F.D.N.

# IN THE SUPREME COURT OF SOUTH AUSTRALIA

#### BETWEEN

ANDRE CHAD PARENZEE

applicant

and

THE QUEEN

respondent

# PROSECUTION WRITTEN SUBMISSIONS

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# OVERVIEW OF ARGUMENT

- 1. The evidence given by the witnesses called by the applicant would not be admissible at a re-trial. The witnesses lacked the requisite expertise to assist the Court in the provision of an expert opinion. The evidence would also be inadmissible in the form that it was presented by the applicant's witnesses to the Court.
- 2. The evidence presented by the applicant does not satisfy the "fresh evidence" test in that it was not of such "cogency, plausibility and relevancy" that a jury acting reasonably might have reached a different verdict if the evidence had been before them.

  With reasonable diligence this evidence could have been presented by the applicant at trial.
- 3. It has not been established that there is even a genuine scientific debate in relation to the issues raised by the witnesses for the applicant, namely:-
  - 1. HIV has never been proved to exist;
  - 2. It has not been proved that HIV is sexually transmissible other than by receptive anal intercourse; and
  - 3. The diagnostic tests are unreliable.

The totality of the evidence has established that the evidence given by the applicant's witnesses was spurious, without scientific merit and contrary to the internationally accepted opinions of the experts in this field.

# 1. EXPERTISE OF THE APPLICANT'S WITNESSES

1.1 It is the respondent's submission that the two witnesses called by the applicant were not properly qualified experts in the areas about which they purported to provide an opinion. Further, during the course of their evidence, they failed to demonstrate a balance and impartiality that the court expects of expert

witnesses. It became clear that they had their own agenda<sup>1</sup> which was inconsistent with the role of an expert witness in court.

The first question that arises in considering the admissibility of expert evidence is:

"Whether the subject matter of the opinion falls within the class of subjects upon which expert testimony is permissible. This first question may be divided into two parts:-

- (a) whether the subject matter of the opinion is such that a person without instruction or experience in the area of knowledge or human experience would be able to form a sound judgment on the matter without the assistance of witnesses possessing special knowledge or experience in the area, and
- (b) whether the subject matter of the opinion forms part of a body of knowledge or experience which is sufficiently organised or recognised to be accepted as a reliable body of knowledge or experience a special acquaintance with which by the witness would render his opinion of assistance to the court." <sup>2</sup>
- 1.3 There can be no doubt that this evidence related to topics well beyond ordinary human experience. The evidence traversed a number of fields of expertise including medicine, virology, immunology, microbiology, electron

An illustration of this was the evidence of Ms Papadopulos-Eleopopulos about the Perth Group's Website and using court cases to assist in conveying their "message" T201 and 262 and the posting of Dr Turner's Affidavit on the internet T736-737 and 201.

<sup>&</sup>lt;sup>2</sup> R v Bonython (1984) 38 SASR 45 per King CJ at 46-47.

microscopy, molecular biology and epidemiology<sup>3</sup>. Curiously in these circumstances, at no stage did either of the witnesses called by the applicant, indicate that they were being asked questions that went beyond the realms of their expertise.4

- Whilst it is accepted that a witness can acquire a degree of expertise through 1.4 study or experience, even though they have no formal qualifications, it is the respondent's submission that neither of the applicant's witnesses have obtained a level of knowledge such as to render their opinion of assistance in resolving the issues before the court. Further, both demonstrated a lack of understanding of their role as expert witnesses and their obligation to attempt to assist by providing an unbiased, non-partisan opinion.
- The only formal qualification held by Ms Eleni Papadopulos-Eleopopulos is a 1.5 degree in Nuclear Physics obtained from the University of Bucharest in 1960. Since that time she has worked as a Laboratory Assistant and then as a Physicist at the Royal Perth Hospital. It would appear that Ms Papadopulos-Eleopopulos developed an interest in biology in the mid-1970's and in the cause of AIDS in the early to mid-1980's.5
- Since that time, Ms Papadopulos-Eleopopulos has done no further formal 1.6 study or training in any of the relevant fields of expertise. She has not conducted any of her own experiments, laboratory work or testing for HIV<sup>6</sup>,

It was for this reason that the respondent called a large number of witnesses with different relevant areas of expertise.

The closest that Ms Papadopulos-Eleopopulos came to this was to say that she was "not interested" in other viruses like hepatitis C T239-242.

T14-17 and exhibit A1 Affidavit of Ms Papadopulos-Eleopopulos

The one exception appears to be the commencement of some testing which she described as a "collaboration" with Professor Martyn French T234 and 417. Professor French denies any such collaboration and most certainly refutes the claim by Ms Papadopulos-Eleopopulos that he agreed to co-(Footnote cont. on next pg)

nor has she ever been involved in the diagnosis, treatment or care of a person who has been diagnosed as being HIV positive.

- 1.7 The extent of Ms Papadopulos-Eleopopulos' education in these complex fields of expertise has been to read and critique published literature. Whilst it is accepted that someone can educate themselves in such a way<sup>7</sup> there remain great limitations to the extent of the witnesses' expertise and the assistance that they can provide the court. At best, Ms Papadopulos-Eleopopulos can give evidence about what she has read in the published literature as opposed to relying on her own knowledge, experience or work. However, even that knowledge appears to be limited in time to a period of about the mid-1980's. Ms Papadopulos-Eleopopulos demonstrated a complete lack of understanding of modern scientific developments, particularly in the fields of microbiology and molecular biology.
- 1.8 Even if it is assumed that Ms Papadopulos-Eleopopulos has developed some level of self-taught expertise, her evidence fell well short of what is expected from an expert in this court. An expert witness has an overriding duty to assist the court on matters relevant to that expert's area of expertise. They are not an advocate for any party or cause. In *National Justice Compania Naviera SA v Prudential Assurance Co Ltd*, <sup>8</sup> Cresswell J said that expert evidence presented to the court should be and should be seen to be the independent product of the expert uninfluenced as to form or content by the exigencies of litigation and

author any papers that arose out of this work. T786-787. His attitude toward Ms Papadopulos-Eleopopulos at that time was reflected in the fact that he wrote to the CEO of the Royal Perth Hospital expressing concern about public comments that she was making.

Weal v Bottom (1966) 40 ALJR 436 per Barwick CJ at 438-439; Normandale v Rankine (1972) 4 SASR 205; R v Barker (1988) 34 ACrimR 141

<sup>8 (1993) 2</sup> Lloyds LR 68 at 69.

that an expert witness should provide independent assistance to the court by way of objective, unbiased opinion in relation to matters within their expertise<sup>9</sup>. As Mulligan J said in *R v Karger*:-

"Expert witnesses stand in a special place in our trial system. These days science is imported more and more into the justice system to assist in the accurate resolution of matters in issue. The courts are entitled, and often obliged, to place their trust in men or women of science and it is essential that scientists respond accordingly so that a miscarriage of justice may be avoided. Courts are entitled to expect that they will undertake their work with appropriate investigation and impartiality." 10

It is submitted that this did not occur with the witnesses called by the applicant.

- 1.9 It is submitted that Ms Papadopulos-Eleopopulos had an obvious bias and a cause to promote. Her powerpoint presentation was at the very least, incomplete and at worst, deliberately misleading. Two examples of this approach were her evidence in relation to the Nancy Padian studies<sup>11</sup> and her deliberate deletion of words in powerpoint slides purporting to set out direct quotes.<sup>12</sup>
- 1.10 In relation to the Nancy Padian studies, Ms Papadopulos-Eleopopulos initially told the court that she was aware of a response published by Dr Padian as a result of her concerns about the manner in which her studies were being

<sup>&</sup>lt;sup>9</sup> His Lordship's Judgment has been used in this State as a model for Practice Direction 46.

<sup>&</sup>lt;sup>10</sup> [2001] SASC 64 at para 612.

<sup>&</sup>lt;sup>11</sup> A8 slides 37-44, T142-170.

<sup>&</sup>lt;sup>12</sup> A8 slide 12

misused and misinterpreted<sup>13</sup>. When subsequently further cross-examined on this topic, the witness first claimed that prior to giving her evidence in court she did not know about the existence of the Padian response. This then changed to an assertion that she did not know whether she had been aware and then again changed to an acceptance that she had not only known about the Padian response but that members of her own group in Perth had been in correspondence with Dr Padian at the relevant time.<sup>14</sup>

- 1.11 It is the respondent's submission that on this topic, Ms PapadopulosEleopopulos was less than frank with the court. When one has regard to the
  detail of Dr Padian's response it is highly unlikely that the witness was simply
  mistaken or confused about whether she was aware of it at the time of giving
  her evidence. Of particular concern was the fact that the witness failed to
  appreciate the inappropriateness of relying on the Padian studies as support for
  her position in circumstances in which she was aware that the author of the
  reports had made clear her views that this was a misuse and distortion of the
  studies<sup>15</sup>.
- 1.12 Ms Papadopulos-Eleopopulos presented her evidence by way of a "powerpoint" demonstration. As part of her presentation she used slides that purported to contain direct quotes from various studies or articles. At no stage in her evidence in chief did she attempt to put any of the original documents

13 T343. This was the very sort of misrepresentation that the respondent submits that Ms Papadopulos-Eleopopulos is guilty of.

<sup>&</sup>lt;sup>14</sup> T559-577.

In a similar vein the authors of the report P19 (referred to as the 'Rodriguez' study) published a statement about their concerns about the misinterpretation of their work, namely that it was being incorrectly used in support of an argument that HIV does not cause AIDS and thus death. The authors described that those who used their work to support that conclusion demonstrated "either a combination of sloppy thinking, sloppy reading or malicious intent" (p.20). Again, Ms Papadopulos-Eleopopulos attempted to misuse the studies in exactly the way that the authors had criticized.

before the court.<sup>16</sup> This only occurred during cross-examination when the respondent attempted to put the excised passages into context. When looked at in context, the passages relied on, almost without exception, did not accurately reflect the full contents of the article or the view of the author. A stark example of this was in relation to slide 12 in A8. In that slide, the following passage was set out:-

### Gay men

"Data from this an (sic) previous studies have shown that receptive rectal intercourse ... is an important risk factor for HTLV-III ("HIV") infection (positive antibody tests) ... We found no evidence that other forms of sexual activity contributed to the risk."

Stevens CE, Gallo R et al. Human T-Cell Lymphotropic Virus Type III Infection in a cohort of homosexual men in New York City. J Am Med Assoc 1986; 255:2167-72.

What was deliberately omitted from that passage and replaced by the first series of dots were the words "for example". This deletion from the quote clearly altered the interpretation of that sentence. Perhaps even more significant was the omission of the following words which immediately followed the cited passage:-

"However, these data should not be taken to indicate that other forms of sex are safe. It is possible that the virus may be transmitted by sexual

<sup>&</sup>lt;sup>6</sup> As it transpired, some of the studies or reports could not even be located by the witness.

<sup>&</sup>lt;sup>17</sup> Ms Papadopulos-Eleopopulos' initial explanation for deleting the words was "just to make the quote smaller that's all, because it does not aid or misinterpret because analytical (anal intercourse?) is a risk factor. That's all they say and all introduced that" T452-453.

activities other than receptive rectal intercourse, although probably with less efficiency and therefore not detectable in our present study." 18

Ms Papadopulos-Eleopopulos attempted to present this study as support for her position in relation to sexual transmission, namely that receptive anal sexual intercourse is the only route of sexual transmission in circumstances in which the authors of the report, in the very next sentence, made it clear that their study should not be relied on for that purpose.

This is one example of the approach adopted by Ms Papadopulos-Eleopopulos throughout her evidence which demonstrated a level of intellectual dishonesty and a complete lack of understanding of the role of an expert in the court. When asked to provide articles to substantiate the slides presented by PowerPoint, the witness was not able to provide a complete set of articles.<sup>19</sup>

1.13 Dr Valendar Turner obtained an MBBS from the University of Sydney in 1969. He is also a fellow of the Royal Australasian College of Surgery and the Royal Australasian College for Emergency Medicine. He worked in the emergency department of the Royal Perth Hospital for about 20 years. At the time of giving evidence, Dr Turner was employed on a part time basis by the Department of Health in a health call centre supervising nurses who answered telephone calls from people requiring medical advice.<sup>20</sup>

<sup>&</sup>lt;sup>18</sup> Page 27

An example of this approach was in relation to "an article" written by Ian Fraser that the witness referred to repeatedly during the course of her evidence. When Ms Papadopulos-Eleopopulos returned to Adelaide to give evidence on the second occasion, she went to the trouble of bringing an enlarged photocopy of one quote from the article - but failed to produce the actual article. This was despite the fact that she had been well forewarned that she was required to produce all of the publications that she was to rely on. The witness admitted that this article was only a few pages, yet to this day the entire article has not been produced T548-557, 584-585, 630-643.

<sup>&</sup>lt;sup>20</sup> T657-662

Like Ms Papadopulos-Eleopopulos, Dr Turner has no formal qualifications in any of the relevant specialised fields. He too is at best a self taught expert having spent some years critiquing some of the literature on HIV. Whilst Dr Turner's evidence was generally limited to the topic of HIV antibody tests, in an affidavit provided to the court he purported to give expert opinion evidence about matters that involved an in depth knowledge of various scientific fields that cut across disciplines like virology, immunology<sup>21</sup>, microbiology, microscopy and epidemiology. Like Ms Papadopulos-Eleopopulos, he gave evidence about these various matters without ever acknowledging any limitations to his expertise.<sup>22</sup>

1.15 An aspect of Dr Turner's evidence that demonstrated the problems with his

The closest that Dr Turner got to qualifications in these fields is that he had wanted to be an immunologist as a youngster, so had spent a year learning it. T.746.

HIS HONOUR

1.14

XXN:

An example of this was when Dr Turner was asked about whether P24 antibodies in the semen of HIV patients are monoconal or polyconal. The following exchange followed:

Q: P24 antibodies in the semen of HIV patients are not monoconal they are polyconal.

A: Most antibodies are polyconal.

Q: Do you agree or disagree with that proposition.

A: If there is evidence somewhere for that then I accept that but –

Q: Is your evidence you don't know.

A: I don't know if they are monoconal or polyconal. You haven't presented evidence, I have to have evidence to agree or disagree with a statement like that. It would not surprise me if they were.

Q: You could agree, disagree or you don't know because there are limits to what expertise you have.

A: Your Honour you'll have to help me here, I'm sorry.

Q: I can help you to this extent, that you have been presented to this court as an expert.

A: Yes.

Q: So questions are being put to you in respect of the areas in which you are presented to the court as an expert.

A: Right.

Q: If you know the answer, then say so, if you don't know the answer, equally say so. You can either say 'yes', 'no' or 'I don't know'.

A: So please ask the question again.

Q: P24 antibodies in the semen of HIV patients are not monoconal, they are polyconal.

A: I don't know.

Q: Sorry, that's my mistake I will put it again. What I meant to put to you is, P24 antibodies in the serum of HIV patients are monoconal, they are polyconal.

A: Yes, I accept that.

approach was his account of speaking publicly in South Africa, criticising the antibody tests routinely used for detecting HIV. He did this in the knowledge that if he was confronted by someone who was at risk of having contracted HIV and who wanted to know if they were HIV positive he would advise them to undertake the very tests that he has spoken publicly against.<sup>23</sup>

1.16 The manner in which Dr Turner gave evidence was also somewhat unorthodox for a witness in court. Instead of simply responding to questions and referring to the literature when necessary, he read from a prepared script accompanied by a power point presentation. When asked about this approach, he said:-

"Yes, I had rehearsed it and I had printed it out and I basically spoke what I had written." 24

- 1.17 It is the respondent's submission that many of the criticisms of Ms Papadopulos-Eleopopulos' evidence can be made of that of Dr Turner's. He also demonstrated a bias and a lack of appreciation of his role as an "expert" witness. His own agenda was exposed when he gave evidence that he had placed his affidavit on the internet.
- 1.18 Of particular concern, Dr Turner demonstrated that he had no real understanding of how the antibody tests operate, how they are tested and how they have been developed over time. He also had no real knowledge of developments in molecular biology including the fact that the whole genome of HIV had been sequenced and that HIV genes were used to provide pure

<sup>24</sup> T738.

<sup>&</sup>lt;sup>23</sup> T720-725. See also for discussion about ethical considerations in relation to this approach P46.

antigens for current diagnostic tests. This is somewhat surprising given that / HIV antibody testing was held out as being his particular field of expertise.

It is submitted that in relation to the credibility and "expertise" of these witnesses, Your Honour is entitled to take into account their professional reputation amongst the experts in their fields, about which they purport to provide an opinion.

This reputation was described by the respondent's witnesses in the following terms:-

# Scientia Professor David Cooper AO

"The group is regarded as not having any scientific credibility and we believe in the scientific community that their statements are wrong, mischievous and harmful." <sup>25</sup>

<u>Professor Martyn French</u> (in the context of explaining why he wrote to the CEO of the Royal Perth Hospital):-

"Because I believe that their views are harmful to the patients that I treat, and others treat, with HIV infection. I feel that for a number of reasons. Firstly, I felt very upset about the fact that they had been advising the South African government on the use of antiretroviral therapy, because I believe that the President of South Africa's views were influenced by this group, and I was one of the signatories to the Durban Declaration, which was put together at around about the time of the Durban International Aids Conference. I also

<sup>&</sup>lt;sup>25</sup> T681

was very concerned at a more local level about what effect this would have on uninfected people with HIV. I think their views send completely the wrong message to the general population about- and we have been trying for the last two decades to ensure that people practice safe sex, and I think that their views very undermine the public health messages. I also was very concerned about their views on antiretroviral therapy, because I am telling my patients that antiretroviral therapy will improve their quality of health and save their

lives because these drugs are suppressing the replication of the HIV virus.

They are telling people that that the virus doesn't cause AIDS and therefore some — and this has happened in my clinic — patients have actually come in and said 'Does HIV really cause AIDS? I have read, in the local newspapers, that it doesn't. Should I be taking these drugs?'. So it does have a tangible effect on the management of patients on a day-to-day basis."<sup>26</sup>

# Professor Elizabeth Dax AM:-

"I think if we went through the entire transcript we could come to points that they have delivered, but I find a lot of the delivery of the points that they make sort of half truths, quite frankly, so they don't deliver the full picture. It's like what I was talking about the world is flat this morning; that information is incomplete, so some of the information in the transcript that I have read starts off to be true, if you like, but then is cordoned off from the vast amount of information and evidence that's available, scientific evidence, not court evidence, it's cordoned off so you don't get the whole truth so, yes, they start off from something that may have been true, but they don't develop it. I would

<sup>&</sup>lt;sup>26</sup> T787.

think we would be here for the rest of the day if we went through the transcript and chose little bits of those sort of examples."<sup>27</sup>

#### Professor David Gordon:-

"I don't think they have any reputation or credibility amongst the scientific community." <sup>28</sup>

"Such groups have no credibility at all amongst scientific or medical groups with expertise in the field and their 'conspiracy theories' are akin to UFO supporters. Unfortunately, such groups have had enormously harmful impacts on the spread of HIV in Africa, most notably South Africa, as a result of President Mbeki being influenced by these views; as a result his country has the worst record of all Africa in controlling the spread of, and death from, AIDS."<sup>29</sup>

#### Emeritus Professor Peter McDonald AM:-

"The basis for the appeal relates to literature and beliefs that have not been substantiated by subsequent science and public health strategies. The writings of Eliopoulos do not constitute expert opinion in terms of public health, epidemiology or virology; Eliopoulos is not an expert in these fields. Her writings have been based on technical comments about testing methodology and conjecture that has not been vindicated by world events." 30

<sup>28</sup> T1012.

<sup>&</sup>lt;sup>27</sup> T892.

<sup>&</sup>lt;sup>29</sup> T72.

<sup>&</sup>lt;sup>30</sup> T88.

# Professor Robert Gallo:-

"WHO evaluated this problem, the National Institute of Health evaluated this problem, the National Academy of Sciences USA evaluated this problem, UNA evaluated this problem, less so, and the Pasteur Institute. All have come to the same conclusion, that the evidence is overwhelming. You're relying on a non-scientist, who works in an emergency room, that hands you an affidavit, that you take to court to debate with me, who spends, since 1970, full-time in retroviruses and showing and studying disease and the origin of disease." 31

1.20 There are practical reasons why there are limits as to how wide ranging an enquiry can be made by a court into scientific questions such as these. For this reason, the court is entitled to take into account that many other well equipped scientific bodies and international organisations have considered these issues and have universally reached a conclusion that is contrary to that of Dr Turner and Ms Papadopulos-Eleopopulos.<sup>32</sup>

#### 2. FRESH EVIDENCE

- In order for the applicant to succeed in this application, he must demonstrate that it is at least reasonably arguable that there has been a miscarriage of justice arising from the absence of evidence from Ms Papadopulos-Eleopopulos and Dr Turner in his trial.
- 2.2 Whilst there have been various formulations or "working rules" for a fresh evidence test it is now generally accepted that the additional evidence must be

<sup>&</sup>lt;sup>31</sup> T1301.

<sup>&</sup>lt;sup>32</sup> See, for example, P5, P6 and P8.

<sup>&</sup>lt;sup>33</sup> R v Reci (1997) 70 SASR 78 per Doyle CJ at 92

of such substantial importance and of such cogency, plausibility and relevancy, that when considered with the other evidence given at the trial, it is a significant possibility that the jury, acting reasonably, would have acquitted the applicant.<sup>34</sup>

- It is the respondent's submission that the evidence presented by the applicant falls a long way short of satisfying this test. This is particularly so when considered in the context of the expert evidence presented by the respondent.
- It is conceded that if the applicant's witnesses are found to have the requisite expertise and if there was a genuine scientific forensic issue then this evidence would have been relevant and admissible at the applicant's trial. It is, of course, disputed that the witnesses are properly qualified experts and that this is a legitimate scientific debate.
- 2.5 It is also disputed that this evidence had the cogency and plausibility to impact on a reasonable jury in such a way that there may have been a different verdict. Put simply, it is the prosecution's submission that these witnesses lacked any real scientific credibility to the extent that their evidence became, at times, incredible. The evidence presented by the applicant's witnesses was contrary to all current international scientific opinion. They expressed views that failed to take into account, modern scientific developments, particularly in the area of molecular biology. Their evidence was illogical, at times, unintelligible and presented from such a blinkered point of view that it is highly unlikely that it would have impacted on the jury's verdict.

<sup>34</sup> R v Mickelberg (1988-89) 167 CLR 273.

SXPRI

A further relevant consideration as to whether a conviction should be set aside is "whether the evidence relied upon could, with reasonable diligence, have been produced by the appellant at trial" Whilst the courts have held that this is not a "universal and inflexible requirement" it is still a relevant

consideration to be taken into account. This is particularly so when the whole of the applicant's argument relies upon the assertion that this is a legitimate scientific debate that remains unresolved in the international arena. The witnesses relied upon claimed to have been engaged in this "debate" for the better part of two decades. One would have thought that in those circumstances the evidence was readily available for presentation at the applicant's trial.

3. IT HAS NOT BEEN ESTABLISHED THAT THERE IS A GENUINE SCIENTIFIC DEBATE IN RELATION TO THE ISSUES RAISED BY THE WITNESSES FOR THE APPLICANT, NAMELY:-

# 3.1 HIV HAS NEVER BEEN PROVED TO EXIST

#### Montagnier's first experiments

3.1.1 On 20 May 1983 Professor Luc Montagnier published a paper entitled 
"Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for 
Acquired Immune Deficiency Syndrome ("AIDS"). This paper is 
recognised in the global scientific community as providing the first 
evidence of the Human Immunodeficiency Virus ("HIV").

36 Ibid.

<sup>35</sup> Gallagher v The Queen (1986) 160 CLR 392 at 395; Winslett v The Queen (1992) 60 SASR 1 at 3

Of particular significance was Montagnier's detection of enzyme activity, namely reverse transcription.<sup>37</sup>

- 3.1.2 The paper did not purport to provide a definitive and complete account of the virus thereby alleviating the need for any further research or investigation into HIV, but was of enormous significance insofar as it identified a novel retrovirus that was associated with the clinical syndrome of AIDS.<sup>38</sup>
- 3.1.3 Montagnier's initial paper in 1983 was followed by a series of five papers in 1984 published by Professor Robert Gallo outlining further research and demonstrating significant scientific progress in relation to the virus. Of particular importance was Gallo's achievement in being able to "isolate" or mass produce HIV by way of virus culture.<sup>39</sup>
- 3.1.4 Montagnier and Gallo's papers of 1983 and 1984 in combination, are therefore considered to be the initial ground breaking research which resulted in the discovery and identification of HIV and also provided the basis for diagnostic testing.
- 3.1.5 The applicant places great weight on alleged limitations in Montagnier's initial research as the basis for the assertion that HIV has not been proven to exist. This fails to recognize the enormous body of research and scientific progress in the area of HIV which has

<sup>&</sup>lt;sup>37</sup> Exhibit A17.

<sup>&</sup>lt;sup>38</sup> T948, 1001-1002.

<sup>&</sup>lt;sup>39</sup> T1255-1257.

subsequently arisen out of these initial findings over the past two decades. It is misleading and inaccurate to simply deny or omit more recent achievements in the area of HIV from any debate relating to the existence of the virus.<sup>40</sup>

- 3.1.6 Similarly, the applicant has repeatedly relied on remarks made by Montagnier in an interview given to Djamel Tahi in 1997 in support of the fact that HIV has not been isolated or "purified" and therefore not been proven to exist. It is submitted that reliance on this interview is inappropriate and misleading in light of the following:
  - (i) the interview itself is hearsay and inadmissible;
  - (ii) it is unclear whether the extract of the interview provided by the applicant comprises the entire interview, nor are the circumstances or the context in which the interview was given able to be ascertained;
  - (iii) contrary to the assertions made by the respondent, the views expressed by Montagnier in the interview do not support the respondent's position insofar as:
    - Montagnier disagrees with the definition of isolation adopted by the respondent and states that the criteria for isolation have been achieved in relation to HIV;
    - Montagnier claims that isolation of retroviruses does not require purification;

<sup>&</sup>lt;sup>40</sup> T821, 823, 892, 1150, 1206.

- Montagnier states that these days characterization of a virus is achieved by genetic cloning and sequencing;
- Montagnier confirms electron micrograph pictures of HIV exist;
- Montagnier states it is clear that HIV exists, that he has seen it and encountered it.<sup>41</sup>

#### **Virus Isolation**

- 3.1.7 It is submitted that the applicant's assertion that HIV has never been isolated and therefore does not exist, is grossly inaccurate, without scientific foundation and unsupported by the international scientific community.
- 3.1.8 There are a number of ways in which a virus can be isolated. Indeed, there exists a whole microbiology and considerable literature on the purification of viruses.<sup>42</sup>
- 3.1.9 "Virus isolation", as it is most commonly referred to, is a routine technique whereby a clinical sample containing virus is added to a cell culture in order for it to replicate and produce free virus at the end of the culture which can then be assessed and measured. In this way a virus is able to be mass produced and said to be purified. Virus isolation is also commonly known as "virus culture". 43
- 3.1.10 HIV was first isolated, and purified, in 1984 by Professor Robert Gallo who was able to mass produce the virus by adapting it to permanently

<sup>&</sup>lt;sup>41</sup> Exhibit A3, A5. T7, 52, 69-71, 822, 1176-1177.

<sup>&</sup>lt;sup>42</sup> T847-848.

<sup>&</sup>lt;sup>43</sup> T953, 1214, 1256-1267, 673, 688, 789, 816, 1210, 1224.

growing cell lines. Indeed, out of 48 HIV virus isolates, Gallo succeeded in growing 6 in permanently continuous culture. HIV has been routinely isolated worldwide since that time.<sup>44</sup>

3.1.11 Any argument advanced by the applicant that HIV has not been isolated based on Montagnier's initial 1983 paper fails to take into account Gallo's subsequent achievements and those of innumerable scientists since that time and it is a misrepresentation of the Montagnier

paper which showed electron micrographs of the virus growing from

For example, the applicant has repeatedly alleged that Montagnier's 1983 detection of enzyme activity, namely reverse transcription, did not amount to isolation and that therefore HIV can not be said to exist. This is a misleading assertion insofar as it is based solely on experiments conducted over 20 years ago which have since been superseded. The argument is clearly implausible and unsustainable in light of current isolation and molecular techniques.<sup>45</sup>

3.1.12 Virus isolation for any virus (including HIV, measles, rubella and influenza) does not require that the virus be separated from the culture medium. A virus can be identified in a cell culture, measured, photographed and genetically sequenced, despite the presence of other cellular proteins or other cellular debris.

patient material.

<sup>&</sup>lt;sup>44</sup> T1257-1258.

<sup>&</sup>lt;sup>45</sup> T1256, 1258, 1260-1262, 673, 822-823, Exhibit P86.

virus isolation to ensure that the growth of the virus is pure and not A range of controlled tests are carefully conducted during the course of contaminated.

Therefore, there is no scientific basis for requiring further purification after replication of the virus in the cell culture or to allege that all cellular debris must be removed to ascertain whether a particular virus is present in a cell culture.<sup>46</sup>

- 3.1.13 It is submitted that the applicant's requirement of viral isolation or "purification", namely separation of a virus from all other cellular debris prior to the identification of a virus, is not supported by scientific evidence or practice, and is severely flawed on the following bases:
  - given the nature of viral replication, all viruses retain some (i) cellular debris from the host cell. A retrovirus comes out of its integrated DNA state in the host chromosome, undergoes "reverse transcription" to RNA and buds out of the host cell. In so doing, HIV and all viruses incorporate some host cell proteins. Therefore, no virus can ever be said to be pure of all other host cellular material. As Professor Gallo said in relation to Ms Papadopulos-Eleopopulos' requirement for "purification":

<sup>&</sup>lt;sup>46</sup> T852, 956-958, 973-974, 976.

"The witness shows a complete lack of understanding because a sucrose gradient barely purifies. She is always talking about purifying it into a gradient and then you have to do that to copurify. The court should know that a retrovirus comes out of chromosome membrane. In so doing, it incorporates some cellular proteins in the virus. You could do it until hell freezes over and you get viral proteins" "47;

- (ii) it ignores the ability to mass produce the virus in a continuous culture which accomplishes virus purification insofar as it is possible to produce masses of virus with only small amounts of cell;<sup>48</sup>
- (iii) it does not reflect advancements in molecular technology whereby the exact genes of the virus can be cloned resulting in "pure" virus.<sup>49</sup>
- 3.1.14 With respect to HIV, virus isolation is not routinely undertaken for diagnostic purposes due to the time and expensive involved in the process and has now primarily been superseded by nucleic acid testing. However, isolation of the HIV virus is routinely undertaken for the purpose of HIV research, including vaccine development, which require mass production of the free virus and also in the confirmation of HIV infection in the newborn. 50

<sup>&</sup>lt;sup>47</sup> T950-951, 1257-1258, 1277.

<sup>&</sup>lt;sup>48</sup> T1258, 1278.

<sup>&</sup>lt;sup>49</sup> T1258-1259, 1283.

<sup>&</sup>lt;sup>50</sup> T953-954, 1246-1247.

# **Electron Microscopy**

- 3.1.15 Numerous electron micrographs have been taken of the HIV virus. In 1983 Montagnier first published electron microscope pictures of white cells producing virus. <sup>51</sup>
- 3.1.16 Gallo's laboratory also published pictures of the virus in the series of papers published in 1984 and has published many pictures since.<sup>52</sup>
- 3.1.17 The first published report of HIV actually being seen in human tissues was by John Armstrong, a pathologist specializing in electron microscopy, in an article in the Lancet in 1984.<sup>53</sup>
- 3.1.18 These photographs have improved since the initial discovery of HIV in 1983 due to technological improvements in the area of electron microscopy. In more recent times, photographs of purified HIV virus have been taken which depict the core and structure of the virus, and include the virus within host cells and budding from host cells. Many electron micrographs of the virus can be found in the scientific literature and textbooks.<sup>54</sup>

#### Nucleic Acid Testing - Genetic Sequencing

3.1.19 The core part of any virus contains genetic material, namely RNA or DNA. In the case of HIV, the genetic material is comprised of RNA

<sup>&</sup>lt;sup>51</sup> T1214 Exhbit A17. Ms Papadopulos-Eleopopulos claims that Montagnier did not publish any picture of the virus in the culture (T25). This is clearly incorrect as can be seen from p869 of Montagnier's 1983 paper. <sup>52</sup> T1283, 1300, 1302-1304. Exhibit P86.

<sup>&</sup>lt;sup>53</sup> T790.

<sup>&</sup>lt;sup>54</sup> T951-953, 673, 690, 790, 838-847, 1148-1149. Exhibits P70, P62, P63, P63A, P64, P70, P91, P16.

- 3.1.20 Nucleic acid testing is a method by which the genetic material of a virus is identified. It is a technique distinct from viral isolation or viral culture and represents a revolution in molecular biological techniques whereby small amounts of genetic material are amplified, manipulated and sequenced.<sup>55</sup>
- 3.1.21 Using nucleic acid methods, the whole genome or genetic sequence of the HIV virus has been identified. The entire HIV genome was sequenced and published by Professor Robert Gallo in 1985, some two years after Montagnier's first identification of the HIV virus.<sup>56</sup>
- 3.1.22 Nucleic acid technology has progressed to the extent that a whole HIV genome can now be sequenced within 48 hours. Indeed, tens of thousands of copies of the full length of the HIV genome have been identified and stored in databases around the world, one of the largest databases being in Los Alamos in the United States.<sup>57</sup>
- 3.1.23 The genetic structure of HIV is complex and consists of "conserved" parts of the genome which are unique to HIV and do not change, and other parts of the genome which are capable of variation and mutation.

  Both are able to be identified and sequenced. <sup>58</sup>
- 3.1.24 As a result, a number of different strains or "clades" of the HIV virus have been identified. Genetic sequencing of these strains can now be used to track the epidemiology of HIV it is possible to track the

<sup>55</sup> T689.

<sup>&</sup>lt;sup>56</sup> T689, 791, 1259, 1279.

<sup>&</sup>lt;sup>57</sup> T673, 791, 959-960, 1259.

<sup>&</sup>lt;sup>58</sup> T855, 960-963.

movement of people with HIV infection around the world by looking at the various parts of the genome to identify where different strains emerge. This has become extremely important in understanding the epidemiology and public health implications of infection.<sup>59</sup>

- 3.1.25 Nucleic acid testing is now commonly used in a HIV diagnostic setting given its reliability, cost effectiveness and the speed with which it can be performed. Nucleic acid tests are used to assess the extent or burden of infection (viral load) and these tests are routinely applied in managing treatment as well as diagnosis. Virus isolation is rarely undertaken routinely for clinical purposes.<sup>60</sup>
- 3.1.26 The identification of the full HIV genome now allows a molecular clone of the HIV virus to be made. HIV antibody tests are now done with recombinant proteins generated from molecular clones, representing a significant advance.<sup>61</sup>
- 3.1.27 Our knowledge and research into the genetic structure of HIV has progressed to the extent that candidate vaccines are now being developed which are intricate enough to produce antibodies that block the entry of the virus into the cell and also address the problem of the genetic variability of the virus.<sup>62</sup>

<sup>59</sup> T855, 965-966.

way be

<sup>&</sup>lt;sup>60</sup> T962-963.

<sup>61</sup> T976, 1159, 1209.

<sup>62</sup> T1246-1248.

- 3.1.28 A virus does not need to be purified to the extent that there is only the viral protein present in order to detect the genetic sequence of the virus.<sup>63</sup>
- 3.1.29 It could be argued that genetic testing has now become the ultimate "gold standard" in HIV diagnosis.<sup>64</sup>

# **Endogenous Retroviruses**

- 3.1.30 There is no merit or scientific basis for the argument that in the absence of further "purification" the retrovirus HIV could be mistaken for an endogenous retrovirus when undertaking current virus isolation techniques, on the basis of the following:
  - (i) There are very few endogenous retroviruses which can themselves be cultured most endogenous retroviruses consist of small amounts of genetic material, are incomplete retroviruses and are not replication competent;
  - (ii) it has never been demonstrated that that an endogenous 7
  - (iii) unlike HIV, endogenous retrovirus particles of humans have never transmitted to another cell in artificial culture;
  - (iv) It is molecularly straightforward to distinguish endogenous retroviral sequences from HIV. The genome of endogenous

<sup>63</sup> T998.

<sup>&</sup>lt;sup>64</sup> T919-920, 1219. The respondent does not accept that there is a requirement for a gold standard as described by Dr Turner.

retroviral particles is also already known in sequence and it is not the same as the HIV genome.<sup>65</sup>



#### **P24 Protein**

3.1.31 Likewise, the argument made by the applicant that the presence of the P24 protein is not indicative of the specific HIV virus is without scientific foundation. A P24 protein is part of the core of a virus which has a molecular weight of 24. Whilst other retroviruses may have other proteins also with a molecular weight of 24, there is a P24 protein unique to HIV whose genetic structure is distinct and identifiable.<sup>66</sup>

#### **Does HIV Cause AIDS?**

- 3.1.32 In the mainstream global scientific community, the scientific debate as to whether HIV was the cause of AIDS was over by the mid 1980's.<sup>67</sup>
- 3.1.33 At a press conference on 23 April 1984, the Secretary of Health of the United States announced that the cause of AIDS was known. The announcement was based on research conducted by Professor Robert Gallo and his colleagues which was later published in a series of five articles throughout 1984.<sup>68</sup>

<sup>65</sup> T703, 998, 1204, 1260, 1275-1276, 1298.

<sup>&</sup>lt;sup>66</sup> T792, 702-703, 871.

<sup>&</sup>lt;sup>67</sup> T949, 1259-1260.

<sup>68</sup> T1254-1255, P86.

- 3.1.34 It has been argued that there is no disease of microbial origin for which there is more evidence of causation than there is for HIV being the cause of AIDS.<sup>69</sup>
- 3.1.35 That HIV is the cause of AIDS was confirmed in 2000 by the international medical/scientific community in a document known as the Durban Declaration. The declaration was stimulated by the controversy in South Africa as to whether HIV was the cause of AIDS.

  There were some 5000 signatories to the declaration, including Nobel prize winners, directors of leading research institutions and thousands of scientists of MD, PhD level or equivalent. 70
- 3.1.36 Likewise, the United Nations and the World Health Organisation also accept and acknowledge that HIV is the cause of AIDS. Indeed, the United Nations resolved to form a special branch of the UN, namely UN AIDS, in which all UN agencies would be represented to promote the cause of HIV/AIDS around the world and address the epidemic. In 2001, a special session of the United Nations General Assembly was convened solely to address the issues relating to the AIDS epidemic.<sup>71</sup>
- 3.1.37 A person is diagnosed with AIDS if they have had a positive HIV specific antibody test and demonstrate clinical evidence of an impaired

<sup>&</sup>lt;sup>69</sup> T1281-1282.

Ms Papadopulos-Eleopopulos' response to the Durban Declaration was to claim "It is nothing, it is a consensus of specialist people who don't know anything about the subject", despite later admitting that she had never actually looked at the list of signatories. T217, 229; P6.

T667-668, 230; Exhibits P5, P8.

immune system. It is absolutely necessary that a person be infected with HIV to be diagnosed with AIDS.<sup>72</sup>

- 3.1.38 One of the most definitive pieces of evidence confirming that HIV is the cause AIDS is the overwhelming success of antiretroviral therapy in the treatment of AIDS. 73
- 3.1.39 Maternal to child transmission is now virtually non-existent in the industrialized world thanks to the use of antiretroviral therapy.

  Professor Cooper notes that "...this is one of the triumphs of antiretroviral therapy". 74
- 3.1.40 A long term study in Europe, the EuroSIDA study, followed the course of almost 10,000 people with HIV infection and demonstrated that the rates of AIDS and death declined substantially after combination antiretroviral therapy.<sup>75</sup>
- 3.1.41 The AIDS epidemic in South Africa has been exacerbated by the delay in the provision of antiretroviral therapy to persons infected with HIV. The recent introduction of antiretroviral therapy by the South African government is beginning to have a positive affect on the epidemic.<sup>76</sup>, <sup>77</sup>

<sup>73</sup> T1221-1222, 806, 1261.

<sup>75</sup> Exhibit P51. T806-807.

<sup>77</sup> For a discussion as to the effects of the AIDS dissidents' argument on the AIDS epidemic in South Africa, see P46. T679.

<sup>&</sup>lt;sup>72</sup> T986, 989, 694-696.

Further evidence regarding the success of antiretroviral therapy with respect to maternal to child transmission can be found in the study P31; T686.

<sup>&</sup>lt;sup>76</sup> Curiously, Ms Papadopulos-Eleopopulos denies the existence of an AIDS epidemic in South Africa claiming "There is no massive epidemic in South Africa. There is a massive epidemic of HIV testing and of positive tests but there is no massive epidemic of HIV infection because nobody has proven it". T226, 679.

- 3.1.42 A recent study into the effectiveness of antiretroviral therapy demonstrated that intermittent antiretroviral therapy resulted in the onset of disease and death two and a half times faster than continuous antiretroviral therapy.<sup>78</sup>
- 3.1.43 The drugs used in antiretroviral therapy have been engineered to specifically interact with the structure of HIV and not any other virus, providing another example of the significance of the ability to genetically sequence the virus.<sup>79</sup>
- 3.1.44 In relation to the success of antiretroviral therapy Dr Dwyer noted:
  "Now, I don't want to sort of be anecdotal here, but the greatest thing that I have seen in my career in infectious diseases has been the event of drugs for the treatment of HIV. It has changed clinical practice from looking after people dying of a nasty, unpleasant illness with nasty symptoms to cancer (sic) with healthy people coming to get their script and going off to work or home, whatever it might be. I know-I came after the antibiotic era, but I must say, for the antiretroviral era, it has been a most dramatic thing and all of that is underpinned on the fact that the virus is there, that the virus can be treated and that people will get better."
- 3.1.45 It is submitted that no scientific basis has been established by the applicant requiring HIV to be further "purified" over and above current

<sup>&</sup>lt;sup>78</sup> T669-670.

<sup>&</sup>lt;sup>79</sup> T807.

<sup>80</sup> T1221-1222.

methods of virus isolation, nucleic acid testing and genetic sequencing, before the virus can be identified and said to exist.

Indeed, it is fanciful to suggest that HIV has not been proven to exist in an era when the entire genome of the virus has been identified and sequenced.

# 3.2 IT HAS NOT BEEN PROVED THAT HIV IS SEXUALLY TRANSMISSIBLE

- 3.2.1 Ms Papadopulos-Eleopopulos gave evidence that it has not been proved that HIV (if it exists) can be sexually transmitted. She also appeared to go further and say that there is no proof of other forms of transmission of the virus ie, mother-to-child or through blood transfusions. She offered the court an alternative theory as to how it is that someone may test positive to an HIV antibody test as a result of practising receptive anal intercourse.<sup>81</sup>
- 3.2.2 It is the respondent's submission that Ms Papadopulos-Eleopopulos is demonstrably wrong in all aspects of her evidence on this topic. As she herself said "there are most probably about maybe more than 100,000 articles where the authors say heterosexually transmitted AIDS" There was not one single study or article that she could point to in which the authors supported the proposition that HIV cannot be heterosexually transmitted and there were certainly no

T389-390. This theory seems to be that semen is full of proteins or antigens so the more frequent the anal intercourse is and the more traumatised the gut is, the more foreign antigens you have going into the body (it's not clear why this has to result from anal penetration as opposed to vaginal penetration). This results in a positive HIV antibody test.

82 T346

studies or any support put forward for her somewhat bizarre alternative theory.

3.2.3 Professor John Kaldor, an experienced Epidemiologist who has been working in the area of HIV for the better part of two decades, perhaps best summarised the situation in relation to proof of sexual transmission when he said the following:-

"Q: In your view, has it been proved that HIV can be sexually transmitted.

- A: Absolutely.
- Q: What do you base that on.
- A: There's a range of lines of evidence. As I alluded to before, there was some early case reports showing linked pairs of AIDS cases before we knew there was HIV, then there's a whole range of other types of evidence that came together. We know, from experience, that when a disease is sexually transmissible, it tends to occur more in groups of people who have more sex or more sex partners. For example, a sexually transmissible disease would be more likely to be more common with women who did sex work, or more common in gay men, if they're having multiple partners, or more common in heterosexuals who have more partners. Cross-sectional studies, which simply looked at different groups of people and said 'what is the proportion of HIV, and how does that relate to different types of sexual history' started to create a picture of what looked like a sexually transmissible infection. That is one further element and it is

a bit like the case reports or paired cases - it is not utterly conclusive, in itself, but it starts to add further evidence. Over time, several key prospective studies were done, which really confirmed those early findings and put beyond anybody's reasonable doubt that this was a sexually transmissible infection and there is a couple of key ones: the one by Isabella de Vincenzi, which I think you have a copy of somewhere. That is a study that prospectively looked at the sexual partners of HIV-positive people and showed, pretty conclusively, for example; the couples who used condoms all the time never transmitted, the couples that used condoms more than half the time transmitted, to some degree, and the couples who used condoms less than half the time transmitted more. It was almost like a dosed response: the less used condoms, the more you transmit. That is a pretty strong suggestion of sexual transmission" 83

3.2.4 Ms Papadopulos-Eleopopulos purported to rely on a number of the early studies in support of her argument that heterosexual sexual transmission has not been established. As has been dealt with elsewhere, this was a misrepresentation of the full contents of the article and the view of the authors. Important details of the circumstances of and limitations to the studies were omitted eg, the extent of condom use. There was not one study or author upon which the witness relied that supported her theory about sexual transmission. When this was put to Ms Papadopulos-Eleopopulos in cross-examination she responded by saying "which is the author, could you

<sup>&</sup>lt;sup>83</sup> T1114-1115.

please tell me?" Later when she was again asked whether she agreed that not one of the authors of the reports that she relied upon agreed with her conclusion that HIV is only transmissible via receptive anal intercourse, she said "It's not my conclusion, it's their conclusion". "No, I put their conclusion. Their conclusion is passive anal intercourse. Passive anal intercourse. All the studies in gay men and heterosexuals end up by saying passive anal intercourse. It's not my conclusion, its their conclusion and we quoted them." 85 This was just not true.

3.2.5 Another aspect of the approach adopted by Ms Papadopulos-Eleopopulos was when she was confronted with data or results from studies that were inconsistent with her views she reverted to claims that the studies were flawed and that the participants of the studies must have lied. Professor Kaldor responded to that approach in the following answer:-

"I think it reflects the fact that - these prospective studies are difficult undertakings and, as I have indicated before, they're not perfect watertight evidence - they prove things, to the point that you want to act, in a public health sense, but you can always pick some little flaw. There's always some imperfection of a study you can point to and one classic one of these studies is they do rely on what people tell you about their sexual behaviour - we don't have a study that goes into people's bedrooms to photograph them and prove what they do

<sup>84</sup> T425(9)

<sup>85</sup> T425 (28)-(34)

sexually, on that basis, and there is no blood test to prove what kind of sex people have. We always have to rely on people telling you what they do. Having said that, these studies are done by very experienced professionals, who work through different methodologies of gaining people's trust. What they tell you is confidential and it is not going to be used in some adverse way. There's a lot of thought and effort put into gaining information from people, in a way to be as accurate as possible. If anything, we know epidemiology of people. If they distort in different ways, it tends to reduce the likelihood of finding any difference in the groups, whereas we do see a difference in the groups here. It is plausible, but not likely that - it is remotely possible, but highly unlikely that these distortions would have had any serious effect on the conclusions". 86

- 3.2.6 There are many epidemiological studies which, in combination with other evidence, establish that HIV is heterosexually transmissible. Data collected by UNAIDS has established that internationally, more new cases of HIV have resulted from heterosexual transmission than via any other route. In 2006 there were one million more women diagnosed as HIV positive than in 2004.<sup>87</sup>
- 3.2.7 More recent studies in relation to the heterosexual transmission of HIV include the studies conducted in Rakai, Uganda. These were

<sup>&</sup>lt;sup>86</sup> T1116.

<sup>&</sup>lt;sup>87</sup> P5 at p3-5.

prospective<sup>88</sup> studies that looked at the heterosexual transmission of HIV between discordant couples. The results of this study demonstrated a very strong relationship between the amount of virus in the HIV positive partner and the chance of transmission<sup>89</sup>. In one study, 90 out of 415 HIV negative partners seroconverted and became HIV positive<sup>90</sup>.

- 3.2.8 A further study that was referred to during the evidence of Professor Kaldor was a study conducted in Thailand that came about as the result of a rapid increase in HIV amongst the Thai military. As a consequence of this the Thai Government introduced a "100% condom campaign" in which they convinced the brothels (which were patronised by military men) to enforce very high levels of condom use, coupled with an educational campaign. The consequence of this was a rapid decline in the number of military men being diagnosed as HIV positive over about two or three years<sup>91</sup>.
- 3.2.9 A recent study demonstrating sexual transmission was referred to during the evidence of Professor Gordon. This was a study of people who worked in the pornographic film industry<sup>92</sup>. Given that the practice in that industry was to perform regular HIV tests once a

In the hierarchy of studies, Professor Kaldor described this as being the second best level of study after a randomised control trial. As should be self evident there are clearly important ethical considerations in relation to studies of this type into the transmission of HIV T1105.

<sup>&</sup>lt;sup>89</sup> T1117 and Exhibits P43, 44, 78.

<sup>&</sup>lt;sup>90</sup> P78.

<sup>&</sup>lt;sup>91</sup> T1122-1123.

<sup>&</sup>lt;sup>92</sup> P74.

month, it enabled those conducting the test to trace the transmission after a male participant tested positive. During the relevant time the male had 13 sexual partners of which three became HIV positive. Importantly "molecular and virological data indicated that these viruses were 100% identical." <sup>93</sup>

3.2.10 Another group of studies referred to by the respondent's witnesses were studies that looked at the effect of circumcision on men contracting HIV from having sexual intercourse with HIV positive women<sup>94</sup>. A randomised control trial<sup>95</sup> was undertaken in an area in which circumcision was not a routine practice. Men were randomly allocated a computer number that determined whether they were to be circumcised straight away or two years later. From that study, it was determined that the transmission of HIV to the men was reduced by 60% with circumcision. As Professor French observed "I cannot think of any other explanation for that finding other than that HIV is sexually transmitted." The authors of the report on this study concluded that male circumcision could avert two million new HIV infections and 0.3 million deaths over the next ten years in sub-Saharan Africa. In the ten years after that, it could avert a further 3.7 million new HIV infections and 2.7 million deaths. <sup>97</sup>

<sup>93</sup> P74 p303.

<sup>&</sup>lt;sup>94</sup> P45

<sup>&</sup>lt;sup>95</sup> Professor Kaldor described this sort of study as being at the top of the hierarchy of epidemiological studies T1105.

<sup>&</sup>lt;sup>96</sup> P45 and T798.

<sup>&</sup>lt;sup>97</sup> Ibid.

- Ms Papadopulos-Eleopopulos disagreed that the findings in relation to circumcision were support for the proposition that HIV is sexually transmissible. She came up with an alternative explanation that this could be as a result of women being exposed to smegma found under the males' foreskin. This however completely missed the point in that the studies related to a decrease in the transmission from women to men.
- As well as the evidence of the epidemiological studies there was evidence from the witnesses called by the respondent about their own clinical experience in treating people who have become HIV positive through heterosexual sexual intercourse. Professor Cooper described his own experience in the following way:-

"I care for about four or five hundred HIV infected people at any one time. I've probably cared for two and a half thousand HIV infected people over my career, and it is a pleasure to take care of these people and, you know, we get to know each other and we get to hear their stories and it is extraordinary the number of patients I've had that have been infected on their first sexual exposure, even on the occasion of their sexual debut." In such circumstances it is unhelpful to attempt to come up with a mathematic equation in an attempt to formulate how many sexual contacts are required for HIV transmission.

<sup>&</sup>lt;sup>98</sup> T680.

- In her evidence, Ms Papadopulos-Eleopopulos suggested that to prove sexual transmission of HIV, the virus must be found in genital secretions. Dr Dwyer gave evidence that this has occurred many times. He said "You can find HIV in saliva, you can find HIV in vaginal secretions and seminal fluid and semen, you can find it in the cells in those bodily fluids and you can also take those cells out and find it free in non-cellular material. I couldn't say now where but I have seen, again, electron microscopic pictures of semen with viral particles in them. It must be remembered that genital secretions and saliva and things like that are really made up of many components that are in blood for that matter and plasma and there is no doubt in my mind that viruses present often in very high levels in those bodily fluids."99
- 3.2.14 It is submitted that there is an overwhelming body of evidence that HIV is sexually transmitted and as a consequence Australian and world health initiatives are based on this premise.
- A further piece of evidence in support of sexual transmission is the evidence about the applicant's own situation. After being diagnosed as HIV positive he commenced a sexual relationship with Simone Crispin. Ms Crispin was not involved in any other sexual relationships during this time nor was she in any other risk group.

  She subsequently tested positive for HIV. Within a few years of diagnosis, at a time when Ms Crispin's immune system started to

<sup>&</sup>lt;sup>99</sup> T972. Dr Gordon also gave evidence about the presence of the virus in genital secretions at T1021-1022.

drop away very rapidly, she became extremely unwell to a point that her life was at risk<sup>100</sup>. Ms Crispin's virus was compared with that of the applicant. Out of the 550 viruses on the IMVS data base Ms Crispin's most closely matched that of the applicant.<sup>101</sup> As Dr Higgins said in his evidence at trial, the inference can then be drawn is that they are related to each other in terms of transmission.<sup>102</sup>



### OTHER METHODS OF TRANSMISSION OF HIV

- 3.2.16 Ms Papadopulos-Eleopopulos also asserted that HIV has not been proven to be transmissible via other routes, namely mother-to-child transmission and transmission as a result of blood transfusions. There is now a very large body of evidence that establishes that HIV is transmissible in these two ways. 103
- 3.2.17 Professor Cooper<sup>104</sup>, Professor Gallo<sup>105</sup>, Professor Kaldor<sup>106</sup> and Professor McDonald<sup>107</sup> all gave evidence about how people had previously been infected with HIV as a result of a blood transfusion and how this has now been eradicated in the western world. In her evidence, Ms Papadopulos-Eleopopulos suggested that a blood transfusion of itself could cause a positive HIV antibody test or

<sup>&</sup>lt;sup>100</sup> TT Professor La Broy at 129-131.

<sup>&</sup>lt;sup>101</sup> TT Dr Higgins at 249-251. Dr Higgins explained that in statistical terms, Ms Crispin was about 1% variant from the applicant. The closest unrelated sequence had a 4% variance.

<sup>102</sup> TT251.

There is also a developing body of evidence that it is transmissible in other ways. An example of this is the "Russian Sailor Case" that Professor French gave evidence about (P12) "Intrafamilial transmission of HIV 1 infection from individuals with unrecognised HIV 1 infection by Martyn French and others."

<sup>&</sup>lt;sup>104</sup> T675 and P54. <sup>105</sup> T1254 and P82.

<sup>&</sup>lt;sup>106</sup> T1139.

<sup>&</sup>lt;sup>107</sup> T1351.

alternatively, people who are given blood transfusions are sick so they are likely to die anyway. She said "blood transfusion will lead to a positive test and people who are given blood transfusion they are sick, and they will die. In fact, the vast majority die within a year..." 108 What Ms Papadopulos-Eleopopulos failed to take into account or explain was the change in pattern from a period of many people testing HIV positive shortly after a blood transfusion to one in which such a scenario is now unheard of in the western world. 109 It also fails to explain how viral tracing such as occurred in the Sydney surgeon case 110 can take place.

- 3.2.18 Ms Papadopulos-Eleopopulos also did not appear to accept that it has been established that HIV can be transmitted by a mother to her unborn child. She went on to give an example "If a child dies in Africa from diarrhoea and it tests positive, it dies from HIV infection.

  African children, you know, they die from diarrhoea all the time." 111
- 3.2.19 Professor Cooper gave evidence of his experience of mother-to-child transmission of HIV and of how the rate of transmission reduced from

<sup>108</sup> T288-289.

<sup>&</sup>lt;sup>109</sup> In his report of 31 January 2007, (P73) Prof Gordon provides some statistics from the United States. In the mid-1980's at least half of the haemophiliacs in the USA (8,000 persons) and 12,000 recipients of blood transfusion in the USA had acquired HIV and now almost all of them have died. HIV has now been effectively abolished amongst these groups.

<sup>110</sup> T712-714 and 1015. See also, further studies of the "cluster" or "pattern" of viruses P74 "Epidemiologic Investigation of a Cluster of Workplace HIV Infections in the Adult Film Industry" Los Angeles, California, 2004 and P12 "Intrafamilial Transmission of HIV-1 Infection from Individuals with Unrecognized HIV-1 Infection."

<sup>&</sup>lt;sup>111</sup> T430.

20% - 25% to almost none in the developed world with the introduction of antiretroviral medication. 112

He also gave the particular example of a massive change of police in the World Health Organisation in encouraging women to bottle feed rather than breast feed where it could be done so safely<sup>113</sup>. Dr Gallo<sup>114</sup> and Professor McDonald<sup>115</sup> also gave evidence of their own observations of and involvement in the use of antiretroviral medication to remove the risk of transmission of HIV from mother-to-child.

Professor McDonald told the court of his own involvement in a project conducted in Thailand and Cambodia that involved the provision of antiretroviral medication to HIV positive pregnant women in order to prevent the transmission of the virus to the unborn child. This had the consequence of children being born without the virus but becoming orphans within a year or so as the result of their mothers dying of AIDS. As a consequence of this the United Nations' Global Fund has committed to providing treatment for HIV positive mothers. <sup>116</sup>

<sup>&</sup>lt;sup>112</sup> T686.

<sup>&</sup>lt;sup>113</sup> T687.

<sup>&</sup>lt;sup>114</sup> T1254-1255.

<sup>&</sup>lt;sup>115</sup> T1329-1330.

<sup>&</sup>lt;sup>116</sup> T1330.

# 3.3 UNRELIABILITY OF HIV TESTS

Each of the expert witnesses who gave evidence for the respondent spoke highly of the reliability, specificity and sensitivity of the HIV antibody tests. They said the following:-

<u>Professor David Cooper AO</u> (in the context of it being suggested that the ELISA and Western Blot tests are not reliable):-

"Right. Again that is absolutely wrong. Diagnostic tests in medicine are sometimes problematic and we say that diagnostic tests should be sensitive and specific, and, you know, diagnostic medicine is sometimes not easy because we don't have the best tests for diagnosis to include a disease or to exclude a disease. In this case, we have one of the best tests ever. There is no diagnostic test in medicine that has the sensitivity and specificity of the HIV antibody test, whether it is done by ELISA or by Western blot. The test is 99. – very close to 99.9% sensitive and 99.9% specific. So there is no better diagnostic test in medicine that I know of." 117

## Professor Martyn French:-

"I base it on, I have to admit no personal experience but data I have read in the literature that shows that these tests are highly specific and sensitive and I suppose anecdotal experience that I have, in my

<sup>117</sup> T674-675.

20 years of experience in HIV medicine, very, very rarely seen false positives or false negatives." 118

# Associate Professor Elizabeth Dax AM:-

"There's a huge amount of clinical, epidemiological, blood transfusion-generated, molecular techniques generated evidence that suggests that these HIV tests are highly sensitive, specific, predictive, operate under with great precision and follow high quality mechanisms of preserving their ongoing performance." 119

"Its very intricate these days, it really is. It's brilliant." 120

## Dr Dominic Dwyer:-

"But I must say, to be honest, the ability of the current commercial assays to distinguish specific antibody versus non-specific binding is much better with HIVs than it is with many other systems." 121

and:

"I think in fact the antibody testing has proven to be extremely reliable, specific and sensitive, as Dr Dax described it, when tested against molecular testing." 122



<sup>&</sup>lt;sup>118</sup> T793

<sup>&</sup>lt;sup>119</sup> T1162.

<sup>&</sup>lt;sup>120</sup> T835

<sup>&</sup>lt;sup>121</sup> T1217.

<sup>&</sup>lt;sup>122</sup> T1219.

### Professor David Gordon:-

"The ELISA antibody test when strongly reactive is, in my experience over 25 years, never ambiguous and always indicates HIV infection.

HIV virus can virtually always be detected in such cases. It is true that a small percentage of people have very weak reactions in the ELISA test and have a 'false positive result'. This is the case for all serological and virtually diagnostic tests."123

### Professor John Kaldor:-

"The antibody test for HIV is one of the most well characterised tests in modern medicine." 124

# Professor Robert Gallo:-

"That test has been verified world-wide except in the minds of the witness, not Dr Turner - I guess Dr Turner too - but everyone else in the world that an ELISA test followed by a Western blot will score with enormous sensitivity and enormous precision." 125



#### Emeritus Professor Peter McDonald AM:-

"I spent a lot of my time engaged in debates about how low the barrier should be put and at what level of false positives would we accept it, and, ultimately, the whole problem got solved, as it were, when cloned proteins were used, because the level of cross-reacting

<sup>&</sup>lt;sup>123</sup> T73.

<sup>&</sup>lt;sup>124</sup> T1133.

<sup>&</sup>lt;sup>125</sup> T1279.

antibody to contaminating proteins was – it was no longer a problem, and that's the point at which the tests went from 95, 96% sensitive and specific up to 99.5 or 9, but, from my perspective, it was an important debate to have at the time and it was solved really by the cloned protein product." <sup>126</sup>

3.3.2 The observations about the reliability of the antibody tests by the respondent's witnesses are important in that each of the witnesses has significant experience in the use and development of the tests in both Australia and throughout the world. It is one thing to pick out theoretical problems arising from the use of the tests but quite another to have been involved in their development and observed their use on a regular basis. The former was the sort of approach that Professor Cooper was referring to when he said:

"They are always referring to exceptions rather than rules, and sort of very rare exceptions." 127

3.3.3 Associate Professor Elizabeth Dax is the Director of the National Serology Reference Laboratory. That institution has the responsibility for the quality of HIV, hepatitis and blood-borne viral testing in Australia. This institution also collaborates with the World Health Organisation and works together with the Therapeutic Goods Administration in determining the safety and quality of HIV test kits.

<sup>&</sup>lt;sup>126</sup> T1355.

<sup>&</sup>lt;sup>127</sup> T681.

As the Director of this institution, Dr Dax is uniquely equipped to give evidence about the sensitivity and specificity of HIV test kits. In all material respects her evidence was supported by the other expert witnesses called by the prosecution.

- 3.3.4 In 1985, at a time when scientists were still grappling with how HIV tests should be interpreted and which tests were to be used, the government set up the National Reference HIV Laboratory (later called the National Serology Reference Laboratory), to collect blood samples against which HIV tests could be conducted to evaluate their effectiveness. That sample bank has grown and become refined and currently contains up to 10,000 blood samples that are used to test the HIV test kits. 128
- 3.3.5 It was clear from the evidence of Associate Professor Dax that since the introduction of HIV antibody tests, there have been great developments in the technology underpinning these tests. She told the court that the National Reference Laboratories evaluations of these test kits are well recognised throughout the world.<sup>129</sup>
- 3.3.6 Associate Professor Dax explained to the court that the various antibody tests rest on identifying the interaction between an antigen (HIV) and the antibodies that a person produces in response. This is the case for ELISA tests and the Western blot.

T827-828. This sample bank contains negative samples, samples from people who have previously tested HIV positive with some other test and samples that have been shown to be cross-reactive. Samples are also collected from other countries to ensure that the tests are capable of detecting the different strains of HIV.

T837.

Associate Professor Dax described the four generations of HIV testing in Australia:-

"At first, in 1985, the antigen was made from cellular preparations of HIV. So when the tests were put together and the antigen was put on the plate to capture the antibody in the blood there were a lot of other proteins involved, cellular proteins because the virus was not isolated at that time, it was made from these cultures. So, in the first instance you did get much more cross-reactivity. At that time the cross-reactivity was perhaps 4 or 5%, but very quickly, as science evolved, those viral preparations were purified more thoroughly, the human proteins were taken out of the antigen preparations so that tests very quickly became more specific. Those tests were called the first generation tests, they were viral preparations made from cells. And the next generation tests, the second generation tests then used preparations of proteins that were either recombinant or synthesised. Recombinant means that you grow the protein in a cellular melior and you get the cells by various tricks to grow the protein for you, so the protein comes out of the cell, can be purified from the cell as a particular protein that is related to HIV by its genetic sequence - by its sequence. That's recombinant and synthetic means you know the sequence of the aminoacids in the proteins so you put them together in a sequencer, a special machine, and grow that protein. So once they were grown without cells those tests became more specific again, in fact their specificity was then around 99%.

When HIV 2 was isolated it became clear from the blood transfusion services that it was not acceptable not only to block the transmission of HIV 1 but HIV 2, so HIV 2 proteins were included on the plates, that's the third generation.

The fourth generation employs synthesised or recombinant antigens on the plate, this is antibody tests, and they are applied in such a way that there's a series of steps before you get the signal to denote. And this series of steps makes this test more specific, more sensitive than any other test, antibody test in history. So that's the antibody tests and they have done four generations, they are highly specific, they are highly sensitive." 130

- 3.3.7 The tests are now being developed to such a point that the National Reference Laboratory has developed a test that can distinguish early infection from late infection. That test focuses on a particular class of antibody that appears very early in HIV infection and then falls away.<sup>131</sup>
- 3.3.8 Associate Professor Dax also explained the quality assurance programs that the National Reference Laboratory puts into place to ensure that the laboratories throughout the country are conducting the tests appropriately.<sup>132</sup>

<sup>&</sup>lt;sup>130</sup> T856-857.

<sup>&</sup>lt;sup>131</sup> T834-835.

<sup>&</sup>lt;sup>132</sup> T827-829, 837-838, 869-870 and 830. Associate Professor Dax there describes the national HIV testing policy that was set in Australia in 2005.

- 3.3.9 As to the contention of Dr Turner that these tests can result in high numbers of false positive results, Associate Professor Dax explained that whilst it is true that some antibodies are cross-reacting at low levels, the four current HIV tests have been refined in such a way as to minimise this problem. In Australia, this issue is monitored and the non-specific finding is "extraordinarily low, way less than 1%". 133
- 3.3.10 What is important is that in Australia, no single test is relied on but rather a testing strategy is used. Initial screening occurs using an antibody immunoassay test (until recently an ELISA test). This test is designed to be highly sensitive, given the need to ensure that contaminated blood doesn't enter the blood supply. If the result of that test is negative, the chance that it is a truly negative result is close to 100%. <sup>134</sup> If that first test is reactive, the test is repeated to ensure true reactivity. Whilst false positives have been known to occur with the initial screening test, as a result of some non-HIV antibodies weakly reacting, this occurs in less than 1% of cases. The difference between these antibodies and HIV antibodies is the strength with which they bind. The cross-reacting antibodies give a weak result whilst true HIV positive antibodies give a strong result. <sup>135</sup>
- 3.3.11 If the screening tests are positive then a supplemental test will be undertaken. This test is commonly a Western blot test which is

T1161. It was the evidence of all of the respondent's expert witnesses that this rate of false positive was entirely consistent with or less than that found with other viral tests.

<sup>134</sup> T861. The only risk is if someone is testing during the very few days after contracting the virus, in the "window period" before the body has yet developed any antibodies.

T1042. Professor Gordon described a weak result as 1.5 to 2, whilst those with strong results may be in the range of 20-50.

highly specific for HIV proteins. What is important about the Western blot is not the presence of a single protein, but the pattern of bands that appear on the Western blot. As Professor Dax said:

"The chances of that pattern occurring in somebody who doesn't have true antibody are almost zero." 136

- 3.3.12 This completely undermines the assertion of Dr Turner that because  $40\%^{137}$  of people may have one band on the Western blot, that means that 40% of people are at risk of being diagnosed as HIV positive.
- 3.3.13 Whilst these antibody tests together are capable of confirming a diagnosis of HIV positive, it is also of significance that scientists can now identify the genome of the virus. If there was ever any issue about the absence of a "gold standard" for HIV antibody tests, that has been laid to rest with the developments in microbiology and nucleic acid testing. Associate Professor Dax, pre-empting cross-examination, explained the significance of this testing in terms of assessing the reliability of the antibody test:

"How do I know they are highly sensitive and highly specific, that is because over the years we have collected serum or plasma from people who have been infected who have transmitted thorough blood

<sup>&</sup>lt;sup>136</sup> T862 and 809.

None of the respondent's witnesses agreed with this figure and Dr Turner failed to put the basis of his assertion of 40% before the court. Dr Turner has never had any experience in using or interpreting a Western blot test.

The respondent does not accept that there is the requirement for a "gold standard" in the terms suggested by Dr Turner.

transfusions, who have had infection and become ill and those people demonstrate the presence of antibodies, the presence of nucleic acid, RNA, within their cells, they demonstrate the HIV DNA and they can be shown to have virus in their blood or in their tissues that can be purified, and sequenced. So we take those samples and we compare the performance of the tests in those samples that are negative and those samples that are positive and I have also alluded to when we evaluate the kit we look at other characteristics of the kit to make sure the integrity is there, it's robust. So a lot of work goes into evaluating a kit before it goes on the market." 139

3.3.14 As many of the respondent's witnesses said, one of the great successes of the developments in tests for HIV is the eradication of the virus in the Australian blood supply. That of itself speaks highly of the ability of the scientists to detect the virus. As Professor Cooper said:

"That was one of the triumphs of the Australian response to the HIV/AIDS epidemic which was securing the blood supply earlier on and we were the second country in the world to adopt universal screening of our blood supply for HIV and completely eliminated transfusion associated with HIV/AIDS." 140

Even Dr Turner indicated, eventually, that he was prepared to accept

<sup>&</sup>lt;sup>139</sup> T857.

<sup>&</sup>lt;sup>140</sup> T676.

that HIV had been eradicated from the blood supply but went on to qualify that response by saying:

"I accept the fact that whatever tests that she is using to make that claim is true." <sup>141</sup>

3.3.15 Dr Turner suggested that the only possible way to definitively determine whether the antibody test are reliable is to choose two random groups of people and then give one group HIV positive blood and one group HIV negative blood and then test them over a period of years. It is submitted that such a suggestion is completely unrealistic and an example of how out of touch Dr Turner is with current scientific reality. As Professor French said:

"My view is that Dr Turner is completely out of date here and is demonstrating his lack of experience in the assessment and management of patients with HIV infection. We would not do third and fourth tests and use an algorithm. What is undertaken is antibody testing by ELISA and Western blot and, as I indicated earlier, even if it was seen that there was a potential false positive, nucleic acid based tests would be undertaken to determine if the patient has cells that contain DNA of the virus." 142

3.3.16 The relevance of this aspect of the fresh evidence that the applicant seeks to lead must be to suggest to a jury that because of the unreliability of the tests, the prosecution cannot prove that the

<sup>&</sup>lt;sup>141</sup> T767.

<sup>&</sup>lt;sup>142</sup> T1185.

applicant is in fact HIV positive. It is for this reason that the testing and clinical history of the applicant is relevant. The applicant had a highly reactive result at the initial screening test<sup>143</sup>. He then had a further reactive ELISA and Western Blot result from the IMVS. There was also evidence at the trial about the genetic profile of the applicant's virus<sup>144</sup> as well as evidence about his viral load established through nucleic acid testing. There was evidence about the applicant's clinical presentation and a pattern of a decreased viral load when he reported using medication appropriately and an increase when he did not<sup>145</sup>. It is also significant that there was evidence that established that out of all of the virus profiles held on the South Australian IMVS database, that of the accused was most closely related to Simone Crispin - the woman with whom he had been in a sexual relationship.

It is submitted that even if there was some theoretical possibility that someone could be falsely diagnosed as HIV positive with the antibody tests, the applicant's case history indicates that he is certainly not that person.

<sup>145</sup> P75. "A. Parenzee - Lab Results".

<sup>&</sup>lt;sup>143</sup> T1019. His sample cut off was 35.48 in the test conducted at first instance.

<sup>&</sup>lt;sup>144</sup> TT Higgins at 245-259 and trial Exhibit P2 "Pictorial representation of database". The applicant's virus was sequenced on three separate occasions.