IN THE COURT OF ARBITRATION FOR SPORT

FLOYD LANDIS	)	
	)	
Appellant,	)	
	)	
V.	)	**CAS 2007/A/1394**
	)	
UNITED STATES ANTI-DOPING AGENCY	)	
	)	
Respondent.	)	
	)	

WITNESS STATEMENT OF E. JANINE JUMEAU

My name is E. Janine Jumeau. My address is Le Brunissard, Chemin des Roudils, 07380, Jaujac, France.

I. Qualifications

My curriculum vitae is attached.

I obtained a degree in Chemical Physics in 1971 from UMIST (University of Manchester Institute of Science and Technology). I then took a position as lecturer in Physics and Mathematics in a College of Further Education in England, followed by a two-year position as a post-graduate researcher in Nuclear Physics and a five-year employment as Development Engineer in the BOC group of companies. It is at BOC that I "entered" the world of mass spectrometry. Throughout this period, my interest was particularly stimulated by Mathematics

and I decided to study the subject. In 1985, I obtained a 1st class Honours degree in Mathematics.

In January 1986, I took a position as Development Engineer in one of the VG Group of companies called VG Isogas. This company merged in 1988 with another company of the same group and became VG Isotech. In early 1995, VG Isotech was integrated into Micromass (another company of the former VG Group). Later, the Inorganic part of the Micromass business was purchased and renamed GVI. The Stable Isotope product range, which includes the IsoPrime systems, became products of GVI.

In January 1986, I was given the responsibility for the development of a system for analysis of samples using a method known as Gas Chromatography-Combustion Isotope Ratio Mass Spectrometry or GC/C/IRMS. There had been two or three attempts to develop such a system at a few other locations around the world, but to the best of my knowledge, none at the time had led to a commercial product. In this capacity, I developed the hardware that made it possible to interface a gas chromatograph with an isotope ratio mass spectrometer. Subsequently, I was involved in the development of a mass spectrometer (called Isochrom) dedicated to this new technique. The Isochrom mass spectrometer was a forerunner of the IsoPrime mass spectrometer.

I was principally responsible for the development of the interfacing technology, in collaboration with the University of Lyon in France. The development led to a commercial product in 1988, which to my knowledge was the first ever. In 1989, the Isochrom won the "R&D 100" award in Chicago as one of the top 100 innovations for the year.

In parallel to the development of the GC/C/IRMS hardware, I was heavily involved with the development of its software. As the technology was completely new, software did not exist. I defined the requirements for the full control of the instrument, together with the mathematical algorithms for the data processing.

The instrument that the Laboratoire National de Dépistage du Dopage (LNDD) used in the testing of Mr Landis's Stage 17 urine samples was called IsoPrime 1. This system consists of (1) a gas chromatograph (commercially available from another manufacturer); (2) the interface technology that I had previously developed; and (3) a mass spectrometer that uses the same optics as used in the mass spectrometers I identify above. The IsoPrime 1 uses the same software as we had developed at VG Isotech for the Isochrom system . This software includes the same instrument control and the same data processing features.

During the development phase of the GC/C/IRMS system, I was involved in all aspects of its validation. Through that work, I know the system's strengths and limitations well. I built up a thorough understanding of what made the system work and what did not, together with the reasons why. Both the hardware and the software were subjected to extensive testing at each stage of their development. I personally carried out these tests. In the later stages of development, I turned to validation of the instrument and software in real-life applications, requiring me to understand and apply the science of chromatography.

As soon as the system became commercially available, it became one of my responsibilities to promote the product in the many market segments in which it had potential application, including the biomedical, pharmaceutical, petroleum industry, marine biology, food industry, flavours and fragrances industries, fraud detection and others.

I participated in the analysis of a wide array of samples, from amino acids in the Murchison meteorite, to the dirtiest oil fractions from oil companies, to the cleanest heroin samples supplied by police labs. My involvement in the analyses of samples resulted in several publications by the various laboratories with which I had collaborated.

In parallel, I was responsible for the demonstration of the GC/C/IRMS system to prospective customers. I was flown to many laboratories worldwide to help them apply the GC/C/IRMS system in their respective fields of application, giving me even more experience with sample analysis. In the ten years I was involved with the GC/C/IRMS system, I personally analysed thousands of samples. This led me to scrutinize chromatograms, assess their quality in terms of their likelihood to yield reliable isotopic data, and identify molecules of interest, sometimes within very complex matrices. I also made extensive use of the software's reprocessing features that I had built into the software suite.

I wrote the manual entitled "Isochrom GC User Manual" for Micromass (with the exception of the first fifteen pages describing the theory of IRMS in general terms). The Isochrom GC User Manual is the only manual that was issued to LNDD for the IsoPrime 1 instrument. The Isochrom GC manual defines the linearity specification, which Mr. Landis's expert Dr Davis claims LNDD failed to satisfy during the analysis of the Stage 17 samples. I was responsible for not only writing but also devising the various quality check tests and for the quantification of various quality specifications, including those relating to the linearity test and acceptable levels of pressure in the vacuum.

II. Background in Landis Matter

I was first contacted by the United States Anti-Doping Agency (USADA) in early April 2007. As one of my first tasks, I reviewed the full documentation packages for Mr Landis's Stage 17 A and B sample analysis. I visited LNDD on two occasions. The first occurred on April 24-25, 2007, under the supervision of Dr F. Botrè, with Dr Bowers (USADA), Dr J. de Ceaurriz (LNDD), Dr C Buisson (LNDD), Dr S. Davis and Dr W. Price (experts for Mr Landis). On this visit, after reaching an agreement on which files were to be extracted, electronic data files (EDFs) from the analyses of the Stage 17 A and B samples were extracted, together with the linearity tests LNDD had performed. We also extracted the data files for the 10 blind "B" samples and their log files from the MassLynx software. One copy alone of each was made, on three different CDs.

These CDs remained in the custody of Dr Botrè, until my second visit on May 3-4, 2007, under the supervision of Dr F. Botrè, with Dr Brenna (scientific expert for USADA), Dr J. de Ceaurriz, Dr C. Buisson, C. Mongongu and C. Frelat (director, IRMS supervisor and lab technicians for LNDD), and Dr S. Davis. On the second visit, I witnessed the reprocessing of all Mr Landis's Stage 17 samples, both on the IsoPrime 1 computer (using OS2 software) and on the IsoPrime 2 computer (using MassLynx software).

The A samples were reprocessed by C. Mongongu and the B samples by C. Frelat on the Isoprime 1 system. Three outputs were produced for each sample: (i) applying the automatic background subtraction; (ii) applying manual adjustments to the background and peak integration limits; and (iii) with no background subtraction. The two batches containing the A and B samples, together with the Linearity tests acquired on June 26 and July 31, 2006were then

reprocessed on the IsoPrime 2 computer using MassLynx software. Reprocessing with the Masslynx software, was conducted in an automatic way, with no operator adjustments. At the end of the reprocessing, we were allowed to inspect the outputs.

I also attended the Malibu arbitration hearing from May 18, 2007 through May 23, 2007. I witnessed the testimonies of F. Landis, Drs S. Davis, Ayotte, Meier-Augenstein, Brenna, Buisson and Goldberg, and another cyclist Joe Papp. Since the Malibu hearing, I have reviewed the Arbitrator's Award dated 9/20/07, the transcripts of the testimony of Mr Landis's experts Drs Davis, Meyer-Augenstein and Goldberg, the briefs Mr Landis and USADA submitted in this hearing, and various documents submitted in the Malibu hearing.

I also spoke with LNDD personnel regarding the operating manual that accompanied the IsoPrime 1 system.

III. Testimony

A. Summary

The analysis of Mr Landis's Stage 17 urine sample was conducted by GC/C/IRMS on an IsoPrime 1 mass spectrometer, under the control of OS2 software. A first set of analyses was carried out on July 23, 2006 for Sample A, and a second set of analyses was carried out on August 4, 2006 for Sample B. On each of these two days, the GC/C/IRMS instrument was shown to be:

- Stable within specifications (three stability runs were acquired prior to sample analysis)

- Precise within specifications (three Mix Cal IRMS runs were acquired prior to sample analysis)
- Accurate within specifications (a mixture of pure analytes (Mix Cal Acetate) with known isotopic values was analysed before and after sample analysis)

The mass spectrometer was also shown to be linear over the period that Mr Landis's stage 17 samples A and B were analysed. The mass spectrometer linearity was checked on June 26, July 31 and August 21, 2006.

All quality control checks were performed correctly and demonstrate that the instrument was in excellent working order on the days Samples A and B were analysed.

The athlete's urine sample was extensively purified prior to analysis and further separated into three fractions F1 (containing 11-keto-etio), F2 (containing andro and etio), and F3 (containing 5 beta diol, 5alpha diol and pdiol). The analytes were converted to their acetate derivatives to improve chromatographic quality. The level of chromatographic quality achieved for each of the fractions allowed isotopic values to be reliably calculated. In parallel, a Blank urine sample was prepared in the same way. The Blank urine sample was a pool of urine collected from an individual known not to have taken any exogenous testosterone.

During analysis, each fraction from the athlete's urine sample was preceded by the analysis of the equivalent fraction from the Blank urine pool. For each of the Blank urine fraction, the analytical findings were negative, consistent with the absence of exogenous testosterone. This negative finding, not only validates the method used for the sample preparation, but demonstrates that the analytical system, together with the data processing software, had the capability of returning a negative finding in the absence of exogenous testosterone.

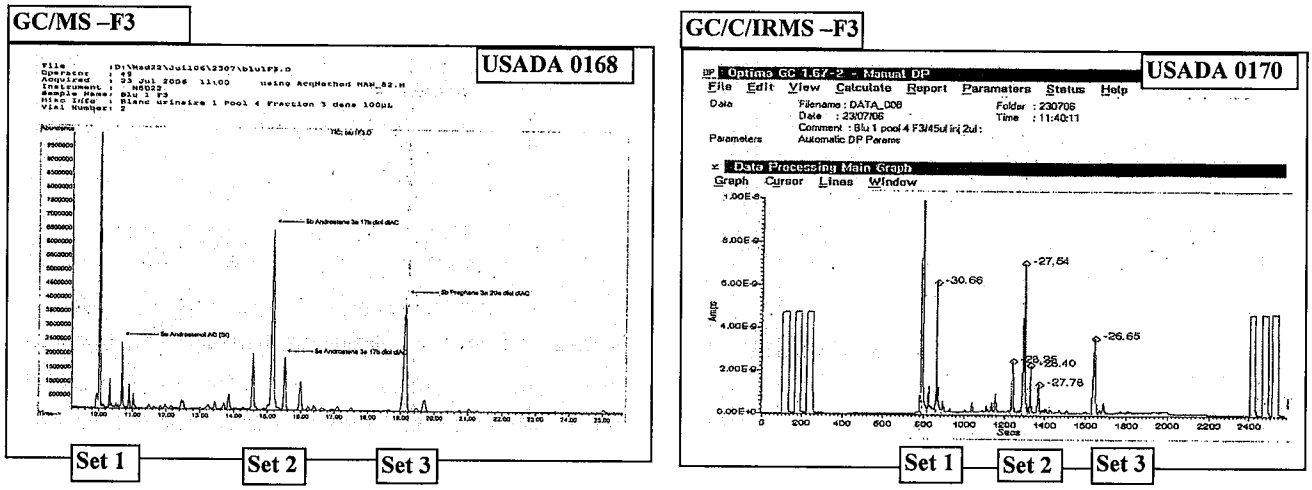
The data obtained were manually adjusted subsequent to analysis for the purpose of improving the accuracy of the results. Manual adjustments were made to both the integration limits and to the background ratio fit curves. In each fraction, the analytes were correctly identified either by comparison of retention times obtained by GC/C/IRMS from the Mix Cal Acetate mixture, which contained three of the analytes of interest, or by comparison of the sequence of elution obtained by GC/MS from the corresponding fractions that contained all six analytes of interest.

It is my opinion that the data obtained from the athlete's sample (N°995474 A and B) are reliable and trustworthy, and that LNDD's Adverse Analytical Finding (AAF) of the presence of exogenous testosterone that was made on the basis of that data is correct.

B. GC/C/IRMS Compound Identification

LNDD's identification of the analytes of interest for the GC/C/IRMS analysis was performed in two basic steps. In the first step, LNDD produced GC/MS chromatograms or traces of each sample fraction from Mr Landis's Stage 17 urine sample. The urine sample had been split into two bottles (Bottle A and Bottle B, later referred as Sample A and Sample B). The GC/MS traces provide irrefutable identification of the analytes of interest isolated in urine fractions F1, F2 and F3. LNDD had introduced 5α-androstanol acetate (referred to as "5-alpha AC") to each fraction to serve as a chromatographic reference standard or GC retention marker. The chromatograms obtained from the GC/MS produced very characteristic patterns for each fraction, as can be seen by the traces obtained from fractions F1, F2 and F3 that appear in the laboratory documentation packages for the A and B samples (at pages USADA 0156, 0159, 0162, 0165, 0168, 0171, 0332, 0336, 0339, 0342, 0345, 0348).

The GC/C/IRMS traces obtained from fractions F1, F2 and F3 appear in the laboratory documentation packages for the A and B samples (at pages USADA 0158, 0161, 0164, 0167,0170, 0173, 0333, 0337, 0340, 0343, 0346, 0349). As one can see from a comparison of the corresponding GC/MS and GC/C/IRMS traces, there is an excellent correlation between the patterns obtained from the GC/MS system and the patterns obtained from the GC/C/IRMS system. The chromatograms from the F3 fraction below provide a good example.



The GC/MS trace on the left shows three sets of peaks, which I have labeled Set 1, Set 2 and Set 3. Set 1 shows two main peaks with a minor peak between them and several minor peaks to the right. Set 2 contains four peaks and Set 3 contains one major peak followed by a small peak. Turning now to the GC/C/IRMS trace on the right, one sees the very same pattern. Hence, there is no question that the LNDD analysts were able to accurately identify the analytes of interests.

In the second basic step of the compound identification, LNDD prepared a standard or control mixture called Mix Cal Acetate, which consisted of four steroids whose delta values are certified by an independent reference laboratory, Eurofins. The four steroids are:

- 5α-Androstanol (5 alpha AC): The GC retention marker or chromatographic reference standard that we find in each of the fractions F1, F2 and F3

- Etiocholanolone (etio): One of the two analytes of interest we find in fraction F2

- 5β-Androstanediol (5 beta diol): One of the three analytes of interest we find in fraction F3

- 11-Keto-Etiocholanolone (11-ketoetio): The only analyte of interest we find in fraction F1

LNDD analyzed this standard mixture using the GC/C/IRMS system. The retention times for all four materials are reflected in the chromatograms contained in the LNDD A and B sample documentation packages (at USADA 0181, 0182, 0183, 0184, 0360, 0361, 0362 and 0363) and are presented in the table below.

SAMPLE A

Sample Name	Data N°	Retention Times (seconds) from the GC/C/IRMS instrument			
		5 alpha AC	Etio	5 beta diol	11-ketoetio
Mix Cal Acetate	007	867	1230	1302	1474
Blu 1pool4 F3	008	867		1306	
995474-F3	009	867		1304	
Blu 1pool4 F1	010	867			1473
995474-F1	011	867			1478
Blu 1 pool4 F2	012	868	1232		
995474 -F2	013	866	1229		
Mix Cal Acetate	014	867	1230	1302	1474

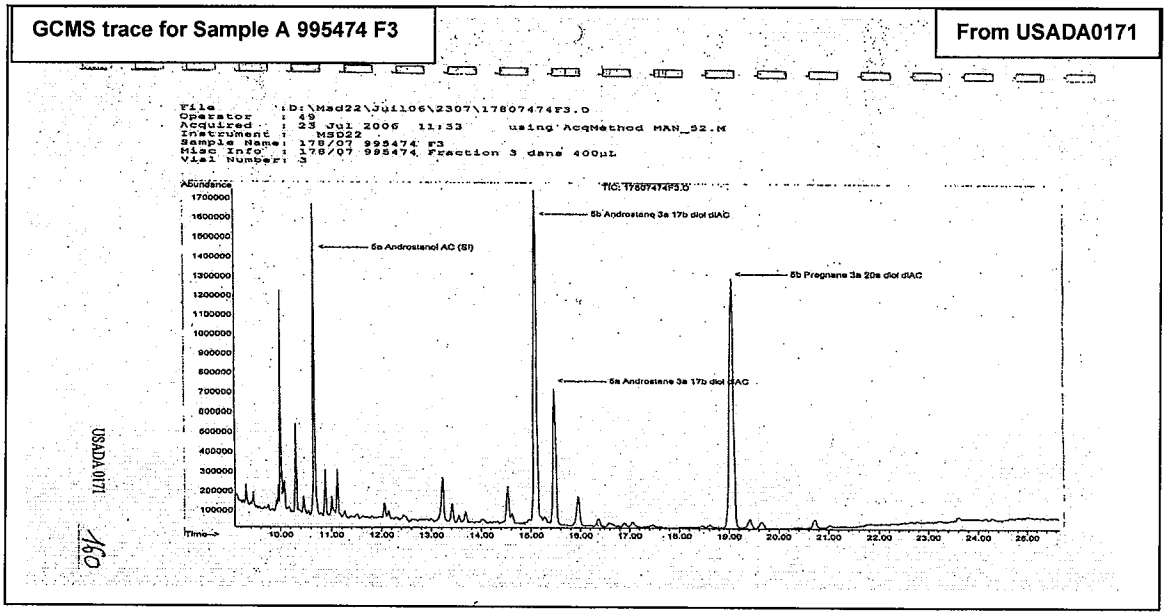
SAMPLE B

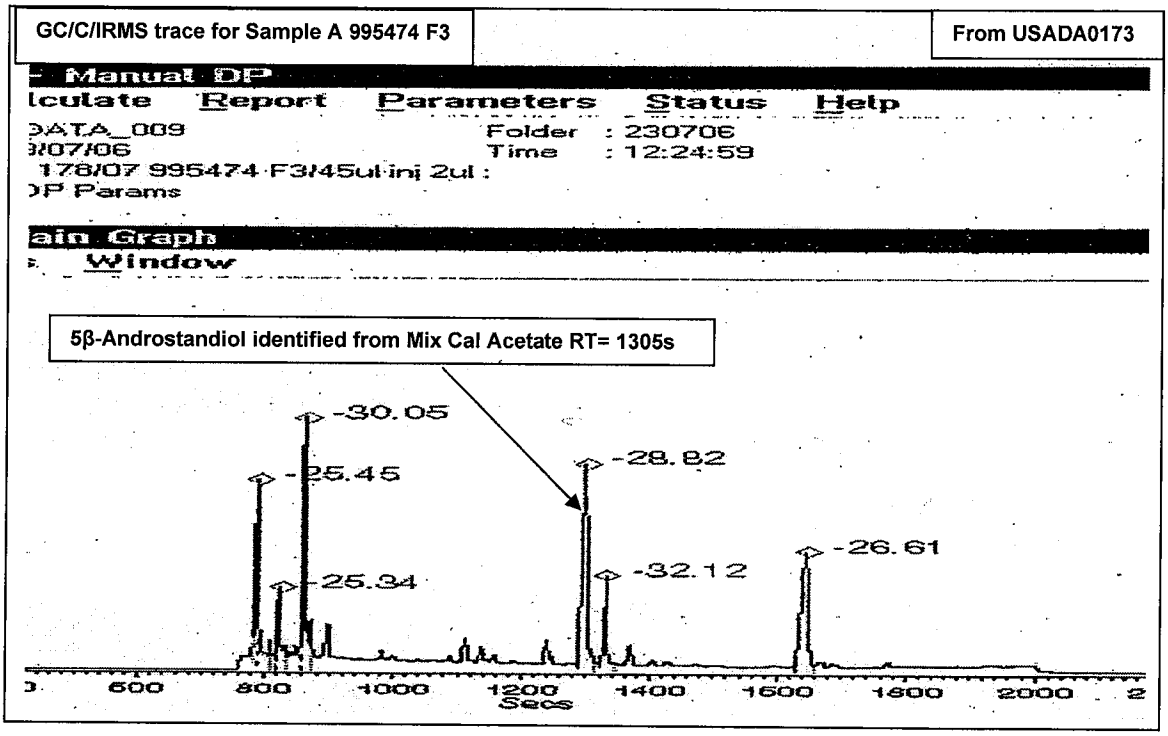
Sample Name	Data N°	Retention Times (seconds) from the GC/C/IRMS instrument			
		5 alpha AC	Etio	5 beta diol	11-ketoetio
Mix Cal Acetate	009	870	1242	1316	1491
Blu 1pool4 F3	010	872		1323	
995474-F3	011	871		1318	
Blu 1pool4 F1	012	869			1490
995474-F1	013	870			1490
Blu 1 pool4 F2	014	872	1241		
995474 -F2	015	871	1241		
Mix Cal Acetate	016	870	1241	1316	1490

If we look down the tables, we see immediately that, for each fraction, the GC retention marker or chromatographic reference standard (5 alpha AC) and each of the other three analytes of interest (etio, 5 beta diol and 11-ketoetio), which were analyzed contemporaneously, can be clearly identified from their retention times. The retention times are extremely close and well within the 0.2 min or 1% error allowed by WADA. (Although LNDD did report relative retention times (see USADA 0351), they were not necessary because the retention times alone

were sufficient to allow for correct compound identification.) LNDD, without any reasonable doubt, identified the three analytes of interest correctly in each of the three fractions.

In addition, the fractions contain three other analytes (5α-Androstanediol (5alpha-diol), 5β-Pregnanediol (pdiol) and Androsterone (Andro)). These other three analytes were not present in the Mix Cal Acetate mixture and thus could not be identified in that mixture; however, they were properly identified by comparing the GC/C/IRMS traces with the previously acquired GC/MS traces, as shown in the chromatograms for fractions F2 and F3. The traces for the F3 fraction are reprinted below (USADA 0171 and 0173).





These chromatograms are straightforward. Each contains a few very large peaks that stand high above small to moderate backgrounds. Further, one can also readily see that the backgrounds on

each contain contaminants of very low intensities. The overall patterns obtained from the GC/MS traces and the GC/C/IRMS traces are very similar.

For the F3 fraction, we already know from the standard Mix Cal Acetate mixture that 5β-Androstandiol (5 beta diol) (with a retention time of 1305 s) is the second peak in the central set of four peaks. From the GC/MS trace, we know that the next large peak in line is 5α-Androstanediol (5 alpha diol) and that the large isolated peak towards the end of the chromatogram is 5β-Pregnandiol (pdiol). I therefore identify the analyte eluting at a retention time of 1337s unambiguously as 5α-Androstanediol (5 alpha diol) and the analyte eluting at a retention time of 1651s unambiguously as 5β-Pregnandiol (pdiol). LNDD identified the analyte eluting at a retention time of 1337s as 5α-Androstanediol and the analyte eluting at a retention time of 1651s as 5β-Pregnandiol. In my judgment, LNDD identified correctly all the compounds of interest in the fraction F3.

I repeated this same comparative exercise for the F1 and F2 fractions. LNDD correctly identified the compounds of interest in these other fractions as well. In summary, LNDD identified correctly all six target analytes found in the three fractions F1, F2 and F3. Mr Landis's arguments to the contrary are simply wrong..

Pattern Recognition

On page 44 of his brief, Mr Landis states that "Indeed 'eyeballing' the peak heights to try to identify the substances in the GC/MS phase with the substances in the GC/C/IRMS phase is illogical because the peak heights do not represent the same thing. In the GC/MS phase peaks heights are a function of ion current, whereas in the GC/C/IRMS phase, the peaks are proportional to the amount of carbon (in the form of CO_2) that has entered the ion source of the

IRMS." This stated concern might have some merit when the target molecules have widely differing numbers of carbon atoms; however, the criticism has no merit where, as is the case here and as shown in the following table, the set of analytes contains similar numbers of carbon atoms. In these cases, the relative heights of analytes from the GS/MS will in fact be very similar to relative heights from the GC/C/IRMS.

Analyte	Carbon Atoms
5 alpha-AC	21
Etio-AC	21
11-ketoetio-AC	21
Andro-AC	21
5 beta diol-diAC	23
5 alpha diol-diAC	23
Pdiol-diAC	25

I therefore strongly disagree with the statement that visual comparison of peak heights is "illogical" in this particular case.

Flow Rates and Temperature Differences

I am aware that neither flow rates nor temperature profiles were the same in the GC/MS system as those in the GC/C/IRMS system, as Mr Landis points out at pages 35 and 36 of his brief. A difference in flow rates can cause differences in retention times, but it will not change the sequence of elution. A difference in temperature profiles can cause differences in both retention times and relative retention times, but, again, the differences in temperature profiles will not change the sequence of elution. This is in fact what occurred in this case, where differences in

retention times occurred between the two machines, but the sequence of elution unquestionably remained unchanged.

The differences in GC programming conditions were necessitated by the different geometry of the GC/C/IRMS system when compared to the GC/MS system. In the GC/MS system, the output of the column is directly linked to the mass spectrometer, hence, chromatographic quality is fully preserved. By contrast, in the GC/C/IRMS, the output of the column is connected to additional plumbing. When passing through the additional plumbing, the peaks broaden slightly. In order to minimize co-elution, it becomes necessary to slow down the column flow and to apply a more gradual increase in temperature than is used in the GC/MS system, which is exactly what LNDD did. As a consequence, neither retention times nor relative retention times match when comparing the two systems. –Such an effect is entirely expected, normal and in no way detracts from the high quality of the analyses LNDD performed or the reliability of the results it reported. Mr. Landis is simply incorrect when he states at page 36 of his brief that the method files LNDD used to specify temperature and flow rate should have been identical between the GC/MS and the GC/C/IRMS systems.

Different Column Issue

Mr Landis alleges at pages 37-41 of his brief that LNDD used different columns for the GC/MS and the GC/C/IRMS analyses of his samples. He bases his allegation on the reference to the column model "Agilent 1909s-443" that appears in the field labeled "Model Number" on the GC method printouts appearing at USADA 0124 and 0303, and the fact an LNDD operating procedure and accreditation documents show that the GC/C/IRMS analysis was required to use a column with the different model number, "DB17ms." I understand others witnesses for USADA

with knowledge of the facts have established or will establish that Mr Landis's allegation about the use of two different columns is incorrect and that the reference to the Agilent 1901s-443 model number on USADA 0124 and 0303 was a mistake. I can state, however, that the mistaken reference does not in any way affect the validity of the adverse analytical finding of exogenous testosterone in Mr Landis's urine.

C. Mass Spectrometer Performance

1. Linearity

Even if one were to accept Mr Landis's linearity argument, it does not undermine the validity of LNDD's measurement of delta values because the Mix Cal Acetate results establish that the instrument was measuring accurately over the range of delta values for his samples, and because linearity is not a factor when comparing peaks of relatively comparable size, such as the 5 alpha diol and pdiol in Mr Landis's urine. Besides being misplaced, Mr Landis's linearity argument is simply wrong as a matter of fact, for the reasons that follow.

Mr. Landis alleges in his brief that LNDD "failed to maintain their GC/C/IRMS instrument within its linearity specifications," which he and his expert Dr Davis claim is "equal to or less than 0.3 [per mil]," and concludes that the "LNDD technicians simply failed to understand the errors they were making or the importance of those errors." Landis Brief at pages 5 and 49-50.

Mr Landis and Dr Davis are wrong on all counts. First, the operating manual LNDD received from the manufacturer of the GC/C/IRMS instrument used for the Stage 17 analyses does not specify 0.3 per mil anywhere. Instead, it specifies the equivalent of 0.4 per mil as the general linearity standard. Second, LNDD established 0.7 per mil as its linearity standard based on its

particular application of the instrument (see LNDD 0548). It is common for laboratories to set their linearity standard at a level different from the generally recommended manufacturer's standard. Finally, even if one were to assume for the sake of argument that the 0.4 per mil standard applied, the linearity tests LNDD conducted within thirty days of the Stage 17 analyses show that even this more stringent standard was satisfied.

I am the person who was directly responsible for all the quality check tests and the quantification of all quality specifications found in the Isochrom GC operating manual, which is the manual issued to LNDD for the IsoPrime 1 system.[1] The linearity test is described on pages 28 and 29 of Section 6 of the Isochrom GC manual. The linearity specification is specified for the mass 44 ion currents in the range of 1 to 10 nA, as $5E\text{-}7nA^{-1}$ for the 45/44 ratio. "The system is declared to be linear provided that the slope is less than $5E\text{-}7nA^{-1}$." Translated into per mil (a unit we are more familiar with, in this case), this is equivalent to saying that the instrument is linear if the change is less than 0.045 ‰ for every nA change in the ion current, over the normal measuring range of the instrument (1 to 10nA). In other words, this specification amounts to an overall

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[1] The manual LNDD received from the manufacturer of the GC/C/IRMS instrument LNDD used for the Stage 17 analyses bears the name "Isochrom GC User Manual." As mentioned earlier in my testimony, Iso*chrom* is the predecessor name of the Iso*prime* instrument. The manual from which Dr Davis derives his 0.3 per mil standard was either a manual entitled "Isoprime EA [Elemental Analyzer]" or a page Dr. Davis printed off GVI's web-site just before the Malibu hearing. (See GDC 0522, 01368; Landis Brief at page 49-50; Trancript of Dr. Davis's Testimony at page 1986.) The 0.3 per mil standard Dr Davis references appears nowhere in the Isochrom GC manual. However, the Operating Instructions for determining linearity in the Isochrom GC Manual and the Isoprime EA Manual are the same; and each of them specifies the equivalent of 0.4 per mil.

linearity of 0.4‰ (when operating over the full 1 to 10nA range), NOT 0.3‰ as stated at page 50 of Mr. Landis's brief and at page 1986 of the testimony of Dr. Davis at the Malibu hearing.

When I quantified the linearity constraint of 0.4‰ for the Isochrom GC manual, I did so, not because I concluded 0.4‰ was a standard I believed all labs must meet in order to analyze samples properly, but because competitive pressures led Micromass and other instrument manufacturers to market their instruments as being able to meet the most rigorous performance standards. Specifying more stringent standards promoted that market objective.

Micromass sold the instrument with a guarantee that the instrument was capable of measuring each component of the "Micromass mix" to a precision of better than 0.3‰ in the range 1 to 10 nA. I therefore calculated the level of linearity that the mass spectrometer should achieve at a number that would allow Micromass to satisfy this guarantee. Accordingly, we required that installation engineers install each instrument with an overall linearity of at least 0.4‰ for ion currents in the range of 1 to 10 nA. There are no technical reasons, however, why an instrument must meet the linearity standard that is specified in the manual for a certain range of ion currents, if the lab does not analyse samples over that range of ion currents. Indeed, if we look at the data produced by LNDD for Stage 17, we see that the smallest sample peak it analysed has a height of 2.17nA and the tallest sample peak has a height of 6.75 nA. LNDD measured the linearity of the mass spectrometer at least in the range 1.6 nA to 9.3 nA, in each of the linearity test performed on June 26, July 31 and August 21, 2006. This range "brackets" the size of samples LNDD analysed. There are no technical justifications to state, as Mr. Landis does at page 50 of his brief, that "the instrument must be linear over the full range in the spectrometer from 1E minus 8 amps down to 1E minus 9 amps."

I have calculated the linearity of the LNDD IsoPrime 1 mass spectrometer based on the data that LNDD produced from the nine linearity runs it made on June 26, July 31 and August 21, 2006 – which cover times before and after the Stage 17 analyses. The results of these calculations range from 0.020041‰ nA^{-1} to 0.041‰ nA^{-1}. They show without doubt that the instrument was linear, whether one uses LNDD's 0.7 ‰standard or the more stringent 0.4‰ standard from the Micromass manual. Moreover, even though Dr Davis's 0.3 number is mistaken, eight of the nine linearity results are within this specification; and the one exception was immediately preceded and followed by runs that were within this specification. .

I have rarely seen the linearity of a mass spectrometer having as high a quality as LNDD's, especially after several years of use. This level of quality is indicative of extremely clean ion optics (source, flight tube and collectors) and is evidence of a very high level of maintenance.

I categorically refute the repeated allegations made against LNDD that it did not maintain its instrument in good working order. At the time of analysis of the Stage 17 samples, the mass spectrometer of the IsoPrime 1 instrument was linear and in satisfactory working order.

D. Chromatogram Quality

Throughout the Malibu hearing and in his brief in this proceeding, Mr Landis was and remains harshly critical of the quality of the chromatograms that LNDD produced with respect to the GC/C/IRMS analyses of his samples. Based on my experience in reading several thousands of chromatograms and assessing their quality, I can say without reservation that the chromatograms that LNDD produced with respect to Mr Landis's Stage 17 GC/C/IRMS analyses were of a sufficiently high quality to allow reliable isotopic analysis, were properly interpreted, and

confirm the findings LNDD made, including the adverse analytical finding of the presence of exogenous testosterone based on the differences between 5 alpha diol and pdiol..

The chromatograms within the A and B sets of samples show a level of quality well within my expectations from a complex biological matrix. It is not a matter of assigning a grade for their quality, but to decide whether the level of quality achieved will yield accurate and reliable results. Based on my experience, the chromatograms produced by LNDD during the analyses of Mr Landis Stage 17 samples meet this standard.

E. Manual Adjustments and Integration

The OS2 software LNDD used on the IsoPrime 1 instrument provides an Automatic Data Processing facility and a Manual Data Reprocessing facility. Automatic Data Processing relies on a number of integration and processing parameters that are defined by the operator prior to the start of sample analysis. These parameters instruct the software how to perform the calculations automatically as soon as the analysis is finished. All IRMS analysis softwares provide such a facility. The OS2 software gives default values for each of these parameters. I personally defined these default values when I was employed by VG Isotech and involved in the design of the OS2 software. No uniform set of values will suit every single application, so the default values we assigned are simply a starting point.

Operators can elect either to change these default or automatic parameters before performing an analysis as a step to optimize them for their particular application, or they can keep the default values, even if not optimal, and make adjustments or enhancements after they have had the opportunity to inspect the chromatograms resulting from an analysis. (Other enhancements typically are necessary in any event, so some labs reasonably decide to make all adjustments at

one time, after analysis is completed.). Both approaches are perfectly acceptable and valid laboratory practices. LNND opted for the second approach, maintained the default parameters, and then made manual adjustments before reporting the results of the IRMS analysis.

It is not possible for an operator to predict before conducting an analysis exactly what will happen during each analysis. Peak shapes, shoulders on peaks, coelutions, backgrounds, etc. often occur or vary, even if integration and processing parameters are optimised prior to the analysis. In addition, the OS2 software applies the defined automatic parameters to the entire chromatogram at the time of automatic processing. Some parameters may be valid over some regions of the chromatograms, but not over others. This is not an unusual situation.

The OS2 Manual Data Reprocessing facility offers the operator the possibility to inspect the appropriateness of the default integration and processing parameters, and to make adjustments when the default parameters do not reflect reality.

In the case of the OS2 software, a number of manual adjustments are possible, but only two types were used by LNDD during the data integration portion of the original analysis and the subsequent reprocessing of the EDFs from Mr Landis's Stage 17 samples: adjustments to integration limits (i.e. the points where peaks start and stop) and adjustments to background points.

1. Adjustment to integration limits: On inspection of a chromatogram, it is possible to find that some peaks have a "shoulder" or that there is evidence of coelution, peak tailing or sloping background or some other form of less than ideal behaviour or peak shape. This is not indicative of bad chromatography, but is frequently observed when analyzing real life

samples, which are rarely free from any matrix interference despite the best sample preparation. The automatic software function does not always make the best decision of where to locate peak starts and stops. Limits of integration are shown by coloured vertical lines. During manual reprocessing, the LNDD operator was able to pick up any of these limits with a cursor and move them to the proper location, as guided by the 2/1 ratio traces, which are a powerful visual aid to the decision process.

2. Adjustment to background points: On inspection of a chromatogram, it is possible to find that the representation of background is too low, too high, or otherwise does not mimic background correctly. This frequently occurs when the automatic function picks background points on one or more contaminants or does not define enough background points to obtain a proper depiction of background. The OS2 software allows the operator to de-select background points and to add new background points. This is performed solely by reference to the 2/1 trace rather than to the chromatogram itself.

I observed the LNDD operators making manual adjustments when I was at their lab on May 3-4, 2007. LNDD made use of these two facilities to improve the calculations and arrive at more accurate results. They used the 2/1 ratio trace as an aid to determine the best location for the limits of integration and then moved the limits of integration on the chromatograms accordingly. They de-selected background points where they could tell that the automatic function had located these points on a small contaminant. At other times, they added a sufficient number of background points to obtain the best background curve fit to the 2/1 ratio trace. They worked in a systematic fashion throughout the reprocessing session without any attempt that I could

observe to make their adjustments in order to reach, or increase the chance of reaching, a predetermined delta value for any of the analytes of interest.

I conclude that LNDD's manual adjustments were done properly and systematically and with the objective to improve the accuracy of the results. Doing so is not only an acceptable practice, but is required to arrive at accurate and reliable reporting and analysis of data.

F. Retention Time

Retention time is the time that it takes for an analyte to travel through a GC column. Relative retention time is the ratio obtained when dividing the retention time of one analyte by the retention time of a second analyte. It is customary to use the retention time of a known analyte eluting early along a chromatogram as the reference retention time and to calculate the relative retention times of analytes that elute later.

At pages 42 and 43 of his brief, Mr Landis states:

> Further there is a well established procedure to account in the GC/C/IRMS instrument which, because the additional time is a constant, is to simply subtract the period of time that the compounds travel through the additional length of plumbing from the retention times of the compounds...This function is performed automatically by the OS2 software. By default the software is set to subtract 30 seconds, but this can be changed by the operator to reflect the amount of time that is added. Dr Davis indicated that he checked this figure and that it was set to the proper amount...It is well accepted that the "hold up time" (called "delay time" in the OS2 software) – the time that is used by the compound travelling through the "plumbing" – is a constant time that is subtracted from the retention times when calculating relative retention time.

These assertions are incorrect in a number of fundamental respects.

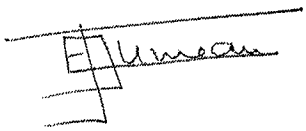
First, the OS2 software contains no procedure or code to subtract the extra time that a compound takes to travel through the additional "plumbing" between the end of the GC column and the mass spectrometer inlet.

Second, the parameter "delay time" in the OS2 software has nothing to do with the "hold-up time" or the extra time that a compound takes to travel through the additional "plumbing" between the end of the GC column and the mass spectrometer inlet. The parameter "delay time" in the OS2 software is a measure of the "wash out" time for the CO_2 reference gas. At the end of an analysis, many operators leave the reference gas valve open, which allows the CO_2 gas to bleed continuously into the mass spectrometer when not in use for analysis. The CO_2 reference gas travels to the mass spectrometer via capillaries that are parallel to the "extra plumbing" mentioned previously and never passes down any of the sample "plumbing." At the start of an analysis, the OS/2 software closes the CO_2 reference gas valve automatically and the signals from the collectors begin to decrease. But they do not reach baseline immediately. Instead, the decrease is an exponential decay and requires time to reach baseline. The parameter "delay time" is a measure of this decay time. It instructs the software to wait until this delay has elapsed before attempting to measure baseline signals. The delay is in the order of thirty seconds hence, thirty seconds is the default value OS2 specifies. (Page 40 of section 6 of the Isochrom GC manual and page 36 of Section 6 of the IsoPrime-EA manual(GDC 0522) are identical and both explain and set for the procedure for measuring the "delay time" under the bullet heading "Acquisition delay." Finally, the "hold-up time" is not a constant time, as Mr Landis and Dr Davis suggests.

G. Quality Controls

LNDD used a number of quality controls. One of them was instrument checks. I have reviewed the instrument checks LNDD made on July 23, 2006 and August 4, 2006, and conclude that they were properly done and that the instrument was operating properly.

I declare under the penalty of perjury under the laws of France and the State of New York that the foregoing is true and correct and that this declaration was executed on March 7, 2008 in Jaujac, France.



E. Janine Jumeau

Curriculum Vitae

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Date of birth : June 9th 1948
Nationality : French

EDUCATION

1966 **Baccalauréat (Sciences Expérimentales)**
Lycée Gérard de Nerval, 02200, Soissons, France

1971 **B.Sc. Honours Degree (Chemical Physics) - Class II**
University of Manchester, Institute of Science and Technology, Manchester England

1985 **B.A. Honours Degree (Mathematics) - Class I**
Open University, Milton Keynes, England

Additional training:

Sponsored by VG Isotech Ltd:

1989 **Management Course** – Two days per month for a whole year.

1990 **Marketing Course-** Two weeks of intensive training by the 'Chartered Institute of Marketing'.

1989-93 **Company Organisation and Development** – Two days every six months over 4 years.

Software:

- Design of user interfaces for the control of various scientific instruments.
- Development of data processing algorithms.
- Daily use of: **Microsoft Word, Excel, Access and Power Point**.

Languages:

Bilingual: French/English

EMPLOYMENT HISTORY

2000-to date Part-time position

EuroVector SpA, Milan, Italy

Responsibilities:
Production of all technical manuals, technical and commercial literature
Design of software interface for the control of instruments, data processing and reporting of results.
Design of the software interface for the control of autosamplers from keypads.
Testing of new software.
Preparation of patent applications.

1995-1999 Marketing & Applications Manager

Analytical Precision Ltd, Northwich, England

Based on the experience previously acquired, I was recruited to manage the introduction of a new product line for the company: a routine and low cost analyser for the analysis of stable isotopes in simple gases. The biomedical market was targeted for this new diagnostic tool. I assumed responsibilities in:

Marketing

I conducted the Market Research in Europe, USA and Canada, this study lead to:

* a five-year development strategy.
* a quantification of maximum allowed costs and margins.
* a detailed definition of technical specifications for the product to be developed

Technical

I assumed the full responsibility for:

* the development of a fully automated prototype including novel technologies. (**2 patents applied for**)
* the design of the software interface for the control of the instrument, data processing and results reporting, in accordance with the regulations governing medical diagnosis.

The work lead to the commercialisation of the first instrument, in September 1996.

In December 1996, I re-localised in France to work in collaboration with existing laboratories. The objectives were to develop further applications and extend the use of stable isotopes into further markets.

Other responsibilities included:

* Production of technical manuals and commercial literature.
* Training of test and installation engineers.
* Sales on the French territory.
* Remote troubleshooting and advice to operators by Modem.

In October 1999, the company ceased to trade

1988-1995 Product Manager

VG Isotech (Fisons Group), Middlewich, England

Marketing role:

Market evaluation. Product definition, costs and margins regulations in relation to market capacity and demand. Evaluation of competition

Production of technical and commercial documentation, in French and English
Scientific publications, oral presentations at scientific meetings
Development of Applications
Training of worldwide sales force

Technical role
Definition and supervision of technical specifications (design, software)
Supervision of external collaborations and product demonstration
Extensive sample analyses for the production of publications, for the development of new application areas

Production role
Supervision of the production for the instruments. Control of production costs, Definition of Quality Control criteria.
Training of test and installation engineers, production of test procedures.
Training and supervision of subcontractors.
Reliability evaluations. Support to the "After Sales" service department.

Results: **Turnover in 1987 :Nil in 1993: 1.9 M£**

1986-1988 Senior Product Engineer

VG Isogas (later VG Isotech), Middlewich, England

Responsabilities: Full responsibility for the development and production of an interface between a Gas Chromatograph and an isotope ratio mass spectrometer. Development of the Isochrom mass spectrometer.

Results: Commercialisation in 1988, of a new instrument (Isochrom) leading to the development of a new product line for the company.

In 1989 in Chicago the Isochrom received the "R&D 100" award as one of the top 100 technical innovations for the year.

I obtained two patents. (refer to page 7)

1983-1986 Research Associate

Alder Hey Children's Hospital, Liverpool, England
Project financed by BOC Heath Care, Madison, Wisconsin, USA.

Responsibilities: Development of a technology for the in-vivo monitoring of blood gases.

Results: A micro intravascular catheter suitable for premature infants was successfully developed. I also assumed the full responsibility for its production; this involved the development of miniature tools compatible with the micro dimensions of the probe. I also developed the environmental conditions for its production, which was carried out in "clean room" conditions.
I obtained **one patent as the sole inventor for a micro valve** of inner volumes in the nanoliters. (refer to page 7)

1981-1983 Development Engineer

BOC Health Care, Keighley, England

Responsibilities: Development of a technology for the in-vivo monitoring of anaesthetic vapours.
The investigations included the following technologies: mass spectrometry, IR and UV absorption, opto-accoustics, photoelectric effects, NMR, dynamic dielectric properties of materials in alternating electric fields.

Results: Development of a micro-analyser for the in- vivo monitoring of Halothane, **commercialised in 1983.**

1979-1981 Post Graduate Research in Nuclear Physics

Bradford University, England.
Two nuclear reactions were studied by nuclear spectroscopy, which led to **the discovery of new nuclear levels.**

1975-1980 Lecturer in Physics and in Mathematics

Percival Whitley College of Higher Education, Halifax, England

Levels taught:	"A" Level, "O" Level, ONC, TEC.
Subjects in Physics:	Mechanics, Optics, Electrostatics & Electromagnetism, Electricity, Acoustics, Thermodynamics.
Subjects in Mathematics:	Pure Mathematics, Applied Mathematics, Statistics.

ORAL PRESENTATIONS AND POSTERS

April 1980 ***A study of the ^{26}Mg (t,α) ^{25}Na reaction at E_t=15 MeV***
E.J. Jumeau. Annual Conference in Nuclear Physics; Manchester, England

April 1981 ***A study of the ^{10}B (^{7}Li,p) ^{16}N reaction at E_t=28 MeV***
E.J. Jumeau. Annual Conference in Nuclear Physics; Oxford, England

Sept 1987 ***Advances in GC-IRMS measurements***
E.J. Jumeau, R. Guilluy, J-P. Riou and C. Pachiaudi. Second German-French Colloquium "Advances in research and use of stable isotopes"; Maria Laach, Germany

Sept 1987 ***Analysis of $^{13}C/^{12}C$ ratio of nanomole bio-organic sample with on-line GC-IRMS***
E.J. Jumeau, R. Guilluy, J-P. Riou and C. Pachiaudi. First International Symposium on Applied Mass Spectrometry in the Health Sciences; Barcelona, Spain

May 1988 ***Experiences in the application of GC-IRMS over a range of sample types***
E.J. Jumeau, P.A. Freedman. Third German-French Colloquium "Advances in research and use of stable isotopes"; Maria Laach, Germany.

June 1988 ***New Applications in GC-IRMS***
E.J. Jumeau. 36th ASMS Conference on Mass Spectrometry; San Francisco, USA

Sept 1988 ***Determination du $\delta^{13}C$ de la Frambinone***
E.J. Jumeau, C. Schippa and G.George. 3ème Congrès Nationale de la Société Française de Chimie; Nice, France

Oct 1988 ***In-vivo evaluation of a micro intravascular blood gas probe***
E.J. Jumeau, B. Goodwin and R. Chilcoat. American Society of Anaesthesiologists; San Francisco, USA

Oct 1988 ***A micro intravascular probe for blood gas sampling***
E.J. Jumeau, B. Goodwin and R. Chilcoat. American Society of Anaesthesiologists; San Francisco, USA

May 1989 ***Continuous Flow Dual Inlet as an improvement for IRMS and ^{13}C analysis of breath samples***
E.J. Jumeau, R. Guilluy. Stable Isotopes in Paediatric, Nutritional and Metabolic Research; Gronigen, Netherlands

May 1989 ***Gas Chromatography Column Switching and dual inlet dynamic interface as a new improvement for IRMS and ^{13}Cisotopic analysis of breath samples.***
E.J. Jumeau, R. Guilluy, J.L. Brazier, J-P. Riou and C. Pachiaudi. Stable Isotopes in Pediatric, Nutritional and Metabolic Research; Groningen, Netherlands

Aug 1989 ***Gas Chromatography Column Switching and dual inlet dynamic interface as a new improvement for IRMS and ^{13}C isotopic analysis of breath samples.***
E.J. Jumeau, R. Guilluy, J.L. Brazier, J-P. Riou and C. Pachiaudi. 2nd International Symposium on Mass Spectrometry in the Health Sciences; San Francisco, USA

Oct 1989 ***Le point sur la spectrometrie de masse***
E.J. Jumeau. Isotopes stables et spectromètrie de masse dans les explorations métaboliques et pharmacologiques; Lyon, France

Oct 1989 ***Problèmes spécifiques liés aux échantillons gazeux***
E.J. Jumeau. Isotopes stables et spectromètrie de masse dans les explorations métaboliques et pharmacologiques; Lyon, France

April 1990 ***Misuse of Testosterone in sport: an approach to detection by measurement of isotopic abundance using GC-IRMS (Poster)***
G. Southan, A. Mallet, E.J. Jumeau and S. Craig. 2nd International Symposium on Applied Mass Spectrometry in the Health Sciences; Barcelona, Spain

June 1990 ***First Study of geograhic origin of Heroin and related drugs by GC-IRMS***
R. Guilluy, J-L. Brazier, E.J. Jumeau M. Desage and H. Chandron. Diskussionstag der Arbeitsgemeinchaft Massenspektrometrie; Konstanz, Germany

June1990 ***A Review of new applications by the technique of IRMS***
E.J. Jumeau, C. S. Fenwick and S. Craig. Diskussionstag der Arbeitsgemeinchaft Massenspektrometrie; Konstanz, Germany

June 1990 ***On-Line Measurements of Hydrogen,Carbon, Nitrogen and Oxygen isotope ratios in the range of natural abundance by GC-IRMS.***
E. J. Jumeau, R. Medina, K. Kempe, and H L. Schmidt. Diskussionstag der Arbeitsgemeinchaft Massenspektrometrie; Konstanz, Germany

April 1992 ***The analysis of C_1-C_5 components in natural gas samples***
S. Baylis, E.J. Jumeau and K. Hall. 203rd American Chemical Society National Meeting; San Francisco, USA

April 1992 ***The technical design considerations for a continuous flow GC-IRMS system***
E.J. Jumeau, K. Hall. 203rd American Chemical Society National Meeting; San Francisco, USA

April 1992 ***On-line measurement of HD/D_2 ratios by GC-IRMS***
C.S.Fenwick, E.J. Jumeau and K. Kempe. 203rd American Chemical Society National Meeting; San Francisco, USA

May 1992 ***The use of isotope ratio mass spectrometry for the clinical diagnosis of metabolic disorders***
E.J. Jumeau. Klinische Anwendungen in der Magnetischen Kernresonanz spektroskope und der Massenspektrometrie; Bochum, Germany

Sept 1992 ***A new technique for the isotopic analysis of micro quantities of gaseous samples***
E.J. Jumeau. Arbeitsgemeinschaft Stabilie Isotope; Bayreuth, Germany

Jan 1993 ***Le couplage CG/SM isotopique: principes, contraintes d'utilisation et limites d'application***
E.J. Jumeau. Groupe de Travail Spectromètrie de Masse; Elf Aquitaine, CSTJF; Pau, France

Sept 1993 ***The Isochrom μG: Survey of applications in the medical and pharmaceutical fields***
E.J. Jumeau. Medical Seminar; London zoological society; London, England

Sept 1993 ***Features and benefits of the Isochrom μG in medical applications***
E.J. Jumeau. Press Conference; London, England

PUBLICATIONS

1988 ***Design and application of a new instrument for GC-IRMS***
E.J. Jumeau, P. A. Freedman. American Laboratory. June 1988, (114-119)

1990 ***Carbon isotope composition of individual amino acids in the Murchinson meteorite***
M.H. Engel, S.A. Macko, E.J. Jumeau and J.A. Silfer. Nature, vol. 348, 1st November 1990 (47-49)

1990 ***Stable carbon isotope ratio analysis on single components in crude oils by direct GC-IRMS***
M. Boroy, K. Hall and E.J. Jumeau. Trends in Analytical Chemistry, vol. 9 –1990, (331-337)

1991 ***Stable carbon isotope analysis of amino acid enantiomers by conventional IRMS and combined GC/IRMS***
J.A. Silfer, M.H. Engel, S.A. Macko and E.J. Jumeau. Analytical Chemistry –1991, Vol 63 (370-374)

1991 ***$^{13}C/^{12}C$ determinations made easy with GC-C-IRMS***
E.J. Jumeau. Laboratory Equipment Digest -May 1991

1991 ***Gas Chromatography with MS or IRMS in studying the geographical origin of Heroin***
M. Desage, E.J. Jumeau. Analytica Chimica Acta, 247, 1991, (249-254)

1991 ***Determination of δ ^{13}C values of sedimentary straight chain and cyclic alcohols by GC-IRMS***
D.M. Jones, J.F. Carter, G. Eglinton and E.J. Jumeau, . Biological Mass Spectrometry, 1991, vol. 20 (641-646)

1991 ***Stable Carbon Isotope analysis of amino acid enantiomers***
J.A. Silfer, M.H. Engel, S.A. Macko and E.J. Jumeau,. Analytical Chemistry, vol 63, (370-374).

1992 ***On-line purification and ^{13}C isotopic analysis of CO_2 in breath***
R. Guilluy, E.J. Jumeau, and J-L. Brazier. Analytica Chimica Acta ,1992, (193-202)

PATENTS

Aug 1987 **Capillary Switching Valve**
European Patent N° 0232581

Sept 1987 **Method and apparatus for the determination of isotopic composition**
British Patent N° GB 8720586
European Patent N° EP/0306332/A2
United States N° 4866270

Nov 1987 **Valve arrangement**
United State Patent N ° 4706700

May 1988 **Method and apparatus for the determination of isotopic composition**
British Patent N° GB 8811379
European Patent N° EP/0306333/A2
United States N° 4916313

Feb1997 **Preparation of gaseous mixtures for Isotopic Analysis**
British Patent N° 9604037.3
International Patent N° PCT/GB97/005030

June 1997 **A Method of Injecting a Gas into a Mass Spectrometer and Apparatus therefor.**
British Patent N° 9611820.3
International Patent N° PCT/GB97/01541