THE HIGH COURT

[2015 No. 5 CT]

IN THE MATTER OF AN APPEAL PURSUANT TO SECTION 5(15) OF THE HEPATITIS C COMPENSATION ACTS 1997/2006

IN THE MATTER OF THE DECISION OF THE HEPATITIS C COMPENSATION TRIBUNAL TO THE CLAIMANT A.Q. 6th OCTOBER, 2015, REFERENCE 4138/08

AND IN THE MATTER OF AN APPEAL OF THE CLAIMANT, A.Q. APPELLANT

BETWEEN

A.Q.

APPELLANT

AND

THE MINISTER FOR HEALTH

RESPONDENT

JUDGMENT of Mr. Justice Bernard J. Barton delivered on the 19th day of July 2016

1. These Proceedings come before the Court by way of an Appeal from a decision of the Hepatitis C Tribunal delivered the 6th October, 2015 whereby her Application for compensation was refused on the grounds that the Appellant had failed to establish a fundamental prerequisite of proof, namely that she had been diagnosed positive for Hepatitis C within the meaning of s. (1A) (a) (i) of the Hepatitis C Compensation Tribunal (Amendment) Act 2006 (the 2006 Act).

2. The net issue which arises for determination on the Appeal is whether the positive test results for Hepatitis C on a specimen of the Appellant's blood carried out on the 7th 8th and 9th of January 1998 satisfy the requirements of the section.

Background

3. The Appellant was born on 16th March, 1971. She was married in 1991 and has three children, all boys. Her second son was born on the 27th October, 1993 at Portlaoise General Hospital. The Appellant's blood had tested rhesus negative, the blood of her first baby had tested rhesus positive; consequently she was treated with Anti-D Immunoglobulin (Anti-D) after the birth of each of her children. The Anti-D administered after the birth of her second child came from a batch which was subsequently indentified as being potentially infectious for the Hepatitis C virus (HCV).

4. By letter dated 9th June, 2008, the Irish Blood Transfusion Service Board, (BTSB) wrote to the Appellant's solicitor confirming that the likely batch of Anti- D which would have been in circulation at Portlaoise in 1993 was batch number 610. Two recipients of Anti-D from that batch had tested positive for HCV antibodies and Polymerase Chain Reaction (PCR) positive for the virus but each had other significant risk factors for HCV; one of these had also received Anti-D from batch 615 which was known to be weakly infectious. Four others, including the Appellant, had tested positive on what the BTSB mistakenly described at the time as an 'ELISA' test but which subsequently tested negative on the 'RIBA 3' test.

5. On the 6th January, 1998, the Appellant gave a blood donation. All blood donations are routinely screened by the BTSB laboratory for the presence of human immunodeficiency virus (HIV), Hepatitis B virus (HBV) and HCV antibodies. The method of test used to test by the BTSB to test the Appellant's specimen was the Abbott Prism test, which is an *in vitro* chemiluminescent immunoassay ('ChLIA') for the detection of antibodies to HCV in human serum and plasma.

6. The 'ChLIA' tests were reported positive. A PCR test was also carried out to determine whether the virus was still active. It was reported negative.

7. Following best practice clinical guidelines, the BTSB, in common with other blood transfusion services, has a protocol in place which provides for confirmatory testing of any specimen testing positive on the 'ChLIA'. That service is provided by the National Virus Reference Laboratory (NVRL), Department of Microbiology, at U.C.D.

8. Different methods of confirmatory testing for HCV antibodies were and are utilised by the NVRL, namely, the Ortho EIA developed by Ortho Diagnostics, the Abbott Axsym, developed by Abbott Industries – both of which are Enzyme Linked Immunosorbent assays, (otherwise known as 'ELISA' tests) – and the Recombinant Immuno-blot antibody assay ('RIBA 3') which is an Immuno-blot assay. Although the Appellant's specimen had tested 'ChLIA' positive, the NVRL reported on the 20th January, 1998, that the specimen had tested negative using these methods.

9. All of the Immunoassays used to test the Appellant's blood sample are classified as 3rd generation anti-HCV assays. They are based on the same principals of antibodies binding to antigens – in other words, they share the same structure and are designed to detect the reaction between an antibody and an antigen. However, they differ on the precise mechanism by which the binding of an antibody to an antigen is detected and communicated, the essence of which is the form of the marker used to identify and deliver the result of the test. It is pertinent to refer to the respective mechanisms in turn.

10. A Radio-Immuno Assay (RIA) uses a radioactive molecule which is read by a Geiger counter. An 'ELISA' involves the use of an enzyme to which a substrate for that enzyme will be added which, in the presence of the enzyme, will change colour and is then detected by measuring the optical density of the solution. A 'ChLIA' involves adding a substance such as hydrogen peroxide which records the emission of light that can be measured in a chemi-luminometer.

11. Whether the immunoassay is an 'RIA', an 'ELISA' or a 'ChLIA', they all work on exactly the same principle; the only difference being the type of marker conjugate and, consequently, the different type of signal – whether radioactivity, colour change, or light emission – which is generated. It is the binding of the conjugate, whether an enzyme or chemiluminescent substance, to the antibody which generates the signal which can then be read.

12. The results of all tests on the Appellant's specimen were communicated to her by letter dated 27th April, 1998. She was advised that whilst her sample of blood had tested reactive in one of the screening tests, those results were not confirmed by subsequent testing. Notwithstanding, under the guidelines then applicable, she was also advised that the BTSB would not be in a position to use her donations because her blood had shown a reaction, albeit on the 'ChLIA' only.

13. On the 13th January, 1999, the BTSB again wrote to the Appellant making reference to the letter of the 27th April advising that, while she had tested 'ELISA' positive, she had also tested 'RIBA' negative and that therefore the initial result was considered to be a false positive reaction.

14. It is quite clear from the papers before the Court that references in the letter to the Appellant having tested 'ELISA' positive were factually incorrect; it was the 'ChLIA' rather than the 'ELISA' tests which had tested positive. The error was repeated in other documentation, including a letter from Dr. Eimear Lawlor dated 11th August, 1999, which begs a question: what was the understanding of the BTSB and its medical staff concerning the differences between the tests used to screen and, if found positive, to confirm the presence of HCV in a specimen.

15. It was submitted on behalf of the Appellant that this was significant for a number of reasons, not least of which was that not only was the BTSB using these terms interchangeably, but so too were its highly qualified medical staff. In effect, the 'ChLIA' and 'ELISA' tests were being treated as one and the same – a view, it was argued, which was consistent with the intention of the provision and purpose of the 2006 Act. Moreover, the Tribunal had also dealt with claims on that basis.

16. In passing, I consider it pertinent to observe here that there was no evidence that the Tribunal dealt with claims in this way in connection with applications made to it after the 20th June 2006, this being the date from which the provisions of that Act applied.

17. In her evidence to the Tribunal, the Appellant referred to correspondence received from the BTSB, the content of which she had taken as a reassurance that she did not have HCV. The significance of the potential exposure was not appreciated by her until April 2008, when she had had a discussion with Dr. Courtney to whom she had been referred; this led to her Application for compensation dated the 2nd April, 2008.

18. On 22nd May, 2012, the Tribunal decided that the Application was statute barred and held that there were no extenuating or exceptional circumstances which warranted an extension of time within which it could be brought. That decision was the subject of a successful appeal to the High Court: by Order dated the 31st July, 2012, Cross J extended the time and remitted the matter back to the Tribunal for

19. It follows from the decision of the Tribunal refusing her Application that the kernel of the Appellant's entitlement to proceed with a claim is whether or not the positive 'ChLIA' test results satisfy the requirements of S.(1A) (a) (i) of the 2006 Act. As the answer to that question is dependent upon a construction of the wording of that provision, it was agreed between the parties that that matter should be dealt with by way of a preliminary issue.

Statutory framework

20. Subsequent to the publication of the report of the Tribunal of Inquiry into the BTSB on the 6th March, 1997, the Oireachtas enacted the Hepatitis C Compensation Tribunal Act 1997 (the 1997 Act). The purpose of the 1997 Act was to establish a Tribunal to award compensation to certain persons who had contracted Hepatitis C within the State from Anti-D or other blood products or blood transfusions. Section 4(1) of the 1997 Act made provision for the categories of persons entitled to make a claim for compensation to the Tribunal which included:-

> *(a) a person who has been diagnosed positive for Hepatitis C resulting from the use of human immunoglobulin Anti-D within the State,*
>
> *(b) a person who has been diagnosed positive for Hepatitis C as a result of receiving a blood transfusion or blood product within the State,*
>
> *(c) children or any spouse, of a person referred to in para. (a) or a person referred to in para. (b), who have been diagnosed positive for Hepatitis C.*

It follows from the foregoing that one of the essential proofs to be satisfied in order to establish an entitlement by any of these categories of claimant to an award of compensation is a positive diagnosis for Hepatitis C. However, that Act was silent with regard to what constituted a positive diagnosis. That lacuna was addressed by the 2006 Act, which amended the provisions of both the Act of 1997 and the Hepatitis Compensation Tribunal (Amendment) Act 2002.

21. Section 1 of the 2006 Act amended subs. 1 of the 1997 Act by inserting the following provisions:-

> *"(1A) Subject to subsection (1B), a person has not been diagnosed positive for Hepatitis C for the purposes of this Act unless—*
>
> *(a) the diagnosis is—*
>
> > *(i) based on a positive test result arising from an enzyme - linked immunosorbent assay, or*
> >
> > *(ii) in the case of a recombinant immunoblot assay which indicates antibodies to individual viral antigens on 4 different antibody bands identified as C-22, C-33, C-100 and NS-5, based on a positive test result—*
> >
> > > *(I) of not less than 2+ on the C-22 antibody band, or*
> > >
> > > *(II) of not less than 3+ on each of any 2 of the other antibody bands,*

or

> *(iii) based on a positive test result arising from a polymerase chain reaction (PCR) test,*
> *(b) the person displays symptoms of acute infection by reference to the presence of jaundice, or raised alamine aminotransferase (ALT) levels, not later than 16 weeks after the person has been administered anti-D, or*
>
> *(c) the diagnosis is based on a positive test result arising from a test specified for the purposes of this subsection in regulations made under section 7(1)(e).*
>
> *(1B) Subsection (1A) does not apply to or in relation to a claim for compensation to the Tribunal made before 20 June 2006.".*

The Court notes in passing that it is not contended by the Appellant that her claim comes within the meaning of S. (1A) (a) (ii) and (iii), nor S. (1A) (b) or (c) and that in relation to sub paragraph (c) no Regulations providing for other forms of testing have been made under s. 7(1) (e).

22. Prior to the coming into force of the 2006 Act, both the non-statutory Tribunal, which had been established by the Department of Health on the 15th December, 1995, and the Statutory Tribunal, established by the Act of 1997, entertained claims and made awards of compensation to claimants on the basis of positive medical diagnoses for Hepatitis C which, on the face of it, would not now satisfy the requirements of s. (1A) the 2006 Act.

Medical evidence
23. In a report dated 6th October, 2008 Dr. Gary Courtney, Consultant Physician and Gastroenterologist, took issue with the opinion of the BTSB that the 'ChLIA' test results were "false positive" results. In his opinion, the Appellant could have received a contaminated dose of Anti-D and then cleared the Hepatitis C virus early. The antibody response may have waned due to the passage of time or may never have been that strong because the virus may have been weakened and effete at the time of infusion due to extraneous factors, such as conditions of storage, etc. He confirmed that testing by 'RIBA 3' and PCR were negative and expressed the opinion that the Appellant was not then infected with the Hepatitis C virus and that she would not develop any serious health consequences.

24. While acknowledging that he was not a specialist in the area, the Appellant's G.P., Dr. Fitzgerald, in a report dated 13th October, 2009, expressed the opinion that the Appellant had been infected with Hepatitis C through contaminated Anti-D administered to her in 1993. A view to the contrary was expressed in a detailed report dated the 28th January, 2013, by Professor John Crowe, who had been retained to advise the Tribunal. For the reasons given, his opinion was that the 'ChLIA' tests constituted false positive results. He concluded his report by observing that:

> *"In a study to estimate the specificity of the Abbott Prism HCV assay, reactivity in 6,742 blood and blasmapheresis donors, 28 (0.42%) were found to be initially reactive and 26 (.039%) repeated reactive. Of this group of 26, 8 were actually confirmed positive (13.77%) on RIBA testing and 18 were negative"*

His opinion was forcibly reiterated in a further detailed report dated the 11th March, 2016

25. The Appellant's solicitors had invited Dr. Courtney to consider all of the papers and to express an opinion in relation to two questions, namely:

(i) Whether or not the Abbott Prism ('ChLIA') was an 'ELISA' test and if not, whether there was any real significance between the two? And,

(ii) Whether the positive HCV Abbott Prism ('ChLIA') test result constituted a false positive?

26. Dr. Courtney replied by way of letter dated the 14th August, 2013. In relation to the first question he expressed the view that, whilst there was a technical difference between the two assays, in practical terms they were the same test designed to achieve the same object; namely, the detection of HCV antibodies. He also observed that the BTSB had not been using 'ELISA' testing for several years (it would appear from as long ago as 1997) and expressed the opinion that they had upgraded their automated testing procedures in the interests of accuracy and efficiency.

27. In formulating the 2006 Act, Dr Courtney did not believe that the Oireachtas could have intended to be so prescriptive in limiting the nominated test to a single and very specific type which would have had no regard to future scientific progress and advances in technology. Moreover, he considered that a narrow interpretation of the 2006 Act would not make any sense since that would have the effect of placing the BTSB, and all of the patients whom it tested, outside the relevant law.

28. With regard to the second query, he considered that :

> *"the crux of the matter lies in whether we plump for more sensitive tests, which will not let a genuinely infected patient be missed, but which will also test positive for a small number of patients who were never affected (false positives), or do we choose more specific test which will not include those who were never infected but will exclude a small number of patients who are genuinely infected (false negatives).*
>
> *The former approach is more patient centred but worse for the State in that compensation costs are increased whilst the latter approach reduced compensation costs to the State by excluding some genuinely infected patients.*
>
> *As a treating physician, I have favoured the "sensitive test" rather than the "specific test" route as I did not want to countenance leaving a truly infected patient without recompense."*

29. Professor William L. Irving, Professor and Honorary Consultant in Virology, University of Nottingham and Nottingham University Hospitals NHS Trust, prepared a report dated 26th August, 2015 and gave evidence on the Appeal. He explained the structure and technologies used by the different immunosorbent assays. He accepted that the 'ChLIA' was not an enzyme-linked immunoassay because it does not use an enzyme as a marker for the conjugate. Nevertheless, in common with an 'ELISA', both are immunoassays; it was this commonality between the tests which was important. In his opinion they were equivalent to each other in terms of the function they fulfil; namely, to detect the presence of virus-specific antibodies.

30. He expressed similar views to those of Dr. Courtney concerning the statutory test requirements. He could not believe that the law makers intended the definition of a positive result to be based precisely on the absolute detail of the particular assay used to determine the result. Rather, he thought that the key part of the definition must sensibly be the use of an immunoassay as the determinant for the presence or absence of antibodies to HCV. He explained his opinion: it should make no material difference which type of immunoassay was used for that purpose since the different technologies were inter-changeable and perform the same function. Significantly, the fact that different markers were used was simply irrelevant to the purpose of the assay.

31. Accepting that the Appellant had long since cleared the virus, it was his opinion that, on the balance of probabilities, she had been exposed to the virus at some stage in the past. In his report, he had stated that the 'ChLIA' was the only test "*sensitive enough to pick up a low level of HCV antibodies*". In evidence he said that the 'ChLIA' and 'ELISA' tests were comparable in terms of sensitivity and specificity.

32. A comprehensive report, dated April 2016, was prepared on behalf of the Respondent by Dr. Jeff Connell PhD, Assistant Director of the NVRL; he too gave evidence to the Court. In his opinion it was not uncommon that a sample collected from an individual who was not HCV infected was repeatedly positive in one of the HCV assays but not in any other anti-HCV tests. Although there were nuances in approach and somewhat different terminology had been used in their reports, it was evident during the hearing that both Dr. Connell and Professor Irving were in agreement concerning the science of immunoassays.

33. With regard to the rationale for confirmatory testing, he did not think that there was any significant difference between the sensitivity of the 'ChLIA' and the 'ELISA' tests, though he considered the two 'ELISA' tests, directed as they were to detecting the presence of HCV antibodies, to be more specific and consequently more appropriate for use as a confirmatory test, whereas the 'ChLIA' was more appropriate as a screening test since, in the first instance, it enables the BTSB to check different markers at the same time for HIV, HBV, HTLV and HCV – a much faster alternative to carrying out a series of separate 'ELISA's. He also gave evidence concerning the protocol for the confirmatory testing of 'ChLIA' positive samples referred to the NVRL by the BTSB; a practice which was well defined and internationally accepted before and after 2006. It remains place.

34. Professor Irving also commented on the rationale for different types of testing. Given the necessity of protecting the blood supply and the scale of testing involved, it was understandable that the BTSB would want to have a system of testing , such as the 'ChLIA', which was as automated as possible and capable of carrying out several tests at the same time. Although he did not know the reason why the BTSB had decided to switch from 'ELISA' to 'ChLIA' testing, he was not surprised that there had been a switch though he could equally imagine why other services would continue to use the 'ELISA' method. I took this to be a reference to services such those offered by the NVRL.

35. The Tribunal itself was concerned to understand the rationale behind the decision of the BTSB to choose the 'ChLIA' method of testing; that matter was addressed on behalf of the BTSB by Dr Louise Pomeroy in an email to the Secretary of the Tribunal dated 23rd February, 2012. She had stated that "*Both the Abbott Prism (ChLIA) HCV assay and the previously used Abbott ELISA are 3rd generation Hepatitis C screening assays. The Prism technology was introduced in 1997 for blood screening largely because it is a fully automated system. The overall sensitivity of Hepatitis C antibody detection is similar in both assays.*" In relation to the question of 'specificity' it was stated that "The *Ortho EIA for Hepatitis C antibody is at least as sensitive as the Prism test but it has greater specificity i.e. less false positive reactions."*

The information and advice expressed in that email is broadly consistent with the expert evidence given to the Court in relation to those matters. The 'ChLIA' and 'ELISA' assays are unquestionably similar and designed to achieve the same object. However, they are not the same as one another: they differ in the markers used to identify and deliver the result of the test; both experts were agreed that 'ChLIA' is not an enzyme-linked immunosorbent assay.

Submissions

36. Written and oral submissions were made on behalf of both parties and have been considered by the Court. It is not intended to recite these here but the essence of the submissions may be briefly summarised as follows:

37. It was submitted on behalf of the Appellant that a literal interpretation of s. 1(A) would result in the Act having retrospective effect. Had the Appellant made a claim prior to the 20th June, 2006, based on the medical evidence then available, which included the positive 'ChLIA' test results, it was beyond controversy that she would have been entitled to an award of compensation.

38. As it was, the literal interpretation of the relevant statutory provisions taken by the Tribunal had the retrospective effect of excluding the 'ChLIA' test results as qualifying for a positive Hepatitis C diagnosis, thereby depriving the Appellant of a right to proceed with her claim – a right which she had enjoyed up to the 20th June. That right would not have been affected had the positive diagnosis been based on the result of an 'ELISA' test. Moreover, in respect of applications made after that date, claimants testing positive would be differentiated only by having undergone different but similar tests; such a result was absurd given the express purpose of the Acts to provide compensation to the victims of Hepatitis C contracted in the State through the administration of Anti-D, and the transfusion of blood or other blood products.

39. It was submitted that such a consequence was not and could not have been intended by the Oireachtas when enacting the provision in question. In these circumstances, the provisions of S5 of the Interpretation Act 2005 were triggered and warranted the Court adopting a purposive approach to interpretation. When so construed, the 'ChLIA' test results satisfied the requirements. Moreover, the provisions of S.6 of the Interpretation Act were also applicable. In that regard the general understanding at the time and subsequently was significant. It was clear from the correspondence evidence that the BTSB and its medical staff regularly referred to 'ChLIA' and 'ELISA' interchangeably and had treated the tests as being the same or similar.

40. Importantly, there was agreement between the experts on the science of the relevant tests: they shared the same principals, were designed to achieve the same objective and were similar in all respects save the way in which the result of the test was identified and delivered; such evidence should inform the Court. While accepting that by enacting the 2006 Act, the Oireachtas ordained a threshold which had to be satisfied in order to establish a right to an award of compensation, it was contended that there was neither sense nor reason to choosing one type of immunoassay over the other. The term '*enzyme-linked'* added nothing to the definition. Rather, what was relevant was that the qualifying threshold should be a positive immunosorbent assay test result for Hepatitis C antibodies. Such a conclusion was admitted by a purposive construction of the provision which was permissible in the circumstances and which avoided the absurd result of a strictly literal interpretation; namely, the exclusion of all claims, including that of the Appellant, arising from 'ChLIA' tests.

41. On behalf of the Respondent it was submitted that the amendment introduced by the 2006 Act was intended to restrict the category of claimants deemed to having been diagnosed positive with Hepatitis C. Accepting that the intention of the Oireachtas was

to be ascertained from the words employed in the subsection, it was contended that the wording of S.(1A) was crystal clear: in short, a person is not diagnosed Hepatitis C positive for the purpose of the Acts in respect of applications made after 20th June, 2006 unless that diagnosis is based on a positive test result arising from specified named tests or , in one limited case, the claimant displays certain clinical symptoms subject to certain specific requirements. The suggestion that a limitation on the entitlement to obtain compensation based on a particular test would fail to reflect the plain intention of the Oireachtas was demonstrably incorrect and without foundation.

42. Furthermore, it was abundantly clear from a consideration of s. (1A) that not all immunoassays were intended to constitute the qualifying threshold. Rather, the qualifying tests were limited to enzyme-linked immunoassays. In this regard, the attention of the Court was drawn to the fact that not all 'RIBA' tests qualify to meet the threshold – they too need to meet certain specific test result levels – and nor do all clinical diagnoses qualify – only those which meet particular standards within a defined time period will suffice. When the provisions of s. (1A) are taken together, it apparent that the Oireachtas gave careful consideration to and must have been aware of the precise tests that it selected. Moreover, it was clear that consideration had been given to the existence of other tests which might qualify in the future. Such a conclusion was apparent from the provision of a power to include such tests by way of Regulations to be made under s. 7(1) (e).

43. The undisputed evidence before the Court discloses that the 'ELISA' test was in common use by the NVRL in 2006 as a confirmatory test of specimens referred to it by the BTSB which had tested positive by the Abbott Prism ('ChLIA'). It was also of some significance that the 'ELISA' test was Hepatitis C specific and could be configured to reduce the risk of false positive results. It could be presumed that the Oireachtas was possessed of this knowledge. Accordingly, it was entirely appropriate and permissible for the Oireachtas to take the view that compensation should be limited to those persons who had tested positive on the confirmatory test carried out by the NVRL and not solely on the initial 'ChLIA' screening test carried out by the BTSB.

44. The contention that the provision which required a positive enzyme-linked immunoassay test result in order to establish a right to apply for compensation was in some way obscure, ambiguous, absurd or failed to reflect the plain intention of the Oireachtas was unsustainable. There was nothing on a literal interpretation of the provision which would render it devoid of meaning or effect, or which could admit several meanings. Rather, it was sensible and reasonable and enabled a plain legislative intention to be discerned. There was nothing in the wording which would attract the operation of the provisions of s. 5 of the Interpretation Act 2005. On the contrary, the wording of the provision was clear and unambiguous, and there was nothing absurd in choosing and specifying a qualifying test for entitlement to make a claim. In such circumstances, there was nothing further that the Court was required to do when construing the provision other than to expound those words in their ordinary and natural sense, disclosing as they do a plain legislative intention. So construed, it was perfectly clear that a positive diagnosis for Hepatitis C based on an enzyme-linked immunoassay test was required to establish an entitlement to make a claim for compensation.

45. With regard to the Appellant's submission concerning the retrospective effect which would follow as a consequence of a literal interpretation of the provision, it was submitted that the Oireachtas understood that there would be claims made which in all probability would be based upon test results reported prior to that date. As a matter of near certainty, applications made immediately and for some considerable time after the 20th June, 2006 would have to be based on test results obtained before that date.

46. It was argued that the matter of retrospective effect of the provisions was also considered by the Oireachtas. That this was so was manifestly evident from the wording of s. (1A) (b) which excludes the application of the 2006 Act to any claim for compensation made to the Tribunal before the 20th June 2006. Had the Oireachtas intended to exclude claims made after 20th June 2006 based on test results reported before that date there would have been no difficulty in doing so and it would have so provided.

47. The Appellant's claim was made after the 20th June, 2006. Accordingly, it was clear from the wording of S. (1A) (b), notwithstanding that it was based on test results reported in 1998, that the provisions of the Act applied. It was not the date of the tests but rather the date on which the claim was made to the Tribunal which was relevant for that purpose.

48. It was also submitted that the purpose of the Act was not to provide compensation for all victims of Hepatitis C contracted in the State by specified means. Rather, the intention, plainly ascertainable from the wording used, was to limit the right to compensation to those victims who had tested positive according to specific requirements. Furthermore, there was nothing in the wording of the section, nor in the 2006 Act as a whole which would warrant a construction that the intention of the Oireachtas was to select 'immunoassays' in general, rather than 'enzyme-linked immunoassays' in particular, as the qualifying test.

The law

Literal interpretation

49. The first and foremost source for the ascertainment of legislative intention is the text of the provision itself. The very considerable corpus of law on the subject of interpretation of statutes available to the Court requires an approach to the interpretation of any statutory provision by firstly giving the words employed their ordinary and natural meaning. Where the result of that task produces a meaning which is entirely plain and unambiguous, then it is said that nothing remains for the Court except to give effect to that plain meaning.

50. In *O.H. v. O.H.* [1990] 2 IR 558 at 563 Barron J. cited Brandon J in the English case of *Powys v Powys* where he stated:-

> *"The true principles to apply are in my view, these: that the first and most important consideration in construing a statute is the ordinary and natural meaning of the words used; that, if such meaning is plain, effect should be given to it; and that it is only if such meaning is not plain, but obscure or equivocal, that resort should be had to presumptions or other means of explaining it."*

51. In *Howard v. Commissioners of Public Works* [1994] 1 IR 101, Blaney J. approved the traditional statements of principle contained in Craies on Statute Law and Maxwell on the Interpretation of Statutes. He quoted the statement of principal enunciated by Lord Blackburn in *Direct United States Cable Co. v. Anglo-American Telegraph Co*. [1877] 2 App. Cas. 394:-

> *"The cardinal rule for the construction of Acts of Parliament is that they should be construed according to the intention expressed in the Acts themselves. If the words of the statute are themselves precise and unambiguous, then no more can be necessary than to expound those words in their ordinary and natural sense. The words themselves alone do in such a case best declare the intention of the lawgiver."*

This statement of the rules or principals applicable to the construction of statutes has been cited with approval in many cases subsequently.

52. The purpose of and limits to the function of the Court when interpreting a statutory provision was considered in *McGrath v. McDermott*, [1988] IR 258, where Finlay C.J. observed that:-

> *"The function of the courts in interpreting a statute of the Oireachtas is, however, strictly confined to ascertaining the true meaning of each statutory provision, resorting in cases of doubt or ambiguity to a consideration of the purpose and intention of the legislature to be inferred from other provisions of the statute involved, or even of other statutes expressed to be construed with it. The courts have not got a function to add to or delete from express statutory provisions so as to achieve objectives which to the courts appear desirable. In rare and limited circumstances words or phrases may be implied into statutory provisions solely for the purpose of making them effective to achieve their expressly avowed objective".*

This approach to the interpretation of statutes gives effect to and respects the separation of powers enshrined in our Constitution since it is not the function of the Court to legislate, a function strictly reserved to the National Parliament by Article 15.2 .1.

53. That the overriding duty and object of the Court in the construction of a statutory provision is to ascertain the true intention and will of Parliament is exemplified by the decision of *Harrisgrange Limited v. Duncan* [2003] 4 IR 1 where McKechnie J. stated:-

> *"The overriding duty of a court when asked to construe any piece of legislation is to try and ascertain what the true will and intention of the legislature is. The first step in this process is to consider, in the context in which they appear, the words themselves and, in the absence of any contraindication, to give to such words their ordinary and natural meaning. If in so doing, the court can in this way, clearly identify what was intended by the Oireachtas then it will not be necessary to invoke any of the very numerous subsidiary rules of construction which have been established over the years."*

54. It follows from these statements of legal principle that the Court commences the task of interpretation by giving, in the context in which they occur, each of the words used in the provision their ordinary and natural meaning; an approach to construction often referred to in case authorities and academic texts as the literal interpretation of the words used.

Purposive Interpretation

55. Where the result of a literal interpretation fails to disclose a plain meaning, resort maybe had to other rules of construction in order to ascertain the legislative intention of the provision or provisions in question. Purposive interpretation of a statute has as its foundation the presumption that each provision of a statute is presumed to be intended to have some purpose and effect. Such an approach to interpretation arises where the provision is obscure, ambiguous, or absurd or gives rise to several meanings. In such cases the Court is required by s. 5 of the Interpretation Act 2005 to give the provision a construction *"… that reflects the plain intention of the Oireachtas or parliament concerned, as the case may be, where that intention can be ascertained from the Act as a whole."*

56. Where one meaning offends against the purpose of an enactment but another is in keeping with it, the meaning which is in keeping with the purpose is presumed to be the one intended by the legislature – see *Campbell v. O'Donnell and Boylan v. MIBI* [2005] IEHC 266 and *O'Brien v. The Revenue Commissioners* [2014] IEHC 347. Where, on a literal interpretation of the provision, the meaning is entirely clear and bears a singular meaning, effect must, in the ordinary way, be given to the plain meaning. However, if on a literal construction of the provision it is rendered devoid of meaning or effect or results in two or more meanings, the purposive approach involves a rejection of the literal meaning and the application of an interpretation which carries out the aim of the Act. It was precisely to deal with provisions which are found to be (i) obscure, (ii) ambiguous, or which on a literal interpretation (iii) would be absurd or (iv) would fail to reflect the plain intention of the Oireachtas, that s. 5 of the Interpretation Act 2005 was enacted. Absent the types of interpretive doubt exemplified in the provision, s. 5 has no application.

57. Examples of the purposive approach to the construction of a provision which, on a literal reading, frustrated the purpose of the legislation in question and rendered it without effect but where a purposive interpretation carried out the aim of the Act can be seen in *O'B v. W* (unreported, Supreme Court, 29th July 1976), and *Maher v. Minister for Agriculture and Rural Development* [2001] 2 IR 139 relied upon by the Appellant. I pause here to observe that the latter authority has to be seen in the context of an interpretation of legislation designed to implement E.U. Directives where there is a requirement to apply a purposive interpretation to national or domestic law so as to achieve the results envisaged by the relevant Directive.

Absurdity

58. Where the literal construction of a statutory provision leads to a blatantly absurd or unintended result, the general rule is that that construction should not be adopted unless the language used in the provision leaves no alternative. This rule of construction is sometimes referred to as the rule against absurdity – see River Wear Commissioners v. Adamson [1877] 2 App. Cas. 743 at p. 764, where Blackburn L.J. exemplified the rule, now substantially codified by s. 5 of the Interpretation Act.

59. It would appear from the authorities that when the consequence of a construction is manifestly inappropriate, makes no sense, or is ridiculous, then it can be presumed that such was not the result intended by the Oireachtas. Where a construction produces manifestly contradictory meanings, or would defeat the clear object of the Act, or renders the subject provision ineffective or gives rise to futility, illogicality or otherwise fails to reflect the plain intention of the Oireachtas, such may be said to be absurd.

60. Although a literal construction may result in an unsatisfactory, surprising or cumbersome meaning, it does not follow that such a consequence is absurd and, if it gives effect to the plain meaning of the statutory provisions in question, effect should given to that meaning – see *Arthur v. Kerry County Council* [2000] 3 IR 407.

61. As a general rule where provisions are obscure, ambiguous, or result in several meanings one or more of which are absurd, the Court should prefer the meaning which avoids absurdity. – see *People (A.G.) v. Ruttledge* [1978] 1 IR 376. A departure from the canon of construction which requires interpretation by reference to the natural and ordinary meaning of the words used is warranted where the result of such a construction results in a blatant absurdity – see *Ebonwood Limited v. Meath County Council* [2004] 3 IR 34. The Appellant argues that that is precisely the consequence of a literal interpretation of the provision in question.

62. In certain circumstances it maybe permissible for the Court in the construction of a provision in a statute or statutory instrument to make allowances for changes in the law, in the meaning of words used in the provision, in social conditions, in technology, or where there are other relevant matters which have occurred since the passing of the Act or statutory instrument as the case maybe – see s. 6 of the Interpretation Act. However, the Court is constrained in what is permissible in this regard by the text, purpose and context of the provision. The Appellant submits that the correspondence evidence in particular discloses a sufficient basis upon which to found the operation of s. 6 on the construction of the provision in question.

Presumption of Constitutional validity and Retrospectivity
63. Reference has already been made to the provisions of Article 15.2.1 of the Constitution which confer on the Oireachtas the exclusive power to enact legislation. All Acts of the Oireachtas passed after the coming into force of the Constitution enjoy the presumption of Constitutional validity. This presumption is based on the premise that the enacted legislation not intended by the legislature to trench upon the fundamental rights of the citizen or otherwise offend against the Constitution. When the Court is called upon to consider and interpret such legislation, the presumption of validity prevails until the contrary is clearly established – see *Hamilton v. Hamilton* [1982] 1 IR 466.

Common law
64. The common law leans against the retrospective operation of a statute and is expressed in the general rule that a statute is intended to operate prospectively. The rule and premise upon which it is based was considered in *Chestvale Properties Ltd v. Glackin* [1993] 3 IR 35, p 43 where Murphy J, stated that:-

> *"At common law there was a presumption, a strong presumption, that a statute is intended by Parliament to operate prospectively and not retrospectively. This presumption is based on the proposition that, ordinarily, the retrospective operation of a statute would cause injustice and that Parliament could not be presumed to have intended such a consequence."*

The presumption is properly understood as a rule of construction; it is not a rule of law. The purpose of the rule is to aid the Court in the ascertainment of the legislative intention of the provision which it is required to construe. Save in the case of a provision the effect of which would offend the Constitution, such as by trenching on the fundamental rights of the citizen, there is no prohibition on the enactment of legislation which has a retrospective operation. However, where the intended effect of the provision is retrospective, then that must be expressed in clear and unequivocal terms and failing which it will be presumed to have been intended to have prospective operation unless deemed to have retrospective effect by necessary implication, as was the case in *Chestvale, supra.* See further, *Gardner v. Lucas* (1878) 3 App. Cas. 582.

65. In *Hamilton*, O'Higgins C.J., addressing the rationale behind the common law presumption on the retrospectivity of statutory provisions, cited the judgment of Wright J. in *Athlumney, In re, ex p. Wilson* [1898] 22.B.547 as an exemplification of the rule where, at pp 551-552 of the report of the learned judge stated:-

> *"Perhaps no rule of construction is more firmly established than this — that a retrospective operation is not to be given to a statute so as to impair an existing right or obligation, otherwise than as regards matter of procedure, unless that effect cannot be avoided without doing violence to the language of the enactment. If the enactment is expressed in language which is fairly capable of either interpretation, it ought to be construed as prospective only."*

66. Where the construction of the provisions of an Act of the Oireachtas enjoying the presumption of Constitutional validity results in two or more possible meanings or intentions, one of which conforms to the Act's validity having regard to the provisions of the Constitution while the other does not, that which conforms must be given effect. O'Higgins C. J. went on to explain that:

> *"This is so because it must be assumed that the Oireachtas intended to act within its powers and with due regard to the Constitution. This approach to the interpretation and construction of Acts of the Oireachtas is required by the Constitution. While it may not replace the common-law rule, it certainly supersedes it once a question of a possible infringement of the Constitution arises."*

See also the decision of the Supreme Court in *Murphy v. Gilligan* [2001] 4 IR 113.

67. The meaning of retrospectivity in a statutory provision was expounded upon by the Chief Justice in *Hamilton* as follows:-

> *"it is necessary to state with some precision what I regard as such in a statute. Many statutes are passed to deal with events which are over and which necessarily have a retrospective effect. Examples of such statutes, often described as ex post facto statutes, are to be found in Acts of immunity or pardon. Other statutes having a retroactive effect are statutes dealing with the practice and procedure of the Courts and applying to causes of action arising before the operation of the statute. Such statutes do not and are not intended to impair or affect vested rights and are not within the type of statute with which, it seems to me, this case is concerned. For the purpose of stating what I mean by retrospectivity in a statute, I adopt a definition taken from Craies on Statute Law (7th ed., p. 387) which is, I am satisfied, based on sound authority. It is to the effect that a statute is to be deemed to be retrospective*
>
> *in effect when it "takes away or impairs any vested right acquired under existing laws, or creates a new obligation, or imposes a new duty, or attaches a new disability in respect to transactions or considerations already past.""*

It is also pertinent to observe here that the presumption that an Act is intended to operate prospectively generally arises where an interpretation of a statutory provision admits to several meanings, one of which gives rise to retrospective and the other prospective operation. The presumption operates to warrant the Court in preferring and giving effect to the latter.

Findings in relation to the factual background and conclusions
68. It is common case between the parties that unless (emphasis added) the Appellant meets one or more of the requirements set out in s. 1(A) for a positive diagnosis of Hepatitis C, she is not entitled to an award or compensation under the Acts. It is also common case that, of the requirements set in out in that section, the only provision under which the Appellant may qualify is s. 1(A)(a)(i) which provides that the diagnosis for hepatitis C is one "(i) *Based on a positive test result arising from an enzyme-linked immunosorbent assay*,". It is the construction of that provision which gives rise to the controversy between the parties.

69. The Appellant argues that on a true construction of that provision, having due regard to the purpose of the Acts, the positive test result referred to in the provision includes, and was intended to include, the positive 'ChLIA' test results dated 7th, 8th and 9th January, 1998. It is clear from the decision of the Tribunal that it applied a literal interpretation to the words of the provision and that, having done so, it concluded that the words were clear and unambiguous admitting to only one meaning; namely, that the positive test result had to be one arising from an enzyme-linked immunosorbent assay. On the evidence before it, the Tribunal decided that the 'ChLIA' test was not an enzyme-linked immunosorbent assay and that to hold otherwise would be to do violence to the wording and plain meaning of the provision.

70. The Court is satisfied that for many years prior to and at the time of the enactment of the Act of 2006, the BTSB adopted the Abbott 'ChLIA' as being the most appropriate test for the purposes of screening blood donations and that it did so for a number of

reasons including those referred to in an email dated the 23rd February, 2012, and sent to the Tribunal by Dr. Louise Pomeroy on behalf of the BTSB.

71. The benefit of a fully automated system of blood screening was explained by Dr. Geoff Connell. Given that the BTSB was concerned to ascertain the presence of antibodies in blood donations for the purposes of protecting the blood supply in relation to certain viruses – namely HIV, HPV, HTLV and HCV – testing by the 'ChLIA' method enabled the detection of any of these antibodies in a single test. This represented a much faster alternative to carrying out a series of separate 'ELISA's. The Court accepts that evidence and the evidence of Professor Irving that he was not surprised that the BTSB had decided to switch from testing by 'ELISA' to 'ChLIA' testing.

72. Two other matters are also of some significance. Firstly, the 'ELISA', while as sensitive as the 'ChLIA' can be configured in relation to specificity for HCV, thus rendering it more appropriate as a means of confirmatory testing. Secondly, both before and at the time of the passing of the 2006 Act, there was a protocol in place between the BTSB and the NVRL consistent with best practice clinical guidelines which involved the referral of specimens testing positive by 'ChLIA' to the NVRL for such testing and on foot of which the Appellant's specimen had been referred and had tested negative by 'ELISA' and 'RIBA 3' assays. As evidenced by the email from Dr. Pomeroy dated the 23rd February 2012, these confirmatory tests were considered by the BTSB to have greater specificity for HCV, thereby producing less false positive reactions.

73. The Court is satisfied on the expert evidence and finds that whilst all immunoassays are designed to achieve the same object, a 'ChLIA' is not an enzyme-linked immunosorbent assay. The Court is also satisfied that the differences in the technology by which the results of the respective tests are identified and communicated were well understood and that the use of these terms interchangeably by the BTSB and its medical staff – as is apparent from the correspondence evidence – most likely arose through mistake or carelessness rather than because the tests were considered by the medical staff to be scientifically the same as one another.

74. When s. (1A) is considered as a whole, it is apparent, especially having regard to s. (1A) (a) (ii), which concerns testing by 'RIBA', that the Oireachtas had before it very specific information relating to the different types of tests in use at the time when it enacted that section.

75. Finally, it was not suggested nor could it have been the case that the Oireachtas was unaware of what was then a well established practice by the BTSB of referring 'ChLIA' positive specimens for confirmatory testing by the NVRL.

76. These findings by the Court are concerned with the establishment of the factual background to the submissions made by the parties and to the arguments addressed on the issue in question. Given the task upon which the Court embarked, it is considered unnecessary for present purposes to resolve the differences of medical opinion as to whether or not the 'ChLIA' test results were false positives or whether the Appellant had actually been exposed to the Hepatitis C virus at all.

Decision

77. Applying the law to the construction of this provision, the first task for the Court is to give all of the words employed by the Oireachtas their ordinary and natural meaning.

78. An 'enzyme-linked immunosorbent assay' has a specific scientific meaning; namely, an immunosorbent assay which uses an enzyme as the marker to detect the presence of HCV antibodies in the specimen being tested and which, if HCV antibodies are present, will result in a measurable change of colour . So understood, the Court is satisfied that when construed with the remaining words of the provision, the wording is clear, unambiguous and discloses a legislative intention which is plain; namely, that the diagnosis of Hepatitis C must be based on a positive test result arising from an enzyme-linked immunosorbent assay.

79. It follows that as a 'ChLIA' is not an enzyme-linked immunosorbent assay, it does not satisfy the requirements of the provision and thus the Oireachtas limited the qualifying tests by excluding it. This, however, is not the end of the matter.

80. The Court is required to consider the submission made on behalf of the Appellant that such a construction produces an absurd result which could not have been intended by the Oireachtas, especially when due regard is had to the purposes for which the Acts were passed. The result was absurd because it acted retrospectively to deprive her of a vested right which she had enjoyed prior to the passing of the 2006 Act, a right which, although not exercised before the 20th June 2006, entitled her to make a claim for compensation to the Tribunal under the provisions of the 1997 Act.

81. The Appellant's case on this point was that the intention of the Oireachtas that the provision was to have a retrospective operation was neither clear nor unequivocal and that, if it operated retrospectively, it wrought an injustice on the Appellant; such was a consequence which was absurd since it deprived her of the right to pursue the claim for compensation. Accordingly, s. 5 of the Interpretation Act 2005 was triggered, thereby warranting a purposive interpretation of the provision. When so construed, the qualifying test intended by the Oireachtas was to be one based upon and arising from *any* immunosorbent assay (emphasis added). Such a construction dealt with the mischief to applicants such as the Appellant which arose from a literal interpretation. Furthermore, it was consistent with the purpose of the Acts which was to provide compensation to specified victims of Hepatitis C.

82. The right of the citizen to bring proceedings before the courts is not unfettered and is regulated by law. The Oireachtas, in the exercise of its powers, has enacted Statutes of Limitation to provide time limits within which proceedings must be brought, failing which, subject to certain exceptions and provisions with regard to the acquisition of the date of knowledge, the cause of action is liable to be defeated by the defence that it is statute barred.

83. A 3 year time limit within which to make a claim to the Tribunal was provided for by s. 14 of the 1997 Act as amended, with time beginning to run from the date upon which the claimant became aware of the fact that he or she may have been diagnosed positive for Hepatitis C, or the establishment day, whichever is the later.

84. It is clear from the evidence before the Tribunal that by 1999 at the latest, the Appellant had been made aware that she had likely been exposed to the Hepatitis C virus in 1993, albeit that, in the view of her medical advisers at the time, she had since cleared the virus. On foot of the advice received, she applied for a medical health card. That evidence was sufficient to cause the running of time. Her knowledge and diagnosis cannot be said to have run from 2007 since had that been so there would have been no need to make an application for an extension of time in respect of an application made in 2008.

85. For reasons which were subsequently explained, and upon which it appears this Court made an Order extending the time within which to bring an application, the Appellant did not exercise her right to bring a claim under the1997 Act prior to the 20th June, 2006.

86. There is no doubt but that the terms of qualification for entitlement to bring a claim and receive an award of compensation which existed up until the time of the enactment of the 2006 Act were altered by that Act. It is accepted by the Respondent that the provision operated retrospectively on the right of the Appellant which she had enjoyed prior to the 20th June, 2006, and in respect of which, had she made a claim before that date, the positive 'ChLIA' test results of 1998 would have been sufficient for a positive diagnoses of Hepatitis C. However, she did not make a claim until 2008. Accordingly, those tests no longer met the qualifying threshold.

87. I am satisfied that by the 20th June 2006, as the date from which the provisions of the Act would apply to applications made to the Tribunal, the question of a retrospective operation of the provisions of the Act was considered by the Oireachtas. It is evident that all applications made to the Tribunal immediately after the 20th June, 2006, and many applications for some considerable time thereafter, would be based on tests carried out before that date. By enacting the provision in question, the Oireachtas clearly and unequivocally intended to restrict the qualifying tests, thereby excluding tests, including 'ChLIA's, which would have qualified in respect of applications brought before that date. That such a result was the plain intention of the Oireachtas is abundantly clear from the wording of the provision and, in my judgment, consistent with the purpose of that Act which was, inter alia, to amend the Acts of 1997 and 2002.

88. Had the Oireachtas intended to exclude the operation of the provisions of the 2006 Act to test results reported before the 20th June 2006 but which would not qualify under the provision in question, it would have had to have said so. Such a provision could have been enacted without difficulty. As it is, the relevant date for the purposes of the legislation is not the date of the tests but rather the date on which the application is made.

89. In my judgment, it was exclusively within the powers and competence of the Oireachtas to regulate the entitlements and the rights of applicants seeking compensation under the Acts by enacting a threshold which has to be crossed in order to receive an award of compensation on foot of an application made after the 20th June 2006, even though the affect of the provision operates to exclude tests which would have qualified for the purposes of applications made before that date.

90. The consequence of construing the provision in the way contended for by the Appellant would result in an indeterminate delay in the operation of the provision on any claim based on a test other than that arising from an enzyme-linked immunosorbent assay, thus defeating or frustrating the purpose for which the provision was enacted. If such was the intention of the Oireachtas, an altogether different provision would have had to have been enacted; the Oireachtas chose not to do so.

91. Absent wrongful interference with the fundamental rights of the citizen enshrined in the Constitution, there is no legal prohibition on the Oireachtas enacting legislation which has a retrospective effect, provided that that intention is plainly evident from the wording employed in the relevant provision. The presumption of Constitutional validity is not challenged and is thus enjoyed by the 2006 Act.

92. The Court is satisfied that the provision in question reflects the plain intention of the legislature to introduce a threshold which has to be met in order to qualify for an award of compensation under the Acts in respect of applications made after the 20th June, 2006, and that the introduction of such a threshold was intended to have the effect of excluding all applications based on immunosorbent assays irrespective of the dates of testing which were not enzyme-linked. Had the Oireachtas intended the positive test results of all immunoassays to qualify for a positive diagnosis, then nothing would have been simpler but to have so provided.

93. I cannot accept the submission that the words "*enzyme-linked*" add nothing to the definition. Rather, they are the very words which convey the restriction of the tests which the legislature intended are required in order to qualify for a positive diagnosis of Hepatitis C. In circumstances where the words "*enzyme-linked*" have and had a precise scientific meaning at the time when the provision was enacted, any construction by the Court disregarding the employment of such words by the Oireachtas would amount to an impermissible legislative interference by the judicial branch of government in the exclusive preserve of the legislature.

94. In that event, the Court cannot accept the Appellant's submission that a literal interpretation of the provision produces an absurd result and is satisfied for the reasons given that s. 5 of the 2005Act does not apply. Furthermore, in my judgment, there have been no changes in the law, in social conditions, in technology, or in the meaning of the words used in the provisions which have occurred since the passing of the 2006 Act which would warrant the application of s.6 of the 2005 Act and a construction other than that given.

95. The Court wishes to observe in passing that it appears from the transcript that the Tribunal found the Appellant to be a most honest and intelligent witness and that it was sensitive to all that she had been through over the last number of years; showing courage in difficult circumstances. I have no reason to doubt that is so and am conscious that the result of this appeal is unfortunate and no doubt disappointing from her perspective. Nevertheless, the Court is constrained on the findings made, for the reasons given and conclusions reached, to dismiss her Appeal.