BEFORE THE AMERICAN ARBITRATION ASSOCIATION
North American Court of Arbitration for Sports Panel

United States Anti-Doping Agency Claimant v. Melissa Price, Respondent	AAA No. 30 190 01126 03

AWARD OF THE ARBITRATORS

We, THE UNDERSINGED ARBITRATORS, 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 as follows:

This case presents as one of first impression in some respects, and arose out of a series of events which led to the discovery of a new, previously unknown, so called "designer" anabolic steroid agent which might be used by athletes in a variety of sports to enhance performance. Hence, some background will be appropriate.

BACKGROUND

In very early June 2003, an employee of 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 Accredited 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.

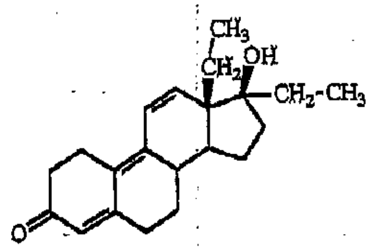
On June 19 2003, Melissa Price placed first in the hammer throw at the Nationals and was selected for testing ("in competition specimen.") Her specimen was received by the Laboratory on Friday, June 20, 2003, where it was screened for all known prohibited substances, but not for the unknown Compound X. Her specimen was negative on those screening tests. The specimen 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 some other sports, specifically for the purpose of determining the prevalence of this unknown compound. On July 29th, Melissa Price gave another urine specimen in compliance with the directive ("out of competition specimen")[1]. Those specimens were delivered to the Laboratory on August 4, 2003, and screened for substances prohibited during non-competition periods[2] on August 5, 2003. Once again, her specimens tested negative for known substances. Those negative test results were not officially reported to USADA and were held by the Laboratory for testing for Compound X.

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.[3]

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

[1] Ms. Price actually provided two specimens on July 29, as the first was determined to be too dilute. Both the dilute specimen and the subsequent acceptable specimen were sent to the Laboratory for testing.
[2] Certain substances, such as stimulants, are not prohibited other than during competition, and so are not part of the standard screen for out of competition specimens.
[3] 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."

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 an anabolic steroid substantially more powerful than a number of other, known anabolic steroids. 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.[4]

A reliable initial screening method was then 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 renders it into a gaseous state. While this screen was not as sensitive as a gas chromatogram linked to a mass spectrometer ("GC/MS"), it is a well known and scientifically acceptable technique which is sufficiently reliable so as to cause a more definitive confirmation test to be conducted.[5]

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. The Athlete's out of competition specimen from July 29, was screened for THG on August 18, 2003, two weeks after that specimen arrived at the Laboratory. The Athlete's in competition specimen was screened for THG on August 22, 2003, two months after receipt by the Laboratory.

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 tests on all three "A" specimens of the Athlete took place in mid-September 2003, and the results were reported to USADA pursuant to the Guidelines on September 23, 2003. (USADA Exhibits 9 & 11). All three specimens showed the presence of THG.

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[4] See Stipulation 8, USADA Exhibit 13.

[5] 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.

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

On November 8, 2003, a confirmation test was done on the athlete's "B" specimen, in the presence of her appointed representative, Dr. Timothy Robert of Aegis Laboratory. That test confirmed the presence of THG, using GC/MS, pursuant to the newly developed and validated procedure.

STIPULATED FACTS

The parties have stipulated to a number of facts[6] 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 Melissa Price;
>
> 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 the test developed to detect the substance in question, THG, properly in accordance with the procedures developed by the UCLA laboratory for THG;
>
> Melissa Price had been tested four times prior to June 2003, all of which were reported as negative for prohibited substances.

CONTESTED FACTUAL ISSUES

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

> Whether the confirmation 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 tested[7]; and

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[6] See, USADA Exhibits 13 and 47.

[7] 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 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.

Whether USADA had presented sufficient evidence to support the level of penalty it seeks to have this Panel impose on the athlete, should it ultimately determine that the evidence supports a finding that doping had occurred.[8]

CONTESTED LEGAL ISSUES

The athlete, through her counsel, argued that:

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; and

The period of time during which expired since her last competition, should be deducted from any period of ineligibility.

DECISION

While counsel for Melissa Price argued ably 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 (perhaps due to the mere two week time period between receipt of the July out of competition specimens and the screening test). 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.[9]

Rather, the crux of the athlete's case was that all available, accurate screens were completed with negative results and, therefore, were required by the applicable rules to be reported as "negative." Thereafter, it was argued, testing for any substance was a "retest" which is not permitted by the Rules, and it would be inequitable to do so.

This argument is based on three prongs:

[8] IAAF Rule 60.2 provides for a "minimum" of a two year suspension, and USADA sought in this case, a four year suspension.

[9] 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.

- 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 testing[10]; 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 Ms. Price. 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 2.45)

Counsel for Ms. Price 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 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 to clarify the question or issue so raised...." (Id. *emphasis added*)

There is no question that USADA had raised a question about the possible presence of what was then called simply Compound X at the time that the initial screening tests were conducted, or that USADA gave strict instructions to conduct such tests 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.[11]

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 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 of 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

[10] USADA Protocol, Rule 10.

[11] Since that is the case, we need not detemine whether a specimen tested and actually reported as negative could have been retested at a later date, and any action taken against an athlete testing positive for a substance at a future date.

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 Ms. Price. 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 its 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. . . ." (*emphasis added*)

In the present case, the athlete presented no evidence in support of her challenge to the validity of the test for THG, merely argument of counsel[12]. Hence, USADA argued, it had no obligation to present affirmative evidence.

However, given the circumstances of a case in which a new substance – THG -- was the basis of the eligibility hearing, USADA did put on substantial evidence. It did so through two expert witnesses: Dr. Don H. Catlin, M.D., a Professor or Molecular and Medical Pharmacology at the University of California at Los Angeles and Director of the UCLA IOC accredited Laboratory, as well as the Chair of the IOC Science and Medicine Committee; and Dr. Larry D. Bowers, Ph.D., the USADA Senior Managing Director,

[12] The Panel notes that, while Dr. Roberts attended the "B" specimen testing on behalf of Ms. Price, no expert testimony was tendered at the hearing.

Technical and Information Resources and Chair of the World Anti-Doping Agency Laboratory Harmonization and Quality Assurance Subcommittee. The evidence presented included 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 in 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 in the IAAF or OMADC Rules for THG in order for a positive result to be reported,. 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 through its expert witnesses, 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.

AWARD

The Panel finds that USADA has met its burden to establish the presence of THG in the specimens provided by Melissa Price, and that she has committed a doping violation. The presence of THG in an athlete does not appear to be possible from any sort of mistake or error, such as by reason of ingesting a food supplement, as the product is not approved by the FDA and cannot be purchased for any lawful purpose. Use of such a powerful anabolic steroid could be for no other purpose than to enhance an athlete's performance in violation of the spirit and absolute proscriptions of the IAAF doping rules. This is not a case of possible negligence and, indeed, the Athlete did not raise any such claim. Therefore, pursuant to IAAF Rule 60.2(a)(i), Melissa Price shall be ineligible to compete for a period of two (2) years[13] from the date of the commencement of the hearing, to and including April 15, 2006.

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

USADA had sought imposition of a blanket four year period of ineligibility for all competition, citing to the clear language of Rule 60.2 (a)(i) that two years is just a "minimum" period of ineligibility. The Panel was unable to find any guidance in the Rules of the IAAF, such as do exist in the rules of some other international sports federations, as to factors which should be considered in imposing a sanction should a doping violation be established. Hence the Panel was left to its own considerations, in light of the evidence submitted by the parties.

In this instance, USADA persuasively argued that the new, secret "designer" nature of the steroid in question should be considered. This took two forms. First, since as the Panel has found above, the steroid in question is not lawfully available anywhere, so concerns as to mere negligence or a contaminated supplement, should not cloud the issue. Second, since the steroid is only available from a single source, which was then the subject of a federal indictment, it should be presumed that the Athlete was a participant in a scheme to create, promote or distribute this prohibited substance.

The Panel agrees that, should competent proofs be submitted as to the participation of an athlete in distribution or promotion of a prohibited substance, that such a factor should weigh heavily in the decision as to the length of the period of ineligibility, to and including a possible lifetime ban. However, in the instant case, USADA did not submit any evidence as to the involvement of Melissa Price in the creation, promotion or trafficking of THG. In fact, there was no evidence submitted that the Athlete was even connected with the entity allegedly manufacturing this substance nor with the track and field team sponsored by that entity. [14] Hence, the Panel declines, on the facts before it, to impose a period of ineligibility beyond that specified in this Award.

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[13] While there were separate positive results from the in competition and out of competition specimens, it was stipulated by USADA that the IAAF Rules provide that they are to be treated as a single, first offense, as the June in competition specimen was not reported as positive at the time the subsequent specimens were taken.

[14] Counsel for Ms. Price made the innovative but frivolous argument that the lack of proof linking her to the alleged source of product should mandate dismissal of the action against Ms. Price. That is, he argued, without proof that the Athlete had secured THG from the indicted entity, the Panel would have to assume that she could not have gotten it anywhere else, and thus the test was inaccurate. This argument fails for any number of reasons. For example, it is well settled that under IAAF Rules, e.g., 55.2 and 55.4, there is no requirement that USADA prove the source of the substance nor the intent of an athlete to have taken it. Second, even if the Panel were to consider such a flawed argument, it fails to take into account that there is also no proof that the athlete did not get it from the accused company, nor that substance was not available elsewhere.

It was strenuously argued by counsel for Ms. Price that any period of ineligibility should be reduced by the period of time which has elapsed since her last athletic competition. No authority was cited for this proposition, other than the aforementioned IAAF Rule 60.2(a)(i), which provides in part:

> "When an athlete has served a period of suspension prior to declaration of ineligibility, such a period of suspension shall be deducted from the period of ineligibility imposed by the relevant Tribunal;"

The IAAF Rules also provide that an athlete

> "shall be suspended from the time [USADA] reports that there is evidence that a doping offence has taken place. * * * Where doping control is the responsibility of [USADA], the National Federation shall impose the relevant suspension. If, in the opinion of the IAAF, a National Federation has failed properly to impose a suspension, the IAAF may itself impose that suspension." (Rule 59.2).

The language of these Rules certainly provides for the potential of such a deduction, but only for circumstances where the athlete "has served a period of suspension," and then only for the period of that suspension. In this instance, it does not appear that the athlete served any period of suspension at all.

USADA cannot declare an athlete ineligible to compete, or otherwise suspend her from competition, until such time as there is a decision following a hearing. It is bound by the mandates the "Ted Stevens Olympic and Amateur Sports Act," 36 USC 220501 et seq. However, while it cannot unilaterally impose a period of suspension, USADA adopted a program of specifically offering athletes the option of taking a voluntary suspension should they wish to take potential advantage of this IAAF Rule.

On two separate occasions, in October of 2003 and again in December of 2003, Ms. Price was offered this option, and given a period of approximately two weeks within which to accept the offer. In the second instance, the offer was made through her counsel who represented Ms. Price at the hearing. The controversy arose as a result of an email request on April 1, 2004 by the Athlete, through counsel, for a voluntary suspension. This was three months after expiration of the December offer, and just two weeks prior to the date of the hearing. USADA wrote back, refusing the request because it had not been accepted within the deadline imposed at the time of the offer in December 2003. It was argued on the athlete's behalf that USADA had no authority to refuse the offer by a track and field athlete to serve a period of voluntary suspension, as it was required by IAAF Rule 59.2 to impose such a suspension.

We decline, on the facts before us, to rule on the issue of the USADA voluntary suspension program, including its assertion that such an offer of a voluntary suspension had to be accepted by a date certain. Given the eleventh hour nature of the request, and given that the Rules are quite clear that, even if granted, the suspension would result in only a two week deduction from the period of ineligibility, we conclude that equity has been served in this instance.

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 the 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

April 28 2004

Edward T. Colbert, Esq.

Arbitrator	Arbitrator
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Christopher Campbell	**Hon. Peter Lindberg**

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Arbitrator
Chris Campbell April 2[illegible] 2004
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__________________ April , 2004
Hon. Peter Lindberg