Martek Biosciences Corporation *v* Cargill International Trading Pte Ltd [2012] SGHC 35

Case Number	: Originating Summons No 1418 of 2009
Decision Date	: 16 February 2012
Tribunal/Court	: High Court
Coram	: Tay Yong Kwang J
Counsel Name(s)	: Dr Stanley Lai, SC and Vignesh Vaerhn (Allen & Gledhill LLP) for the applicant; Daniel Koh (instructed) (Eldan Law LLP) and Wendy Low Wei Ling (Rajah & Tann LLP) for the respondent.
Parties	: Martek Biosciences Corporation — Cargill International Trading Pte Ltd

Patents and Inventions

16 February 2012 Judgment reserved.

Tay Yong Kwang J:

Introduction

1 This is an appeal by the Applicant against the decision ("the Decision") of the Deputy Registrar of Patents and the Principal Assistant Registrar of Patents ("the Tribunal") dated 3 November 2009, holding that the Respondent succeeded in its application to revoke the Applicant's Singapore Patent No. 42669 ("the Patent"). This is the second appeal by the Applicant from a decision of a tribunal of the Intellectual Property Office of Singapore ("IPOS"). The first concerned another patent, Singapore Patent P-No. 49307, which the respondent had similarly applied to revoke and in respect of which I delivered judgment in *Martek Biosciences Corporation v Cargill International Trading* [2011] 4 SLR 429 ("*Martek v Cargill (No 1)*").

2 For the reasons which follow, I allow the Applicant's appeal against the Decision here and dismiss the Respondent's appeal insofar as it relates to certain aspects of the Decision.

3 Unless otherwise indicated, all references to statutory sections below are to the Patents Act (Cap 221, 2005 Rev Ed) (the "Act").

The facts

4 The parties are the same as in *Martek v Cargill (No 1)*. The Applicant is Martek Biosciences Corporation, a company incorporated under the laws of the State of Delaware of the United States of America. The Respondent is Cargill International Trading Pte Ltd, a company incorporated in Singapore.

5 The Applicant is the proprietor of the Patent, which is entitled "Arachidonic Acid and Methods for the Production and Use Thereof". The Patent was granted by IPOS on 30 March 1999.

6 On 20 January 2006, the Respondent filed an application to revoke the Patent on the following grounds:

A) That the invention was not a patentable invention under section 80(1)(a) of the Act;

B) Insufficiency, i.e. that the specifications of the Patent did not disclose the invention clearly and completely for it to be performed by a person skilled in the art as required by section 80(1)(c) of the Act.

7 The Applicant filed an application to amend the claims of the Patent on 6 September 2006. The amendments were advertised in the Patents Journal on 30 October 2006 and no opposition was received by IPOS within the period during which they were open for opposition. The allowability of these amendments is not in issue. They were not challenged by the Respondent. The Tribunal held that the amendments were allowable as they did not result in the specifications disclosing any additional matter nor extending the protection conferred by the Patent. The proceedings before IPOS and before me therefore proceeded on the basis of the claims as amended.

8 At a Case Management Conference on 28 April 2008, IPOS Hearing Officers informed the parties of their intention to cause the Patent to be re-examined under s 80(2) of the Act. The Respondent followed by filing the request for re-examination and the Patent was subsequently re-examined by an examiner from the Australian Patent Office of IP Australia who then produced a report ("the Re-examination Report"). The Re-examination Report dated 24 October 2008 was made available to parties on 6 November 2008.

9 The matter was heard before the Tribunal from 9 to 12 February 2009. It was agreed that the Evidence Act (Cap 97, 1997 Rev Ed) and the Rules of Court (Cap 322, R5, 2006 Ed) would apply to the proceedings.

The Patent

10 The Patent is comprehensively summarised by the Tribunal in the Decision at [13]-[24]. I do not propose to repeat it here but will merely highlight the essence of the Patent.

11 The Patent, as mentioned above, is entitled "Arachidonic Acid and Methods for the Production and Use Thereof". The published extract reads:

> The present invention relates to processes for the production of arachidonic acid containing oils, which preferably are free of eicosapentaneoic acid. This invention also relates to compositions containing oils of very high amounts of arachidonic acid in triglyceride form, and to uses of such oils. In a preferred embodiment, *Mortierella alpina* is cultivated using conditions which yield triglyceride oil having particularly high levels of arachidonic acid residues, biomass is harvested and the oil is extracted, recovered and used as an additive for infant formula.

12 The Patent goes on to explain the context and purpose of the invention. It explains that arachidonic acid ("ARA") is a long chain polyunsaturated fatty acid ("PUFA") of the omega-6 class and is important for the human body in various ways. Despite its importance to human metabolism, however, ARA cannot be synthesized in humans *de novo*. Therefore, most ARA must be provided in the diet, especially during times of very rapid body growth such as infancy. Accordingly, human breast milk ("HBM") contains high levels of ARA and is the most prevalent C_{20} PUFA in HBM.

13 However, many mothers do not breast feed their infants or do not breast feed for the entire period of rapid infant growth, choosing instead to use an infant formula. What this means is that there remains a need for an economical, commercially feasible method of producing ARA, preferably without concomitant production of eicosapentaneoic acid ("EPA"). This is because high EPA levels in

dietary supplements result in a depression of the ability to form ARA from dietary linoleic acid ("LOA").

14 The problem is that of those fungal species which have had their fatty acids characterised, it has been found that most do not make ARA. Of those which do make ARA, many produce significant quantities of EPA in addition to ARA. Accordingly, while the fungal species producing both ARA and EPA can be utilised in the process of this invention, it is preferable to use species which do not produce significant quantities of EPA, such as *Pythium insidiosum* and *Mortierella alpina*. Further, the oil from *Mortierella alpina* is likely to be more economical to produce.

15 The object of the present invention is to satisfy that need. The invention contemplates the use of any microbial oil which contains sufficient ARA to overcome the negative effects of dietary EPA. Typically, in HBM, the ratio of ARA to EPA is about 20 to 1. Preferably, the invention contemplates that an ARA: EPA ratio of at least 5:1 should be achieved. More preferably, the ratio will be at least 10:1. Ideally, it should be at least about 20:1. The higher the amount of ARA in the end product relative to the EPA, the more desirable the result.

16 A further object of the invention is to provide an additive and a source for that additive for use in infant formula such that the ARA levels in the formula approximate those levels in HBM. It is an additional object of this invention to provide an ARA-containing fungal oil for use in enteral, parenteral or dermal products. The method of this invention provides triglycerides having the desired composition by extraction from natural sources. The Patent specifications state that no commercial infant formulas known to the applicant contain triglyceride form.

17 Of the claims in the Patent, only claims 1, 2, 20 and 35 are independent claims and the rest are dependent on one or more of these four claims.

The prior art

18 The prior art cited before the Tribunal were referenced as D1 to D10, with D1, D4, D7 and D10 assuming particular significance before the Tribunal and before me:

A) D1 refers to "Production of Arachidonic Acid by *Mortierella alpina* ATCC 3222" by Bajpai *et al*, published in the Journal of Industrial Microbiology, 8 (1991) 179-186;

B) D4 refers to Japanese Patent No 64-38007, published in 1989 and entitled "External Preparation for Skin" (D4a refers to the English translation thereof and it is this translation that I shall refer to in this Judgment);

C) D7 refers to International Patent No WO 92/13086, entitled "Arachidonic Acid and methods of the production and use thereof", published in 1992;

D) D10 refers to International Patent No WO 94/28913, entitled "Method and Pharmaceutical compositions useful for treating neurological disorders", published in 1994.

19 A useful summary of the prior art can be found at [100] of the Tribunal's Decision. I will analyse the contents of the respective prior art below when I address the validity of the Patent.

The witnesses before the Tribunal

The Respondent's witnesses

20 The two expert witnesses for the Respondent (which was the applicant below) were the same

as in *Martek v Cargill (No 1*). I should clarify at this point that chronologically, the proceedings that are the subject of this appeal took place before the proceedings that were the subject of the appeal in *Martek v Cargill (No 1)*. However, this appeal happened to be fixed before me later than the other appeal. The expert witnesses for the Respondent were Dr Puah Chum Mok ("Dr Puah") and Dr Nga Been Hen ("Dr Nga").

Dr Puah

21 At the time of the hearing below, Dr Puah headed the Technological Centre for Life Sciences in the Singapore Polytechnic. He made three statutory declarations in relation to this matter dated 5 December 2006, 17 October 2008 and 3 December 2008. In his statutory declaration dated 5 December 2006, he claims at paragraph 3 that his specialisation is in Cell Culture and Bioprocess Technology including fermentation technologies and that his industrial experience encompasses research in the field of fermentation.

22 Both at the hearing below and before me, the various alleged deficiencies of Dr Puah's expert testimony were a significant part of the Applicant's case. In particular, the Applicant submitted and continues to submit on appeal that, *inter alia*: (a) Dr Puah lacked the relevant expertise; (b) his evidence pertained to areas outside his area of expertise; (c) his evidence was based on assertions suggested to him by the Respondent and its agents; (d) he was unable to differentiate between total lipids, fatty acids and oil; (e) he had no relevant knowledge of pH profiling and culture conditions; (f) he was not an expert in the strains of *Mortierella*; (g) he did not understand what a fungal oil was; (h) his second and third statutory declarations were unreliable; (i) he did not understand the textbook references and had not formed an independent view of the textbook references; and (j) as a witness, he was generally evasive and unwilling to answer questions directly. In its submissions before me, the Applicant frequently referred to portions of the transcript of Dr Puah's cross-examination to make the points above.

23 The Tribunal declared itself "inclined to share the general thrust of the [Applicant's] submission to exercise caution in relation to Puah's evidence", and found that he "did not appear to possess the relevant expertise" to assist the Tribunal in the hearing or to testify with confidence on the matters in question. As such, the Tribunal held itself unable to draw much assistance from Dr Puah's evidence (Decision at [37]). Dissatisfied with this, the Applicant argues before me that the Tribunal should have gone even further and completely disregarded Dr Puah's evidence.

24 I do not think it necessary for me to do this for the purposes of the appeal. As will be apparent later when I analyse the Tribunal's Decision, the Tribunal did not rely on Dr Puah's evidence in making its findings. Furthermore, at the hearing before me, the Respondent confirmed that it was not relying on Dr Puah's evidence and that it was relying only on Dr Nga's evidence and the objective text of the prior art documents. It follows that Dr Puah's evidence is not relevant for the purposes of the issues in this appeal.

Dr Nga

25 Dr Nga was, at the time of the hearing below, a Research Fellow at the Department of Chemistry, National University of Singapore. At the time of the hearing below, he had 38 years of working knowledge in microbial fermentation.

26 The Applicant argued, both at the hearing below and before me, that Dr Nga's evidence should also be disregarded. The basis for this argument in relation to Dr Nga's evidence was different from that in relation to Dr Puah's evidence: the Applicant argued that Dr Nga's views were made solely with

the benefit of hindsight whereas the question of the inventiveness of a Patent must be assessed from the point of view of a skilled person without any knowledge of the alleged invention (*Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 at [73]). Further to this, the Applicant also alleged that Dr Nga was evasive and unreliable in the sense that he was more than ready to read teachings into the prior art despite already admitting that his views on the prior art were based on hindsight.

27 The Tribunal held that while it did not share the Applicant's characterisation of Dr Nga as an evasive witness, it nonetheless "treaded with caution" in relying on his evidence (Decision at [43]), given that Dr Nga himself had admitted during cross-examination that his views were made with the benefit of hindsight. Once again, as with Dr Puah's evidence, the Applicant argued before me that the Tribunal should have completely disregarded Dr Nga's evidence rather than merely "treaded with caution".

The Applicant's witnesses

28 Two expert witnesses testified for the Applicant (which was the respondent below). They were Dr William R. Barclay ("Dr Barclay") and Dr David Kyle ("Dr Kyle"). Dr Kyle was also one of the Applicant's two expert witnesses in *Martek v Cargill (No 1)*.

Dr Barclay

29 At the time of the hearing, Dr Barclay had been the Applicant's Director of Discovery and Chief Intellectual Property Officer for the Applicant since 1987, in which capacity he had isolated and developed microbial strains for use in the production of omega-3 and omega-6 highly saturated fatty acids. He represented his expertise to be in polyunsaturated fatty acid fermentation.

30 The Respondent submitted below that Dr Barclay was not an objective witness because he was one of the founders of the Applicant and remains an employee and therefore had a direct commercial interest in the Patent. The Applicant rebutted the Respondent's contention and argued that there was no basis for the Respondent to challenge Dr Barclay's objectivity when it had not challenged the objectivity of his evidence under cross-examination before the Tribunal. The Tribunal "reminded" itself that Dr Barclay was "an expert with an interest in the proceedings" by virtue of his relationship with the Applicant and that it therefore had to scrutinise his evidence with greater care and limit its consideration of Dr Barclay's testimony to the technical and scientific aspects of the invention as such (Decision at [48]).

Dr Kyle

31 Dr Kyle is the sole inventor of the Patent. He was employed by the Applicant since 1985 but left in October 2001 to start his own company and was therefore no longer employed by the Applicant at the time of the hearing below. He testified that his expertise was in lipid biochemistry and single cell oil production.

32 As in *Martek v Cargill (No 1)*, the Respondent argued below that Dr Kyle could not be considered an objective witness because he was the sole inventor of the Patent and therefore had an interest in the Patent. As he was a former employee of the Applicant, he also had a pre-existing close relationship with the Applicant. While the Tribunal agreed with the Applicant that there was no basis for the Respondent to allege that Dr Kyle had a pre-existing close relationship with the patentee, it limited its consideration of his testimony to the technical and scientific aspects as such, as it did with Dr Barclay's evidence (Decision at [54]).

The Tribunal's decision

33 The Tribunal held that the Respondent succeeded in its application to revoke the Patent under s 80(1)(a) of the Act and ordered the Applicant to pay the Respondents' costs, save for the costs arising out of a letter submitted by the Respondent to the Tribunal after the conclusion of the hearing but before submissions were made. In reaching this conclusion, the Tribunal analysed each independent claim, *i.e.* claims 1, 2, 20 and 35, in turn and concluded that all four claims were novel over the prior art cited. However, the Tribunal held that each of the four claims respectively lacked the element of inventive step because it would have been obvious to a skilled person to combine the teachings in the relevant prior art to reach the claims in the Patent (Decision at [139], [148], [198] and [241]; see also summary of Tribunal's findings in Decision at [215]). Specifically, in relation to claim 1, it would have been obvious to a skilled person to combine the teachings of D4 and D7 or D4 and D10; in relation to claim 2, it would have been obvious to a skilled person to combine the teachings of D4 and D5 or D4 and D7; in relation to claim 20, it would have been obvious to a skilled person to combine the teachings of D7 and D10; and in relation to claim 35, it would have been obvious to a skilled person to combine the teachings of D4 and D5 or D4 and D7. Given that the four independent claims were found to lack inventive step, the remaining claims also failed and the Patent was found to fail on the ground of patentability; however, the Tribunal did go on to consider the dependent claims separately and held them to lack inventive step as well.

34 Therefore, despite the significant length of the Decision, the Tribunal's Decision was actually quite a narrow one. The only reason the Patent was found to lack patentability was because of the principle in the law of patents that it is permissible in the inquiry for inventiveness to construct a "mosaic" out of the various pieces of prior art (*Muhlbauer AG v Manufacturing Integration Technology Ltd* [2010] 2 SLR 724 at [93] ("*Muhlbauer*")), unlike in the inquiry for novelty (*Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Ltd* [2005] 3 SLR(R) 389 ("*Trek Technology*") at [87]). I will consider below whether, even given this mosaicing" of prior art, the Patent could be said to lack inventiveness. However, as the Respondent also appeals against certain aspects of the Decision which the Tribunal ruled in the Applicant's favour, particularly with regard to the novelty of the Patent's claims, it is also necessary for me to consider these other issues.

The issue before the Court

35 The only issue before me is the patentability of the Patent under s 80(1)(a) of the Act. Although the Respondent framed an alternative issue, *i.e.* whether the Patent discloses the invention clearly and completely for it to be performed by a person skilled in the art as required by s 80(1)(c) of the Act (the "insufficiency" issue), I find that the Respondent is not entitled to challenge the sufficiency of the Patent before me. The Tribunal held at [216] of the Decision that although this ground was initially pleaded by the Respondent, it was subsequently not pursued before it. The Respondent before me argues that the Tribunal was wrong to make this finding – it points out that it made detailed written submissions to the Tribunal both in its Closing Submissions and Reply Submissions below. [note: 1] However, this does not address the Applicant's arguments that the Respondent's Opening Statement below was completely silent on the insufficiency issue [note: 2] and that the Respondent did not challenge the Applicant's expert witnesses on this point during cross-examination [note: 3], only belatedly attempting to revive its challenge by way of closing submissions and reply submissions [note: 4]. I agree with the Applicant that, if the Respondent were to be allowed to rely on this ground in this appeal, the Applicant would be irremediably prejudiced in a way that cannot be compensated for by costs – because the Respondent only canvassed the insufficiency issue in its closing and reply submissions, the Applicant was deprived of the opportunity to lead

evidence from its own witnesses or cross-examine the Respondent's witnesses on this issue during the hearing. [note: 5] In fact, going one step further, I fail to see how the Respondent can canvass the insufficiency issue without having led evidence from its own expert witnesses as to the sufficiency of the Patent. This is because the test of sufficiency is *from the point of view of the person skilled in the art*. Not only is this plain on the face of s 80(1)(c) itself, the very cases cited by the Respondent demonstrate this (see *Genelabs Diagnoistics Pte Ltd v Institut Pasteur and another* [2000] 3 SLR(R) 530 at [59] and *Kirin-Amgen v Hoechst Marion Roussel* [2005] 1 All ER 667 at [103]) [note: 6]. The Respondent's submissions on insufficiency are made completely without any basis in evidence given by persons skilled in the art. [note: 7] For all the above reasons, I find that the Respondent is not entitled to challenge the Patent on the basis of insufficiency under s 80(1)(c) and that the only issue before me is therefore the issue of patentability under s 80(1)(a).

36 I should also note that unlike in *Martek v Cargill (No 1)* where a substantial part of the dispute revolved around *what* the inventive concepts in the patent were (see *Martek v Cargill (No 1)* at [33]-[51]), there is no such dispute here. There is no dispute that the inventive concepts of the Patent are as set out at [12]-[16] above. Despite the more voluminous testimony and more involved scientific arguments in this case as compared to *Martek v Cargill (No 1)*, therefore, the issue here is actually more straightforward, *i.e.* the comparison of the Patent and the prior art to see if the Patent is novel and inventive over the prior art.

Analysis

37 To constitute a patentable invention under s 80(1)(a), an invention must: (1) be new (the "novelty" condition); (2) involve an inventive step (the "inventive step" condition); and (3) be capable of industrial application (s 13(1)). The Tribunal laid out the relevant legal principles at significant length at [70]-[98] of its Decision but there is no dispute as to the applicable legal principles in this case and they are relatively straightforward. The novelty condition is satisfied if the invention "does not form part of the state of the art" (s 14(1)). The "inventive step" condition is satisfied if the step is "not obvious to a person skilled in the art" (s 15).

Claim 1

38 As clarified above at [7], all references are to the claims as amended by the 2006 amendments. Claim 1 of the Patent reads:

> A composition for enteral or parenteral administration to a human comprising an unmodified fungal triglyceride oil obtained from *Mortierella alpina* (*M. alpina*), wherein at least 50% of the fatty acid residues are arachidonic acid (ARA) residues present in triglyceride form, wherein the oil comprises no more than one tenth as much eicosapentaenoic acid (EPA) as ARA and wherein the oil comprises at least 50% ARA.

39 The Tribunal broke this claim down into its individual features as follows (Decision at [108]), the accuracy of which is not disputed by either party:

A) a composition suitable for enteral or parenteral administration to a human;

B) unmodified fungal triglyceride oil obtained from *Mortierella alpina* (*M. alpina*);

C) at least 50% of the fatty acid residues are ARA residues present in triglyceride form;

D) the EPA level of the oil is no more than one tenth of the ARA level;

E) the oil comprises at least 50% ARA.

Novelty

40 The Tribunal held that claim 1 was novel because none of the prior art disclosed all five features. The relevant prior art documents here were D1, D4, D7 and D10.

41 The Tribunal found that, while D1 disclosed features B, D and E, it did not disclose features A and C. There was no dispute that D1 does teach the production of ARA-containing oils by fermentation of *M. alpina* and that Table 1 of D1 discloses an oil with at least 50% ARA. The dispute was over whether the extracted ARAs disclosed in Table 1 were *in triglyceride form*,*i.e.* feature C. The Applicant argued below that the oil in Table 1 was extracted by the mixed solvent procedure of Bligh and Dyer which would yield not only triglycerides but also other glycerol esters such as phospholipids, cholesterol and mono- and di-glycerides, without any indication as to which of these forms would be predominant. The Re-examiner accepted this argument, as did the Tribunal which therefore found that the Patent was novel over D1 (Decision at [116]). As for D7 and D10, the Tribunal found that neither of them teaches a yield of ARA of at least 50% (*i.e.* feature E or that at least 50% of the fatty acid residues are ARA residues in triglyceride form (*i.e.* feature C) (Decision at [126] and [127]).

42 On appeal, the Respondent does not appear to challenge the Tribunal's findings with regard to D1, D7 and D10. Rather its challenge to the Tribunal's finding of novelty is limited to D4a [note: 8] which is the prior art that comes closest to claim 1. The dispute here is with regard to feature A *i.e.* whether D4a teaches a composition suitable for enteral or parenteral administration to humans.

43 On its face, there certainly is no indication that D4 should be suitable for enteral or parenteral administration to humans. The title of D4a, as explained above at [18], is ""External Preparation for Skin". The claims are as follows:

1. A skin cosmetic characterised by containing an arachidonic acid-containing lipid.

2. A skin keratin improver characterised by containing an arachidonic acid-containing lipid.

3. A skin acne treatment characterised by containing an arachidonic acid-containing lipid.

44 As the Applicant strenuously highlights, D4a is concerned with the *topical* treatment of skin conditions. However, the Respondent submits that just because D4a is *intended* for topical application does not necessarily mean that it is not in fact suitable for enteral and parenteral administration. To this end, the Respondent cites the European Patent Office Guidelines for Examiners, C-III at paragraph 4.13 where it states that "… if the known product is in a form in which it is in fact suitable for the stated use, though it has never been described for that use, it would deprive the claim of novelty." [note: 9] I accept this guideline as a correct test for novelty. The issue is therefore whether the composition in D4a is *in fact* suitable for enteral and parenteral administration, despite appearing on its face to be merely for topical administration. In particular, the onus is on the Respondent, as the party challenging the validity of the Patent, to prove this.

45 I find that the Respondent has not discharged its burden of proving that D4 teaches a composition suitable for enteral or parenteral administration. The Respondent submits that the triglyceride oil in D4a is purer in triglycerides and ARA than that taught in any of the examples of the Patent, the oil of D4a having been deodorised to remove phospholipids and de-colorised to remove

pigments and impurities. It further argues that the Applicant presented no evidence that oxidation of the oil of D4a would lead to it being unsuitable for enteral administration and that it was an unfounded assertion on the Applicant's part that the fungal triglyceride oil from *M. alpina* was unsuitable for enteral/parenteral administration in its unmodified form and had to be turned into fatty acid ethyl esters [note: 10]. However, in my view, these arguments made by the Respondent are not sufficiently borne out by the evidence. As stated above, the onus is on the party challenging the validity of the Patent to adduce evidence to refute the novelty of the claims. However, critically for the Respondent, Dr Puah admitted under cross-examination that the composition of D4a could have large proportions of contaminants which were arguably toxic and as such, the composition in D4a could not be suitable for enteral or parenteral administration. [note: 11] This is in contrast to the evidence of Dr Barclay [note: 12] and Dr Kyle [note: 13]. Both maintained under cross-examination – in my view, convincingly – that the skilled reader would have understood from the necessity of a subsequent ester exchange step that such a composition was not necessarily suitable for enteral or parenteral administration. In conclusion, while the ethyl esterification step might have eliminated some of the potential impurities, D4a remains silent on whether there were any toxic components in the total lipid extract. In fact, the cross-examination of Dr Barclay and Dr Kyle by the Respondent's agent below (who was not the counsel for the Respondent before me) merely revealed that the Respondent's agent appeared to have confused edibility with suitability for enteral administration. [note: 14]

46 Here, I should address the issue of the reliability of the Applicant's witnesses. As explained above at [30] and [32], the Respondent challenged the reliability of the Applicant's witnesses on the basis of their lack of objectivity. However, as I similarly held in *Martek v Cargill (No 1)* at [41], for the purposes of determining whether the evidence of an expert should be discounted, the relevant test is one of actual partiality rather than apparent partiality (*Muhlbauer* at [46]-[47]). Similarly, as in *Martek v Cargill (No 1)*, the Respondent did not adduce any evidence of actual partiality here. Furthermore, as the Tribunal rightly noted, this is one of those cases with a high degree of specificity and expertise in the technology involved and where it is therefore not surprising if only a limited number of experts are available, such that pre-eminent experts may have certain work experience which might at first sight appear to threaten their independence (Decision at [58]). The Tribunal was therefore right not to dismiss the testimonies of Dr Barclay and Dr Kyle. It did limit its consideration of Dr Barclay's testimony to the "technical and scientific aspects of the invention as such" (Decision at [48] and [54]). It was therefore for the Respondent to challenge and disprove the technical and scientific aspects of Dr Barclay's and Dr Kyle's evidence. Insofar as the novelty of claim 1 is concerned, I find that the Respondent has failed to do so (see [45] above).

47 The Respondent also cites in its support the Re-examination Report, which (as set out in the Decision at [118]), states as follows:

> A) Composition suitable for enteral or parental [*sic*] administration to a human
>
> Solvent extraction of *Mortierella alpina* biomass by non-polar solvent such as hexane produces an arachidonic acid product suitable for administration to a human (see current application page 4 lines 24-26, page 13 line 15 to page 16 line 9). Note: Although 'enteral' is a term commonly used to mean 'tube feeing' in the context of the current application it also includes capsules etc (page 19) and thus the term has the broader meaning of oral or tube administration. *As D4a also teaches solvent extraction of* Mortierella alpina *biomass by hexane to produce an arachidonic acid product (see D4a example 1), D4a has made available to the public a composition which is suitable for enteral administration to a human. In the submissions made on behalf of the patent holder there was reliance on the fact that in D4a the composition is subsequently derivatised for subsequent topical application. However I consider that it is enough that prior to that step the*

composition is suitable for enteral administration. [emphasis added]

48 However, as with a similar re-examination report in *Martek v Cargill (No 1)* (see at *Martek v Cargill (No 1)* at [42]), it is common ground that the Re-examination Report in this case is not binding on this court. Furthermore, as in *Martek v Cargill (No 1)*, the Re-examination Report was made based on the statutory declarations of the various witnesses taken at face value, without taking into account the witnesses' performance under cross-examination, in particular the concessions made by Dr Puah and the course of cross-examination of Dr Barclay and Dr Kyle (see above at [45]).

Inventive Step

49 Having found that claim 1 meets the requirement of novelty, I now examine whether it meets the requirement of inventive step. As I have already noted, this was the heart of the Tribunal's finding that claim 1 is not patentable.

50 With regards to the test for inventive step, the Court of Appeal in *Muhlbauer* at [20] adopted the four-step formulation of the Singapore High Court in *Trek Technology (Singapore) Pte Ltd v FE Global Electronics Pte Lt*d [2005] 3 SLR(R) 389 of the test established in *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 (commonly known as "the *Windsurfing* test"), thus:

A) Identify the inventive concept embodied in the patent in suit.

B) The court then assumes the mantle of the normally skilled but unimaginative addressee in the art at the priority date, imputing to him what was, at that date, common general knowledge in the art in question.

C) Identify what, if any, differences exist between the matter cited as being "known or used" and the alleged invention.

D) The court then asks itself the question whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.

51 The Tribunal identified this as the four-step test (Decision at [131]). There is no real dispute as to the inventive concept in the Patent or that the prior art constituted common general knowledge in the art at the priority date. The crux of the issue is simply whether the differences between the various prior art and the invention in the Patent would have been obvious to the skilled reader as at the priority date. In this respect, the reasoning of the Tribunal was as follows:

> Finally, the fourth step in Windsurfing [supra] requires the court to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention. *Our answer is yes. As mentioned above, D4a already discloses features B, C, D, and E in claim 1. D7 and D10 also teach features A, B and D. It would have been obvious for him to combine the teachings in D4a with D7 or D4a with D10 and any of these combinations will result in the skilled man meeting all the features of claim 1*. Claim 1 lacks inventive step accordingly. [emphasis added]

52 Therefore, the basis upon which the Tribunal arrived at the conclusion that claim 1 lacked inventive step was an assertion that it would have been obvious to a skilled reader to combine the different features of the various prior art. With respect, the Tribunal erred in doing so. The Tribunal

did not possess the expertise to determine for itself, on the face of the prior art and the Patent, whether the invention would have been obvious to a skilled reader without any basis in evidence as to what a skilled reader would have known or understood. The test of whether a claim involves an inventive step is premised on the viewpoint of the skilled reader. As the English Court of Appeal articulated in *Mölnlycke AB v Procter & Gamble* [1994] RPC 49:

> In applying the statutory criterion and making these findings the court will almost invariably require the assistance of expert evidence. *The primary evidence will be that of properly qualified expert witnesses who will say whether or not in their opinions the relevant step would have been obvious to a skilled man having regard to the state of the art.* All other evidence is secondary to that primary evidence [emphasis added]

This was cited with approval by the Court of Appeal in *Muhlbaeur* at [19].

53 If we look at the evidence before the Tribunal and before me, however, it is clear that there is no evidential basis for the Respondent's assertions. Dr Nga had admitted under cross-examination that his views were made with the benefit of hindsight and, on this basis, the Tribunal already considered that it must treat Dr Nga's evidence with "caution". It is true that the Tribunal did not go as far as urged by the Applicant, *i.e.* to find that Dr Nga was an evasive and unreliable witness and indeed I too find it unnecessary to make such a finding for the simple reason that the fact that Dr Nga's evidence is based on hindsight is already fatal to his evidence as to the inventiveness of the Patent. It is trite law that *hindsight must be avoided in assessing whether an invention involves an inventive step* (see for example *Windsurfing* at [71] and [73]). As for the Respondent's only other witness, the Tribunal had already held itself unable to draw much assistance from Dr Puah's evidence because he "did not appear to possess the relevant expertise" to assist the Tribunal in the hearing or to testify with confidence on the matters in question. As I explained above at [24], counsel for the Respondent confirmed at the hearing before me that the Respondent was not relying on Dr Puah's evidence but only on Dr Nga's evidence and that they were primarily relying on the documents in their own right. I have already explained why Dr Nga's evidence cannot be relied upon to determine whether the invention in the Patent would have been obvious to the skilled reader. Neither is it possible to merely look at the documents on their face and speculate what would have been obvious to a skilled reader – the Respondent's submissions in this regard [note: 15] are insufficient insofar as they are made completely on the basis of the documents on their face and without any reference to evidence from experts who would be able to assist the court in adopting the mantle of the skilled reader.

54 "Mosaicing" of prior art may well be allowed in assessing whether or not there is an inventive step; however, as explained in Ng-Loy Wee Loon, *Law of Intellectual Property of Singapore* (Sweet & Maxwell Asia, Rev Ed, 2009) at para 30.1.50:

> ... the skilled addressee assesses the obviousness of an invention by reference to the whole of the state of the art relevant to this invention, whereas he assesses the novelty of the invention by reference to each individual piece of prior art in this state of the art. There is, however, an exception to this scenario: *'mosaicing' is not permitted in the obviousness inquiry if it would not be obvious to the skilled addressee to 'mosaic' the different pieces of prior art* [emphasis added].

55 As the evidence stood before the Tribunal and now stands before me, therefore, the Respondent proffered no basis – and the Tribunal therefore had no basis – on which to conclude that it would have been obvious to the skilled reader to "mosaic" the teachings in D4 with D7 or D4 with D10. On the other hand, Dr Barclay and Dr Kyle testified that the Patent in general and claim 1 in particular involved inventive steps. Even confining their evidence to the technical and scientific aspects of the Patent as such on the basis that they may be interested parties in respect of the

Patent (see above at [30] and [32]), the inventiveness of the Patent is one such technical and scientific aspect – if the Respondent alleges that Dr Barclay's and Dr Kyle's evidence on this point must be disregarded because they were biased, it is for the Respondent to either make out a case for actual bias (see above at [46]) and put this case to the witnesses under cross-examination or adduce their own expert evidence to scientifically disprove their testimony, neither of which the Respondent has done.

56 In conclusion, I find that the Tribunal erred in finding that claim 1 lacked inventive step when there was no evidential basis for it to so hold. The Tribunal canvassed at length the qualities of the "skilled person" in which the test for inventive step was rooted (see Decision at [84]-[93]) but appeared to have made its eventual finding of fact completely outside this frame of reference. Of course, I do not mean to say that the Tribunal, or indeed any court, is entirely at the mercy of expert witnesses when determining issues of patentability. As I affirmed in *Martek v Cargill (No 1)* at [43], a court is always entitled to examine an expert's evidence based on logic and rationality. However, this does not mean that a court, when called upon to apply a test rooted in the perspective of a skilled reader in the art, will simply substitute its own judgment in the complete absence of any evidence as to whether something would or would not have been obvious to the skilled reader. This is especially when the deficit of evidence is on the part of the party attacking the validity of the Patent and therefore on whom the onus lies to show that there was no inventive step involved (see *Muhlbauer* at [19]).

57 I therefore find claim 1 is both novel and involves an inventive step and that it is patentable.

Claim 2

58 Claim 2 reads:

> Infant formula comprising triglyceride containing ARA in an amount comparable to the amount in human breast milk wherein the ARA is provided by adding to infant formula a sufficient amount of an unmodified fungal triglyceride oil obtained from *Mortierella alpina (M. alpina)*, wherein at least 50% of the fatty acid residues are arachidonic acid (ARA) residues present in triglyceride form, wherein the oil comprises no more than one tenth as much eicosapentaenoic acid (EPA) as ARA and wherein the oil comprises at least 50% ARA.

59 The Tribunal broke claim 2 down into its components as follows – as with the breakdown of claim 1 above at [39]), this is not disputed):

> A) infant formula comprising triglyceride containing ARA in an amount comparable to the amount in human breast milk wherein the ARA is provided by adding to infant formula
>
> B) unmodified fungal triglyceride oil obtained from *Mortierella alpina*
>
> C) at least 50% of the fatty acid residues are ARA residues present in triglyceride form
>
> D) the EPA level of the oil is no more than one tenth of the ARA level
>
> E) the oil comprises at least 50% ARA.

60 As the Tribunal pointed out (Decision at [142]), claim 2 mirrors claim 1 in all its features except that while the first feature of claim 1 is "a composition suitable for enteral or parenteral administration to a human", the first feature of claim 2 is "infant formula comprising triglyceride containing ARA in an

amount comparable to the amount in human breast milk wherein the ARA is provided by adding to infant formula". The only question is therefore whether any of the prior art teaches this first feature – if they do not, then claim 2 must be novel and inventive for the same reasons that claim 1 is new and inventive.

61 The prior art that is relevant to the analysis of claim 2 are D5 and D7. The Tribunal found that, while D5 teaches artificial milk with a trace fatty acid composition that approximates that of HBM and D7 teaches the provision of an additive for use in infant formula such that the ARA levels in the formula approximates those levels in HBM, neither D5 nor D7 discloses all the features of claim 2. Therefore, the Tribunal found claim 2 new over D5 or D7. However, the Tribunal then found that claim 2 lacked inventive step because it would have been obvious to the skilled man to combine the teachings of D4a with D5 or D4a with D7 (Decision at [148]).

62 On appeal before me, the Respondent did not seem to challenge the novelty of claim 2 based on D5 – its challenge is confined, rather, to D7. In particular, it submits that claim 2 is anticipated by the infant formula taught in D7 notwithstanding that the product in claim 2 is obtained by a process of adding the defined triglyceride oil (*i.e.* as defined by features B to E). [note: 16] It makes this submission on the basis that claim 2 is a "product-by-process" claim and therefore it is the product *per se* that needs to be novel, not the process from which the infant formula is produced [note: 17] and to this end it cites *inter alia* the UK Manual of Patent Practice – Patents Act 1977 at [2.15] and the PCT International Search and Preliminary Examination Guidelines at para 5.26 where they explain that a "product-by-process" claim is not rendered novel merely by the fact that it is produced by means of a new process; rather, such a claim lacks novelty if a prior art product appears to be inherently the same as, or indistinguishable from, the claimed invention, even if made by a different or undisclosed process.

63 The assumption in the Respondent's argument is that the product in claim 2 is inherently the same as the product in D7 and that the addition of the triglyceride oil as defined by features B to E is merely a different process by which this same product is obtained. In my view, this ignores the fact that the product in claim 2 is not merely an infant formula product that closely approximates the ARA levels in HBM. This ARA must be in triglyceride form – this is plain even from A2 itself. In my view, the teaching of the addition of triglyceride oil of a very particular specification (*i.e.* as specified by features B to E) makes the product in claim 2 a different product from that taught in D7 and not merely a different process of obtaining the same product. This is borne out by the evidence of the Applicant's witnesses – again unrebutted given the problems with the testimony of the Respondent's witnesses – that the invention in claim 2 was based on the finding that beneficial effects are observed when the oil used to supplement infant formulas is *in triglyceride form* and *contains at least 50% ARA residues* and *where there are low levels of EPA*.

64 Turning now to the question of whether claim 2 involves an inventive step, the Tribunal merely asserted, similarly to what it did with claim 1, that it would have been obvious to the skilled man to combine the teachings of D4a with D5 or D4a with D7. For the same reasons as elaborated upon at [52]-[55] above, I find that the Tribunal erred in doing so because there was no evidence before it upon which it could base such a finding.

65 I should also note at this point that, at the hearing before me, the Respondent alluded to the similarity between D7 and the Patent, the fact that the Applicant was the proprietor of D7 as well and that the validity period of D7 was expiring soon. The Respondent suggested that the Patent could be the Applicant's attempt to "extend" the validity of D7 by registering another patent over essentially the same invention. However, the truth of this suggestion hangs on the Respondent proving that there is nothing new and inventive in the Patent over D7 and, for the reasons above, I find that it has

not discharged its burden to do so.

66 For the above reasons, I find that that claim 2 is new and inventive over the prior art.

Claim 20

67 Claim 20 reads:

> A method for the production of an ARA-containing oil, said oil containing triglycerides wherein at least 25% of the fatty acid residues are ARA and the amount of EPA residues in the oil is no more than one-fifth the amount of ARA residues, comprising:
>
> A) Cultivating M. alpina in an aerated fermentor containing growth medium at a temperature in range of 25-30ºC, wherein a carbon source in an amount equivalent to at least 80g/L glucose and a nitrogen source in an amount equivalent to at least 15g/L yeast extract are added to said growth medium over the course of the fermentation;
>
> B) Maintaining the pH between 5 and 6 during exponential growth phase at the beginning of the cultivation;
>
> C) Maintaining the pH between 7 and 7.5 during stationary phase at the end of the cultivation; and
>
> D) Harvesting biomass from the fermentor and recovering said arachidonic acid containing oil from said biomass.

68 The dispute between the parties revolves around the pH features disclosed in claim 20, *i.e.* (B) and (C). It is common ground that claim 20 meets the requirement of novelty because none of the prior art discloses its pH features as specified in (B) and (C) – the closest prior art is D7 which, at least according to the Respondent and the Tribunal at [193], discloses all the features of claim 20 except (B) and (C). The Respondent did challenge the novelty of claim 20 below but, on appeal, agrees with the Tribunal's finding that claim 20 is new (see Decision at [191]). [note: 18] The dispute is therefore confined to whether these pH features involve an inventive step.

69 This was the subject of fierce dispute below as well as before me, with the Respondent arguing that "pH profiling" was already part of the common general knowledge whereas the Applicant argued that the pH features as specified in (B) and (C) would not have been obvious to the skilled person. The extent of the dispute can be seen from the Tribunal's summary of the parties' various arguments (Decision at [172]-[181]) as well as in the length of the parties' written submissions before me. It seems to me, however, that parties are really arguing at cross-purposes. At the hearing before me, the Applicant submitted that the issue was confused by the Respondent's blanket reference to "pH profiling" which the Respondent then submitted was already part of the common general knowledge when "pH profiling" could refer to a range of things. I agree. The evidence pointed out by the Respondent to demonstrate that "pH profiling" was part of the common general knowledge merely shows that pH values *have an effect* on the cultivation/production of fungal organisms or *M. alpina* or triglyceride oils (as the case may be) [note: 19] :

- that D1 and D2 make mention of the effect of pH on growth and ARA production of *M. alpina*;
- specifically, that Table 3 in D1 shows the amount of biomass and ARA obtained in fermentation experiments conducted at different pH values;

- that Dr Kyle acknowledged that pH profiling was known in the art and was part of the "toolbox" of available steps to the engineer when producing triglyceride oils;

- references to textbooks which state that there is an optimal value at which maximum rates of growth of fungal organisms are observed.

70 The Applicant's case, however, is that the invention in claim 20 is to provide the skilled person with the specific pH profile necessary to achieve increased levels of ARA in the triglycerides. This is something the Respondent's arguments do not address. Indeed, the Tribunal acknowledged this distinction in the Decision at [195]-[196]: it highlighted the difference between, on the one hand, deciding the pH at which to start the cultivation (as in D1) or at which to maintain culture during the whole cultivation (as in D2) and, on the other hand, *controlling the pH at two different values during the fermentation process* which is what claim 20 teaches. The question before the Tribunal was thus whether this difference constituted steps which would have been obvious to the skilled man or whether it required a degree of invention, *i.e.* the last step in the *Windsurfing* test (see above at [50]).

71 Cutting through the myriad of arguments on this issue, therefore, the issue really boils down to something quite narrow: whether the difference as highlighted by the Tribunal – *i.e.* between the specific pH features in (B) and (C) of claim 20 and other pH profiling already disclosed by the prior art – would have been obvious to a skilled reader. The basis of the Tribunal's decision was actually very narrow. The Tribunal held that the specific pH features in (B) and (C) would have been obvious to the skilled man, purely on the basis of Example 5 of D10 (see Decision at [197]-[198]). In the Tribunal's view:

> In view of the teachings in D10 on setting the pH level at the start of the cultivation process, and subsequently allowing the pH level to drift and fluctuate before controlling it during the process, *we find that the skilled person would be motivated to achieve the pH features in claim 20*, which is in essence the dynamic control of pH setting through the cultivation process [emphasis added].

72 With respect, this finding is problematic for the same reasons as explained at [52]-[55] above. Once again, the Tribunal was merely speculating as to the state of mind of a skilled reader without any evidence before it that could support this conclusion. The mere fact that both claim 20 and Example 5 of D10 exhibit a process whereby the pH level is set at the start of the cultivation process and subsequently allowed to drift and fluctuate before controlling it during the process does not necessarily lead to the conclusion that there was nothing inventive in claim 20. In the first place, they pertain to different *specific* sets of pH values – this may well be material if the cultivation processes and/or what is being cultivated are different between that taught in claim 20 and that taught in Example 5 of D10. Claim 20, on its plain reading, pertains to the production of an ARA-containing oil containing triglycerides with specified characteristics (see above at [67]). Example 5 in D10 is entitled "Preparation of *Mortierella alpina* lipid" but it is far from clear whether this lipid would have the same characteristics as specified in claim 20. Indeed, it appears otherwise. Whereas claim 20 is quite specific that the ARA is in triglyceride form, D10 at p 7 explains that "[p]referably the DHA and ARA are in the form of triglycerides, although they also may be in the form of phospholipids".

73 For the above reasons, I find that the Tribunal erred in finding that claim 20 does not involve an inventive step.

Claim 35

74 Claim 35 reads:

> A method of providing triglyceride containing ARA to an infant formula which comprises adding to an infant formula, in an amount sufficient to provide an ARA content which corresponds to the amount of ARA in human breast milk, an unmodified fungal triglyceride oil obtained from *M. alpina*, wherein at least 50% of the fatty acid residues are ARA residues present in triglyceride form, wherein the oil comprises no more than one tenth as much eicosapentaenoic acid (EPA) as ARA and wherein the oil comprises at least 50% ARA.

75 The Tribunal broke down claim 35 into its component parts (see Decision at [211]) and concluded that the component parts of claim 35 corresponded to features B to E of claim 1 (see above at [39]) except that claim 35 has the extra feature of "a method of providing triglyceride containing ARA to an infant formula which comprises adding to an infant formula, in an amount sufficient to provide an ARA content which corresponds to the amount of ARA in human breast milk", which, the Tribunal suggested, corresponded to claim 2 (see Decision at [213]). This appears to be a more complicated way of crystallising claim 35 as the claim to the *method* by which the infant formula in claim 2 is produced. Indeed, the reasoning of the Tribunal seems to indicate that it held claim 35 to lack inventive step for the same reasons that it held claim 2 to lack inventive step (see Decision at [213]-[214]).

76 The Respondent is not challenging the Tribunal's finding that claim 35 is new [note: 20], so the only live issue is whether claim 35 involves an inventive step. I find that the Tribunal erred in holding that claim 35 lacked inventive step for the same reasons I held that it erred in holding that claim 2 lacked inventive step. I need not repeat the points I have already made in relation to the centrality of expert evidence to the test of inventive step (see above at [52]-[55]), except to note that the Respondent's submissions on the inventiveness of claim 35 are, insofar as they are made without any reference to any evidence as to the state of mind of a skilled reader, mere assertions that claim 35 lacks inventiveness. [note: 21]

Conclusion

77 For the reasons set out above, I find that claims 1, 2, 20 and 35 are patentable.

78 As noted above, the Tribunal went on to assess the patentability of each of the dependent claims after assessing the four independent claims. However, as the Tribunal rightly noted, this was technically unnecessary given that the patentability of these claims would depend on the patentability of claims 1, 2, 20 or 35, as the case may be. Given that I have already held all four independent claims to be patentable, it follows that all claims in the Patent are therefore patentable.

79 I therefore allow the Applicant's appeal against the Tribunal's Decision and dismiss the Respondent's cross-appeal. The Respondent is to pay the Applicant its costs of these proceedings here and before the Tribunal, with such costs to be taxed if not agreed.

[note: 1] Respondent's Case at [45]

[note: 2] Appellant's Case at [23]

[note: 3] AC at [24]

[note: 4] AC at [25]

[note: 5] AC at [27]-[28]

[note: 6] RC at [47]

[note: 7] RC at [48]-[58]

[note: 8] RC [95]-[100]

[note: 9] RC at [99]

[note: 10] RC [98]

[note: 11] Transcripts dated 10 February 2009 at pp 35-36, 37-39

[note: 12] Transcripts dated 11 February 2009 at 75-78, 79-85, pp 85-90.

[note: 13] Transcripts dated 12 February 2009 at pp 57, 59-60

[note: 14] See footnotes 12 and 13.

[note: 15] RC [101]-[121]

[note: 16] RC [125]

[note: 17] RC [126]

[note: 18] RC at [170]

[note: 19] See RC at [175]-[183]

[note: 20] RC at [263]

[note: 21] RC [267]-[275]