THE REPUBLIC OF SOUTH AFRICA

# IN THE HIGH COURT OF SOUTH AFRICA
# (WESTERN CAPE DIVISION, CAPE TOWN)

Appeal No: A11/2014

In the matter between:

**PETRUS ALBERTUS VENTER** **Appellant**

**and**

**ROCHE PRODUCTS (PTY) LTD** **Respondent**

**Coram**: **BOZALEK, DLODLO et SCHIPPERS JJ**

**Heard:** **1 & 4 AUGUST 2014**

**Delivered:** **22 OCTOBER 2014**

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**JUDGMENT**

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**BOZALEK J:**

[1] The appellant in this matter was a voluntary participant/patient in an international medical trial partly conducted in South Africa. He sued the respondent (as first defendant) and Dr L Gouws & Partners Incorporated, an oncology practice, (as second defendant) for damages flowing from the perforation of his bowel following the administration to him of medication forming part of the trial.

[2] The merits and quantum of the claim were separated and the trial on the merits was conducted before Fourie J who ultimately dismissed the appellant's claim with costs. Leave to appeal was refused but on petition the Supreme Court of Appeal granted the appellant leave to appeal to the Full Court of the Western Cape High Court but only on the issue of whether or not a tacit agreement was established between himself and the respondent. This was the main basis upon which the appellant initially sued the respondent, his alternative claims being based on a *stipulatio alteri* and, in the further alternative, a delictual claim. Similar claims were advanced against the second defendant.

[3] In his final amended particulars of claim the appellant formulated his claim based on a tacit agreement as follows:

> *'(12) Eiser beweer dat, in die proses van die verkryging van Eiser se toestemming soos voormeld, Eerste Verweerder uitdruklik, alternatiewelik stilswyend, teenoor Eiser onderneem het om te voldoen aan die bepalings en voorskrifte van beide die "SA Guidelines" en die "ABPI Guidelines" vir die hou van mediese en kliniese proewe met betrekking tot die bepaling van vergoeding in die geval van proefverwante beserings, soos voormeld. In die proses het Eerste Verweerder onderneem en kontraktueel daarvoor ingestaan om/dat:*
>
> *12.1 Op te tree ooreenkomstig die kliniese en etiese vereistes vir die hou van sodanige proewe in Suid-Afrika, welke onder andere vereis dat vergoeding, in die geval van proefverwante beserings deur pasiënte in Suid-Afrika, nie deur sodanige pasiënte in Switserland van die Switserse "sponsor" van die proewe so verhaal sou moes word nie, maar in Suid-Afrika deur die Eerste Verweerder as aansoeker vir en "monitor" van die proef, betaal sou word;*
>
> *12.2 Die vergoeding gelyk sou wees aan die skadevergoeding wat normaalweg deur Suid-Afrikaanse en/of Britse howe (dit is dieselfde) toegeken sou word in die geval van die opdoen van beserings waar regsaanspreeklikheid daarvoor aanvaar word;*

*12.3 In elk geval, om self die betaling van vergoeding plaaslik (in Suid-Afrika) te maak en te dan van Le Roche AG te verhaal.'*

[4] The respondent denied the existence of any tacit contract and pleaded that the appellant had furnished his informed consent to participation in the trial in terms of a patient information leaflet and informed consent (PIL-ICON), which he had signed. The PIL-ICON referred *inter alia* to the payment of compensation to a volunteer/patient in the event of a trial-related injury. Given the central importance of that portion of the PIL-ICON to the issues in dispute I quote the Afrikaans version of the relevant clause in full. It reads as follows:

*'Vergoeding ingeval van 'n navorsingsverwante besering*

*As u 'n problem ontwikkel wat mediese aandag verg, en wat nie regstreeks te wyte is aan die studie – spesifieke behandeling of prosedures is nie, sal u of u Mediese Hulpvonds gefaktureer word, soos wat normaalweg sou gebeur;*

*F Hoffman – Le Roche AG sal betaal vir die kostes van mediese behandeling vir enige besering wat regstreeks te wyte is aan behandeling met die studie-medikasies waar die streng volgens die studieprotokol gebruik is. Die vergoeding sal geskied ooreenkomstig die "Vergoedingsrigslyne vir Kliniese Proewe" wat in 1991 deur die Vereniging van die Britse Farmaseutiese Bedryf (ABPI) gepubliseer is.*

*U kan 'n afskrif van hierdie ABPI riglyne by u dokter bekom. Geen ander vergoeding word aangebied nie.'*

[5] The English version of the relevant clause is to all intents the same, the only possible point of contention being that the phrase '*die vergoeding sal geskied'* is rendered as *'the compensation available …'* in the English version.

[6] It was common cause that the appellant had signed the consent at the conclusion of a consultation with Dr S van der Merwe, a medical practitioner in the employ of the second defendant (GVI Oncology), after he had explained and taken the appellant through the PIL-ICON point by point.

[7] It was the appellant's case that Dr van der Merwe had represented the respondent in dealing with him on 15 June 2005.

[8] The respondent denied that Dr van der Merwe had represented it in dealing with the appellant on 15 June 2005 and contended, furthermore, that the compensation undertaking was expressly given by F Hoffman-Le Roche AG ('FHLR'), a pharmaceutical company situated in Basel, Switzerland, which company was not cited as a defendant.

[9] It was common cause that the respondent was a company with limited liability registered and carrying on business in South Africa.

[10] The respondent pleaded further that the compensation undertaking contained in the PIL-ICON was expressly given by FHLR and not by it; further that the compensation provisions in neither the ABPI nor the SAGCP guidelines imposed a legally enforceable obligation on the sponsor of a clinical trial in relation to the payment of compensation for a trial-related injury.

**FACTUAL BACKGROUND**

[11] The following background facts do not appear to be disputed. The multinational medical trial was initiated by FHLR and related to cancer medication which it had registered in various countries for the treatment of colon, breast and lung cancer. That medication was to be evaluated for efficacy and safety in patients whose cancer had not yet spread to other parts of the body.

[12] The trial involved some 3 450 patient volunteers and was conducted in 30 countries, including the host country Switzerland. It involved approximately 350 sites, including five South African sites. Forty-five of the patient volunteers were to come from South Africa.

[13] The protocol for the trial, developed by FHLR in Switzerland, was a lengthy and complex document prepared for presentation to the local regulatory bodies of the different countries seeking authorisation to conduct a trial in such countries.

[14] FHLR concluded a written agreement with the respondent in terms of which the latter undertook to conduct the medical and clinical research trial in South Africa and in so doing to *'act as independent contract clinical development services provider'*. In terms of this agreement the respondent undertook responsibility inter alia for the *'initiation and implementation of clinical trials in the Territory according to the Standard Operating Procedures of the Roche Group'*.

[15] It was common cause that FHLR is a company which engages in research development and the marketing of medicines worldwide. The relationship between it and the respondent was never entirely clarified in evidence but it seems that, although an independent legal entity, the respondent formed part of the overall Roche Group.

[16] Pursuant to the aforesaid agreement the respondent, in its capacity as the local representative of FHLR, applied to the Medicines Control Council of South Africa ('the MCC') for permission to conduct the trial in South Africa. At the same time parallel written applications were made to Pharma Ethics and the Ethics Committee of the Witwatersrand University for ethical approval of the trial in relation to each of the sites. Key documents in these applications included the FHLR protocol and the draft PIL-ICON.

[17] The respondent also annexed certificate to its application to the MCC indicating that insurance had been obtained by FHLR from Zurich Insurance providing cover for *'all subsidiaries and associated companies of the Roche Group*

*and/or all hospitals and physicians contracted to perform clinical trials on behalf of all subsidiaries and associated companies of the Roche Group'* for *'comprehensive general and product liability including clinical trials according to the local law in the concerned country'*.

[18] In due course approval for the trial was granted by the MCC, Pharma Ethics and Witwatersrand University none of which made any material alteration to the draft PIL-ICON. The authorisation by the MCC provided that the clinical trial was to be conducted in accordance with the protocol submitted to it. That protocol included as a specific attachment the 17 page detailed PIL-ICON which inter alia set out the nature and purpose of the study, its aim, the risks and side effects, the benefits, alternative treatment, the confidentiality of records and the compensation payable. The standard consent form signed by the appellant stated, inter alia:

> *'I have read this information and understood the purposes of the study as well as the possible benefits and risks of participating. I have had a chance to ask questions and all of my questions have been answered in a way I understand. … By signing this form I give my free and informed consent to take part in this study. I understand that there may be risks and discomfort associated with the study procedures.'*

[19] The respondent also concluded an *'agreement for clinical study'* with the second defendant to conduct the trial at a site at the Panaroma Hospital, Plattekloof, Western Cape. For the sake of clarity I shall refer to the second defendant, the employer of Dr Van der Merwe, as *'GVI Oncology'*. In terms of that agreement GVI Oncology undertook to use the PIL-ICON to obtain informed consent from each patient prior to the initiation of any study.

[20] Under the heading ***'Insurance and Compensation for Medicine Induced Injury'***, the respondent undertook vis-à-vis GVI Oncology to *'assume liability for injuries that occurred in study subjects or patients whenever a cause or relationship*

*can be established between the event and the clinical study procedure or the Roche compound, …'* in stipulated circumstances, principally that the adverse event resulted from a Roche study substance administered according to the approved Roche study protocol. GVI Oncology undertook to report in full any *'adverse event'* to the respondent according to the protocol as well as notifying the MCC and the Ethics committee.

[21] The appellant had previously undergone surgery for colon cancer and was considered to be a suitable candidate for inclusion in the trial. He was first informed of the trial and that he was a suitable participant by Dr Hannelie du Toit, an oncology specialist, in a consultation on 10 June 2005. He was given a copy of the PIL-ICON for perusal in his own time and, after discussion with his wife over the weekend, called Dr du Toit on 13 June 2005 to confirm his decision to take part in the trial.

[22] Two days later on 15 June 2005 the appellant had the consultation described earlier with Dr van der Merwe of GVI Oncology who took him through the PIL-ICON point by point and secured his signature to the consent form.

[23] The appellant was randomly allocated to one of the three arms of the trial each of which involved a slightly different course of medication but still complying with optimum treatment. He received one round of medicinal therapy in early July but nine days later experienced acute abdominal pain which led to him being hospitalised at Panorama Hospital. He underwent a laparotomy following which a bowel perforation of some 3 – 4mm was repaired leaving him with a temporary stoma and a Hartman's rectal stump. Additionally, in September 2005, the appellant underwent a cholecystectomy in Worcester. The appellant has to date, for reasons which are not material to the appeal, chosen not to have the colostomy reversed

notwithstanding FHLR's acceptance of liability to compensate him for the medical and related costs attendant upon such a procedure.

[24] Dr van der Merwe reported these developments to the respondent as a trial-related serious adverse event ('SAE'). The FHLR Basel-based clinical science leader for the trial initially doubted that the bowel perforation was trial-related. Dr van der Merwe was unhappy with this conclusion, however, and made further submissions furnishing, it would appear, the correct time lines. Thereafter the respondent's local representative was requested by the science leader to convey to Dr van der Merwe *'full acceptance of the relationship of this event to treatment'.* Pursuant to this indication Dr van der Merwe wrote to the appellant on 11 August 2005 stating inter alia, under the heading ***'Accountability for your hospital expenses'***, that *'as far as accountability is concerned Roche has agreed to be responsible for treatment of any injury arising directly from the study medication or procedures arising from the protocol'* and adding *'this obviously is relevant to your recent admission for the perforation of your bowel'*. Some months later FLHR's legal department formally approved payment for the appellant's medical costs arising out of the SAE and he was invited to submit invoices relating to his medical and hospital services in this regard for payment by them.

[25] This process did not appear to run smoothly, however, with the result that the appellant found himself out of pocket and having to pay certain service providers directly himself. Ultimately he consulted attorneys and a dispute arose as to whether the appellant was entitled to claim full compensation, i.e. other than direct medical costs, for pain and suffering, loss of income and general damages.

**THE PLAINTIFF'S CASE, AS PLEADED**

[26] In para's [4-8] of his particulars of claim the appellant sets out the background facts against which the tacit contract on which he seeks to rely is to be inferred. These include the agreement between the respondent and FHLR entitled '*Pharma Clinical Development Agreement',* the respondent's application for regulatory approval to the MCC, including undertakings given by the respondent to the MCC therein, notably an undertaking that the protocol complied with the South African *'Guidelines for Good Clinical Practice'* ('the SAGCP'). He further referred to various aspects of the SAGCP including those requiring that there should be provision for compensation and/or treatment in the event of a trial-related injury. The appellant pleaded that the respondent was to be regarded as the *'sponsor'* of the trial. Further, the appellant pleaded that the respondent used the services of GVI Oncology to carry out the trial in terms of the written agreement between the respondent and GVI Oncology.

[27] The appellant pleaded that Dr van der Merwe explained the terms of the PIL-ICON to him including its provisions relating to compensation but he could no longer remember what, if anything, was said about the precise identity of the party which would be responsible for payment of such compensation. The import of such explanation was, however, that compensation would come from a South African entity, namely, the respondent, and would be in accordance with the relevant *'guidelines'*.

[28] On the strength inter alia of these documents and allegations, the appellant alleged that in the process of giving his consent to participation in the trial the respondent had given him an express, alternatively a tacit, undertaking, that it would comply with the provisions of the SAGCP and the ABPI guidelines with regard to the

payment of compensation for trial-related injuries and, in so doing, that the respondent had undertaken to comply with the clinical and ethical requirements for the holding of trials in South Africa.

[29] The appellant averred further that three components of this contractual undertaking were: such compensation would not have to be recovered by patients in Switzerland from the Swiss sponsor but would be paid in South Africa by the first respondent; secondly, such compensation would be equivalent to that normally awarded by South African and/or British courts in such cases where liability is accepted and; thirdly, in any event that the respondent would pay the compensation locally and thereafter recover same from FHLR.

[30] In response to these allegations the respondent specifically denied that it was the sponsor of the trial or that it gave any undertakings to the appellant that either the SAGCP or the APBI guidelines imposed legal obligations on the sponsor of a clinical trial. Its case was further that the appellant was warned that one of the most serious common adverse effects of the trial medication was a perforation of the bowel (up to one in ten patients) and that he accepted this risk when he signed the PIL-ICON and consented to being included in the trial. It denied that the appellant had any valid claim for compensation save in accordance with the clause in the PIL-ICON quoted in full earlier and then ultimately from FHLR and not the respondent. The respondent denied that either it or FHLR was liable for and of the appellant's damages other than the direct medical costs arising out of the SAE.

**THE COURT A QUO'S FINDINGS**

[31] After reviewing all the relevant objective facts and circumstances and the conduct of the parties Fourie J found that they did not justify the inference that the appellant and the respondent intended to, and did, conclude the tacit contract

contended for by the appellant. He noted that FHLR was the initiator and world-wide sponsor of the clinical trial, the nature of the application which had to be made for authorisation and approval of the trial in South Africa, including the FHLR protocol and the PIL-ICON, the MCC's requirement that a local entity should be appointed as the local contact for the trial, the terms of the agreement concluded between FHLR and the respondent and that the aforementioned applications to the regulatory and ethical authorities indicated that FHLR was the sponsor and the respondent the applicant.

[32] Fourie J noted further the terms of the insurance, which was obtained by FHLR as policy holder, and also had regard to the terms of the written agreement between the appellant and GVI oncology. He also noted that the appellant had been in possession of the PIL-ICON for some five days and thereafter had it explained to him point by point by Dr van der Merwe following which he signed it. Focusing on the PIL-ICON, Fourie J noted its repeated references to FHLR and its terms relating to compensation and he took into account the financial aspects of the arrangements between FHLR and the respondent, which involved the latter having to provide FHLR with a budget for approval and that it recovered its expenses from FHLR on a monthly basis. He noted that the trial was accordingly not financed by the respondent. Fourie J observed further that where medical treatment was required following an SAE an estimate thereof had to be provided to FHLR which thereafter decided whether the respondent could incur such medical expenses and thereafter be reimbursed by it (FHLR). He noted further that all data collected during the trial was sent to the central archives of FHLR and that the respondent had no right to suspend or terminate the trial. Finally, Fourie J noted that in terms of the SAGCP guidelines it was the sponsor's responsibility to pay compensation to patients who

suffered bodily injuries and that there had been no delegation of this obligation by FHLR to the respondent.

[33] Fourie J found that FHLR was the initiator and sponsor of the clinical trial and that the respondent had been the South African contact for the trial; that the SAGCP guidelines placed the obligation on the sponsor to compensate patients/volunteers, an obligation which FHLR had not delegated. He found that the PIL-ICON document made it abundantly clear that FHLR was the initiator and sponsor of the trial and the entity which undertook to pay compensation. He found too that as a result of his exposure to the PIL-ICON document, a reasonable person in the position of the appellant would have been aware of its content and in particular the compensation provisions. The learned judge found that there was no evidence that Dr van der Merwe had the actual authority (expressed or implied) to conclude, on behalf of the respondent, the tacit contract relied on by the appellant. He found that there was no objective evidence to indicate that the appellant intended to contract with the respondent (whose name did not even appear in the PIL-ICON). He found that the agreement concluded between the respondent and GVI Oncology in no way supported the inference contended for by the appellant, namely, that GVI's representative, Van der Merwe who concluded the agreement and dealt with the appellant, had the authority to furnish a compensation undertaking on behalf of the respondent.

[34] Finally, the trial judge concluded that the objective facts and circumstances did not, on a balance of probabilities, justify the inference that the appellant and the respondent had concluded a tacit contract as alleged by the appellant, or at all.

**THE LAW RELATING TO TACIT CONTRACTS**

[35] It is worth emphasising the fundamental requirement of consensus in any contract including tacit agreements. The principle is illustrated by the following passage from *Nedcor Bank Ltd v Withinshaw Properties (Pty) Ltd*[1] where the Court stated the following regarding the requirements for a tacit contract:

> *'The offer and acceptance, indicating unqualified consensus ad idem on all essential aspects of the agreement, must clearly and unequivocally be inferred from the conduct of the parties'.*

[36] In *McDonald v Young*[2] the Court stated:

> *'It is trite that a tacit contract is established by conduct. In order to establish a tacit contract, the conduct of the parties must be such that it justifies an inference that there was consensus between them. There must be evidence of conduct which justifies an inference that the parties intended to, and did, contract on the terms alleged. It is clear from the appellant's evidence that there was no consensus between the parties.'*

[37] The Court in *McDonald* rejected the appellant's case that there had been a tacit agreement between him and the respondent in the form of a joint venture agreement inter alia on the basis that the appellant's reliance on a tacit contract was inconsistent with his evidence.

> *'The appellant believed and gave evidence to the effect that he and the respondent had concluded an express agreement in respect of the property, the aim of which was to ensure that he was financially independent. Implicit in this is the intention that he would not have to rely on the respondent, or any other person, for financial support. In the circumstances, the appellant could not have formed the intention to contract tacitly with the respondent. Having regard to his evidence that the purpose of the joint venture agreement was to render him financially independent, the*

[1] 2002 (6) SA 236 (C) at paras [30]
[2] 2012 (3) SA 1 (SCA) at page 11F – G

*appellant could not at the same time have contemplated that the respondent would continue to support him for the rest of his life.* [At 10 E-F]

*…*

*The appellant's stated belief, that there was an express contract between him and the respondent in respect of the property, precludes this court from drawing an inference to the effect that the parties had entered into a tacit agreement, the terms of which were inconsistent with the express agreement to which he testified.'* [At 11A]

[38] In determining whether a tacit agreement has been concluded the conduct of both parties and the circumstances of the case generally are considered, the ultimate question being whether, to all outward appearances, there was an agreement[3]. One test for deducing the existence of a tacit agreement, the *'traditional statement of principle',* was stated as follows by Corbett JA[4]:

> *'In order to establish a tacit contract it is necessary to show, by a preponderance of probabilities, unequivocal conduct which is capable of no other reasonable interpretation than that the parties intended to, and did in fact, contract on the terms alleged. It must be proved that there was in fact consensus ad idem.'*

[39] Judicial debate has ensued as to whether the aforementioned case, with its requirement of *'unequivocal conduct … capable of no other reasonable interpretation'* might not set too high a standard of proof and rather that a tacit contract should be found to have been established if '*the most plausible, probable conclusion from all the relevant proved facts and circumstances is that a contract came into existence'*[5].

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[3] See *Joel Melamed and Hurwitz v Cleveland Estates (Pty) Ltd* 1984 (3) SA 155 (A)
[4] *Standard Bank of SA Ltd and Another v Ocean Commodities Inc and Others 1983 (1) SA 276 (A) at 292 B-D*
[5] See Corbett JA in *Joel Melamed* at 164I – 165A

[40] The element of consensus was underlined in the recent Full Bench decision of this division in *Woolworths (Pty) Ltd v P Christodoulou and Sons Textiles and Another*[6] where Rogers AJ, on behalf of the court, stated as follows at (para 57):

> *'What is apparent, in my view, is that the courts have always appreciated the special difficulty which arises when a person asserts the existence of a tacit contract. Where a contract is said to have come into existence through proven express exchanges (whether oral or written), it is usually not difficult to decide whether in law the exchanges evidence an unequivocal offer and acceptance and thus the existence of a contract. Where the contract is said to come into existence tacitly, it is generally more difficult to draw that conclusion. One needs to guard against the finding that, because it would have been reasonable and fair for the parties to have reached the alleged agreement if the matter had been specifically discussed, they therefore were in fact tacitly in agreement. The question is not even whether they would probably have reached agreement if the matter had been raised but whether they were in fact in agreement although they did not express it.'*

**THE EVIDENCE OF THE APPELANT AND DR VAN DER MERWE**

[41] Against this background it is important to consider, in the first place, the evidence of the two parties between whom any tacit agreement, if it did come into existence, arose i.e. the appellant and Dr van der Merwe.

[42] The appellant was initially recruited into the trial through Dr Hannelie du Toit during a consultation in Worcester on Friday 10 June 2005. He had undergone surgery for colorectal cancer and was a suitable candidate for inclusion in the trial. On that same day Dr du Toit provided the appellant with a copy of the PIL-ICON which he read and discussed with his wife. Shortly thereafter he resolved to join the trial and telephoned Dr du Toit on 13 June 2005 to tell her of his wish to do so. By

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[6] [2014] ZAWCHC 8 (A391/2012, 3541/2012) (10 February 2014)

then he had already decided to participate in the trial on the strength of what Dr du Toit had informed him. Prior to committing to the trial he had not concerned himself unduly with the PIL-ICON because the terms which were used therein were beyond him. He added that, as far as he was concerned, there were no risks attached to the exercise.

[43] The appellant consulted with Dr van der Merwe of GVI Oncology two days later. He testified that he had little recollection of what his discussion with Dr van der Merwe entailed besides that the latter had taken him point for point through the PIL-ICON and endeavoured to explain to him in layman's terms what every single clause meant. He could not recall whether the name of FHLR was used during the discussion but in any event the identity of the party undertaking to pay medical compensation in the event of a trial-related injury had been of no concern to him. He had also not been concerned whether the trial was being controlled from within or outside South Africa.

[44] The appellant testified that he had understood that in order to participate in the trial (and derive the benefits) he had to sign the PIL-ICON; furthermore, that when he signed it he understood he was giving his assent to all that appeared above his signature. The appellant even went so far as to testify that it was *'irrelevant'* to him who was sponsoring the trial.

[45] The appellant initially testified that it was possible that he had read the PIL-ICON's compensation clause but then testified that he would have read the sentence that provided FHLR would pay for the costs of medical treatment. The appellant conceded that this portion of the PIL-ICON made it clear who would be responsible for any such costs.

[46] The appellant admitted that he had seen that the party undertaking to pay his medical costs in the event of a trial-related injury was FHLR and testified further that he was not aware of any other company, besides FHLR, which bore the name *'Roche'*.

[47] The following exchange in the appellant's examination in chief is illuminating in regard to who he intended to contract with:

> *'Maar U weet dat as daar 'n kontrak is, daar is meer as een party …*
>
> *U is die een party aan hierdie kontrak? ... --- Dis korrek …*
>
> *U het nie omgegee wie die ander party was aan hierdie kontrak nie? --- Nee, ek het geweet wie die ander party op die tafel is.*
>
> *Wie sê u is die ander party? --- Die ander party wat ek op die tafel gehad het daar was GVI Oncology.'*

[48] The appellant's belief that he had contracted with GVI was borne out by his facsimile letter to Dr van der Merwe on August 2005 in which he demanded that "they" accept all responsibility for medical expenses arising out of his injury. The "they" (or more accurately the "u") referred to in his letter was, as the appellant testified, a reference to GVI Oncology, another indication that, at least as far as the appellant was concerned, his agreement was <u>not</u> with the respondent.

[49] If, as he had testified, the appellant had read the PIL-ICON he would have seen that it bore the name of FHLR on the top of the first page and contained an invitation by that company to participate in the trial. He would, moreover, have read its address which would have made it apparent that it was a Swiss company. As was pointed out by the trial judge, FHLR's name appeared 24 times in the PIL-ICON and the respondent's name not at all.

[50] In the final analysis the appellant testified that he had read the PIL-ICON, understood the purpose of the medical trial as well as its principal advantages and risks, and that on three separate occasions in the PIL-ICON he had given his consent to participate to FHLR.

[51] Finally, the appellant admitted that, had he read through the PIL-ICON, which he testified he did, the identity of the other party to the contract would have been apparent to him; it was, however, something that was irrelevant to him:

> *'En as u hierdie inligtingstuk gelees het dit vir u duidelik gewees het wie die ander party is tot hierdie kontrak in die inligtingstuk. --- As ek daarin belangestel het om te weet, ja, edelagbare.*
> *Dit is die punt, as u belangestel het sal dit vir u duidelik geweet het, nie waar nie? --- Dit was vir my irrelevant, dis vandag nog irrelevant, edelagbare.'*

[52] Thus on the appellant's own evidence of the occasion on which any tacit contract was concluded, namely, during his initial consultation with Dr van der Merwe, it is difficult to discern the basis for such an agreement between him and the respondent, as opposed to FHLR. This impression is strengthened when one has regard to the evidence of Dr van der Merwe, who, on behalf of the respondent, is alleged by the appellant to have entered into a tacit agreement with him to pay full compensation in respect of the consequences of medical injuries which he might sustain as a result of his participation in the trial.

[53] Dr van der Merwe testified, moreover, that he would have made it very clear to the appellant that he would not be entitled to receive anything more than medical costs. In this regard he had used a humorous analogy of a patient growing green horns and a green tail as a side-effect of using the trial medication. In that event, he had explained to the appellant, *'Roche'* would pay for the medical costs of removing these growths but not for the inconvenience which they may have caused.

[54] Even if Dr van der Merwe had discussed the identity of the party which would pay for any trial-related injuries which the appellant sustained he would not have mentioned the respondent. He testified that as he understood the position at that time, any decision to pay for medical costs ultimately would have to be made by and from Switzerland.

[55] Of particular significance is the fact that Dr van der Merwe was himself unaware of any distinction between the respondent and FHLR. In this regard he testified that, in dealing with the appellant, he regarded himself as representing GVI Oncology and the entity which he regarded as the sponsor, namely, the Swiss company that was paying for the trial and leading it and which he referred to as Roche International. He testified further that he considered *'Roche'* a Swiss company and the sponsor of the trial and did not even know that the trial's monitor, Ms Matthai, was employed by the respondent. As far as he was concerned, in the event of a trial-related injury the payment of medical costs would come from Switzerland and was merely facilitated locally.

[56] Given the fact that the PIL-ICON refers repeatedly and exclusively to FHLR and Dr van der Merwe's apparent lack of any independent authority to represent or contract on behalf of the respondent, the appellant sought to contend in effect for two concurrent compensation undertakings; firstly, the express undertaking by FHLR contained in the PIL-ICON and, secondly, a tacit undertaking or agreement by the respondent. In support of this tacit agreement the appellant appears to rely upon on various provisions and terms in the respondent's application for approval of the trial to the MCC, the SAGCP and ABPI guidelines, the agreement between FHLR and the respondent and that between the latter and GVI Oncology.

[57] However, the appellant's own evidence was that he was at all material times unaware of the respondent's existence and never saw its application to the MCC nor the various agreements between the aforementioned parties involved in the trial notwithstanding that these documents were cited in aid of the appellant's case in his particulars of claim.

[58] Importantly, although the appellant pleaded in his particulars of claim that the substance of the explanation which he received from Dr van der Merwe was that compensation for any medical injury would take place locally and through a South African entity (the respondent), this was not borne out by his evidence. He could not independently recall whether anything was said to him regarding the identity of the party which would pay compensation for trial-related injuries. As far as he was concerned the identity of the payer was irrelevant to him and he was indifferent as to where it was based. He knew that the undertaking in the PIL-ICON was limited to medical costs and he did not testify that he was led to believe that he was entitled to anything more.

[59] An obvious question is why, had the respondent indeed wished to enter into an agreement with the appellant to pay him compensation for any trial-related injuries, it did not do so explicitly in an agreement, if needs be in the PIL-ICON.

[60] It is improbable, in my view, that there existed an additional agreement or undertaking on the part of respondent to pay compensation for medical injuries arsing out of the trial i.e. over and above that furnished by FHLR in terms of the PIL-ICON. Not only does the appellant run up against the same difficulty which faced the appellant in *McDonald v Young,* namely, contending for an agreement at odds with one explicitly reached, but a parallel agreement would have been unnecessary and confusing. There was evidence, furthermore, that the respondent had been

responsible for adapting Roche's global PIL-ICON for use in the South African trial. Had it wished to do so, therefore, it would have been a simple matter for the respondent to delete all references therein to FHLR and to have undertaken the obligation to compensate trial participants for medical injuries itself. To add to the improbability of it having assumed direct responsibility is the fact that the respondent had no independent resources to pay for any medical compensation claims. It ran the South African trial on the basis of a budget which it submitted to FHLR. There was no evidence or suggestion that this budget made provision for possible medical expenses of this nature. All the evidence before the Court a quo was that after securing FHLR's agreement to pay for medical costs arising out of a trial-related injury the respondent paid, or at least undertook to pay, these upfront and then recover them from FHLR.

[61] On behalf of the appellant Mr van Riet contended that the respondent was the *'sponsor'* of the trial in South Africa and, as such, in terms of the SAGCP guidelines was obliged to compensate trial participants for trial-related injuries. However, in this regard the SAGCP guidelines require only that the principal investigator should be a South African based scientist, as was the case. Furthermore, it is significant that the same guidelines make provision for contract research organisations (CRO's) to facilitate the carrying out of clinical trials in South Africa, which entities do not become liable either for the costs of or the payment of compensation. Nor is there any statement in the SAGCP guidelines imposing an obligation on the sponsor to pay compensation, the requirement simply being that there be an explanation of the compensation available for the patient/volunteer.

[62] In any event, on a proper reading of the documentation and understanding of the process, although the respondent may have implemented the trial locally it was

not its sponsor. The application to the MCC indicated in terms that the sponsor was FHLR and where, in one or two sections of the application, it indicated otherwise, this was clearly a mistake. Although FHLR transferred certain of its functions to the respondent, as in effect its local agent, it did not transfer to the respondent its obligation to compensate patient/volunteers for trial-related injuries. This much appears from the agreement between these two parties read together with para 4.5 of the SAGCP which provides that any duty and function *'not specifically transferred to and assumed by a CRO (contract research organisations) are retained by the sponsor'*. The respondent's position was, for all intents and purposes, akin to that of a CRO. Moreover the evidence led by the respondent was that although the respondent paid, in the first place, for medical costs arising out of trial-related injuries in South Africa this was always after FHLR had approved same and subject to the respondent claiming them back from FHLR.

[63] Another aspect or circumstance relied upon by the appellant was the requirements of medical ethics, the argument being that these required that the compensation undertaking had to be given by a South African entity and be executable in South Africa. This contention was bolstered by the argument that in the absence of the tacit agreement relied upon the appellant would have to sue in a Swiss court for such expenses and/or compensation to which he laid claim.

[64] This argument is flawed at a number of levels, both theoretical and practical. Subject to satisfying the prerequisites for such an action, there is no absolute bar to the appellant suing a Swiss-based company in a South African court. Secondly, the process of applying to and through the MCC for approval of a trial entailed a scrutiny of the application against the provisions of the SAGCP guidelines which in turn give effect to the principles contained in the Declaration of Helsinki adopted by the World

Medical Association in 1964 dealing with Ethical Principles for Medical Research involving Human Subjects.

[65] The SAGCP guidelines do not stipulate that compensation must be offered. They provide no more than that:

> *'… Both the informed consent discussion and the written informed consent form and any other written information to be provided to participants should include explanations of the following:*
>
> *…*
>
> *(k) the compensation and/or treatment available to the subject in the event of trial-related injuries.'*

[66] It is also significant that the ABPI guidance note concerning items that should be covered in the patient information sheet states as follows:

> *'Explain that compensation may be available for any injury attributable to administration of a medicinal product within the trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial. Record that compensation will be considered in accordance with the "Clinical Trial Compensation Guidelines" issued by ABPI …, where applicable, and inform the patient that a copy of guidelines can be made available on request.'*

[67] In any event, even were the ethical position to be that full compensation should have been offered (and by the local entity) this would constitute no more than a single building block in establishing a tacit agreement to the effect that such compensation was offered and accepted.

[68] In the final analysis I am satisfied that all the evidence, including that indicating the procedure followed by Dr van der Merwe and the respondent's local representatives following notification of the SAE which the appellant sustained, all bear out the terms captured in the contractual arrangement, namely, that such expenses, if met by anyone, would be met by FHLR. It will be recalled that Dr van

der Merwe, in the face of an initial negative decision, motivated for the appellant's medical costs to be met by seeking to persuade the overseas team involved in the trial study that the injury flowed out of the appellant's participation in the trial. The respondent's local representatives only agreed to reimburse the appellant for his medical expenses once the decision had been taken by the overseas representative.

[69] It also bears mentioning in this regard that the appellant was not left without a remedy for the consequences of his injury. The evidence is clear that FHLR was willing to compensate him in accordance with the ABPI guidelines and in fact agreed to subject itself to an arbitration process to fix the amount. It appears, however, that the appellant was unwilling to accept this process and instead sought a declaration to the effect that the respondent was obliged to compensate for the full damages which he had suffered, as would be awarded by a British or South African court.

[70] Having regard to the evidence as a whole I am unpersuaded that the Court a quo erred in finding that the appellant had failed to establish the tacit agreement for which he contended. As a starting point I consider that the appellant failed to establish that Dr van der Merwe had any actual authority, either expressed or implied, to conclude a contract with the appellant on any basis other than that contained in the PIL-ICON. Further, in my view the appellant's evidence alone fell well short of establishing unequivocal conduct, capable of no other reasonable interpretation than that the appellant and the respondent intended to and in fact contracted that the latter would be liable for the appellant's full damages in the event of him sustaining a trial-related medical injury.

[71] What the appellant seeks through the device of a tacit contract is the imposition of a full compensation obligation on the respondent on an ethical or policy

basis. This approach is misconceived, however. It goes almost without saying that should the MCC consider thus a policy appropriate it can make such a condition an obligation a prerequisite for the holding of a medical trial in this country.

[72] These findings, strictly speaking, render it unnecessary to determine the precise ambit of the compensation which was in fact offered by FHLR. For the sake of completeness, however, I record that I find myself in agreement with the conclusion reached by Fourie J, namely, that in terms of the PIL-ICON, read together with the provisions of the ABPI guidelines, such compensation as was offered by FHLR fell short of a legal commitment. It amounted to the possibility of compensation on an *ex gratia* basis, on the best case scenario in accordance with the compensation that a British court would accord. That view is in accordance with the decision of a British court in *Morton James Wylie v Dr Donald Grosset, Greater Glasgow Health Board*[7] where it was held that the ABPI guidelines did not impose a legally enforceable obligation. The Court held that the words *'Broadly speaking, the ABPI guidelines recommend that the sponsor without legal commitment, should compensate you without you having to prove that it is at fault'* did not amount to a guarantee that compensation would actually be paid.

[73] In the result I find that there is no merit in the appeal.

**COSTS**

[74] In the ordinary course the respondent would be entitled to his costs on appeal. However, after enquiry with the respondent's counsel, we were subsequently advised that the respondent was prepared to forego its claim for costs in the appeal.

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[7] *[2011] COSH 89 at para [22]*

[75] In the result the order is simply that the appeal is dismissed.

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**BOZALEK J**

**I agree.**

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**DLODLO J**

**I agree.**

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**SCHIPPERS J**

APPEARANCES

| | |
|---|---|
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