.

APPLICABLE RULES

USADA Protocol for Olympic Testing (October 7, 2002)

Notification

USADA will provide the following notification with respect to each specimen

......

Upon receipt of a negative laboratory report, USADA will promptly forward that result to the athlete, the USOC and the applicable NGB.

<u>Annex D</u>

R-33 Evidence

In all hearings conducted pursuant to these rules, the applicable International Federation's categories of prohibited substances, definition of doping and sanctions shall be applied. In the event that an IF's rules are silent on an issue, the rules set forth in the Olympic Movement Anti-Doping Code shall apply. IF and Code rules may be mitigated, as appropriate, by the principles set forth in the decisions of CAS. Notwithstanding the foregoing, (a) The IOC laboratories used by USADA shall be presumed to have conducted testing and custodial procedures in accordance to prevailing and acceptable standards of scientific practice. This presumption can be rebutted by evidence to the contrary, but the accredited laboratory shall have no onus in the first instance to show that it conducted the procedure other than in accordance with its standard practices conforming to any applicable IOC requirements; ... and (d) if contested, USADA shall have the burden of establishing the ... accuracy of laboratory test results by clear and convincing evidence unless the rules of the applicable IF set a higher standard.

Olympic Movement Anti-Doping Code

Appendix D Laboratory Analysis Procedures

General Aspects

- 1.1 (d) * * *
 - Sensitive and comprehensive screening methods to eliminate "true negative" specimens from further consideration must be used. The initial screening procedures shall be an appropriate technique which meets the requirements of the IOC Medical Commission.

(e) * * *

... To exclude possible interferences from the biological materials the sample preparation, including the derivatization . . .can be modified whenever possible or necessary to exclude possible interferences as compared with those used for screening.

Reporting Results

* * * All specimens negative on the initial test . . . shall be reported as negative.

IAAF Rules

Division III Control of Drug Abuse

Rule 55 Doping

The offense of doping takes place when ...:

a prohibited substance is present within an athlete's body tissues or fluids;

Prohibited substances include those listed in Schedule 1 to the "Procedural Guidelines for Doping Control." * * *

It is an athlete's duty to ensure that no substance enters his body tissues or fluids which is prohibited under these Rules is present in his body tissues or fluids. Athletes are warned that they are responsible for all or any substance present in their body.

A departure or departures from the procedures set out in the "Procedural Guidelines for Doping Control" shall not invalidate the finding that a prohibited substance was present in a sample or that a prohibited technique had been used, unless this departure, was such as to cast real doubt on the reliability of such a finding.

Rule 59 Disciplinary Procedures for Doping Offences

Where a doping offence has taken place, disciplinary proceedings will take place in three stages:

suspension; hearing; ineligibility.

The athlete shall be suspended from the time the IAAF, or, as appropriate ... a Member, reports that there is evidence that a doping offence has taken place. * * * Where doping control is the responsibility of ... a

Member, the National Federation of the athlete shall impose the relevant

suspension. * * *

Where a hearing takes place pursuant to Rule 59.3, the Member shall have the burden of proving, beyond a reasonable doubt, that a doping offence has been committed.

Rule 60 Sanctions

For the purposes of these Rules, the following shall be regarded as the presence in an athlete's body tissues or fluids of a prohibited "doping offences" ...

(i)

If an athlete commits a doping offence, he will be ineligible for the

for an offence under Rule 50.1(i) ... involving the substances listed following periods: in Part I of Schedule 1 of the "Procedural Guidelines for Doping Control" first offence - for a minimum of two years from the date of the hearing at which it is decided that a Doping Offence has been committed. When an athlete has served a period of suspension prior to a declaration of ineligibility, such a period of suspension shall be deducted from the period of ineligibility imposed by the relevant Tribunal;

IAAF Procedural Guidelines for Doping Control (2002 Edition)

Analysis of Samples

The analysis of samples should be carried out as soon as reasonably practicable after arrival at the laboratory or mobile testing unit. A fixed time limit may be imposed on any analysis at the request of the IAAF.

If, at any stage, any question or issue arise in relation to the sample, the laboratory ... may conduct any further or other tests necessary to clarify the question or issue so raised and such tests may be relied upon by the IAAF when deciding whether a sample has tested positive for a prohibited

substance.

In analysiing samples to determine whether or not a prohibited substance

is present ..., the laboratory involved may use any method or protocol which it believes to be appropriate and reliable.

Every athlete shall have the right to a hearing before the relevant tribunal of his National Federation before any decision on eligibility is reached. * *

Schedule 1 Prohibited Substances

Part 1

Anabolic Agents

Androgenic Anabolic Steroids e.g.

* * *

gestrinone norbolethone trenbolone

* * *

and chemically or pharmacologically related compounds and precursors.