Reportable
Case No 467/99

In the matter between:

MONSANTO COMPANY **Appellant**

and

MDB ANIMAL HEALTH (PROPRIETARY) LTD
(Formerly MD BIOLOGICS CC) **Respondent**

Coram: HARMS, STREICHER and NAVSA JJA; BRAND and NUGENT AJJA
Heard: 15 FEBRUARY 2001
Delivered: 26 FEBRUARY 2001

Subject: Patent interpretation and infringement

JUDGMENT

HARMS JA/

HARMS JA:

[1] In patent litigation an application of Murphy's Law has special significance: if a word or sentence is capable of two interpretations, the reader will choose the wrong one. In this case the issue is whether alpha tocopherol acetate, a synthetic Vitamin E, is an “oil” within the meaning of the term as used in the patent in suit, namely No 85/7642 entitled “Prolonged release of biologically active polypeptides”. If it is, the respondent is infringing the patent. In spite of the narrow point of interpretation the parties were nevertheless able to generate a record of nearly 1300 pages. (For the sake of convenience I shall use the term “Vitamin E” as a synonym for alpha tocopherol acetate.)

[2] For purposes of this judgment it is unnecessary to deal in any particular detail with the invention. It will suffice to deal with claim 1 which claims:

"A substantially non-aqueous composition useful for parenteral administration comprising at least about 10% by weight of a biologically active bovine somatotropin and, as a continuous phase of said

composition, a biocompatible oil."

A “biologically active bovine somatotropin” is a natural protein produced by the pituitary gland of a bovine and it promotes the use of nutrient energy for milk production. Simply put, it is a hormone which increases milk production. The purpose of the oil is to act as a carrier for the hormone which has to be suitable for parenteral administration, i e, by way of injection. In order to provide for the prolonged release of the hormone in the animal the product has to be substantially non-aqueous. An object of having the oil in a continuous phase is to ensure that there is sufficient oil to envelop substantially the entire hormone. The oil must be bio-compatible in the sense of having no intolerable adverse effect on the hormone, the animal, or, in the case of animals whose products enter the food chain, the consumers of such products.

[3] As in *Selero (Pty) Ltd and Another v Chauvier and Another* 1984 (1) SA 128 (A) 137 F-H, while appreciating that a patent specification should be

construed without reference to what the alleged infringer has done, we deem it nevertheless convenient to focus attention on the allegedly infringing article in order to delimit and define the areas of dispute between the parties. The respondent imports and sells a product known as “Hilac” which is an injectable formulation consisting of active bovine somatotropin and Vitamin E. As mentioned, the only issue at this stage is whether Vitamin E is an “oil” as claimed in the claims. If the answer is in the affirmative, it is common cause that the respondent is infringing claims 1, 2, 4 and 5 of the patent. During the trial the witnesses agreed that Vitamin E is, as ordinarily understood, an oil. The respondent's counsel conceded as much in this Court. In its application for the registration of “Hilac”, the respondent itself described Vitamin E as “a high viscous oil”. Vitamin E is sold by chemical manufacturers as an oil. The works of authority referred to and relied upon in evidence describe it as a yellow, nearly odourless, clear, viscous oil or, sometimes, as a viscous, oily liquid. Finally, the respondent's expert witness, Prof van

Oudtshoorn, whose evidence the court *a quo* preferred, conceded that Vitamin E performs the function of what is required of an oil by the specification and that it has all the characteristics of a bio-compatible oil. He even on occasion called it an oil. In spite of this, MacArthur J (sitting as Commissioner of Patents in the Court *a quo*) held that Vitamin E is not ordinarily classified as an oil, a finding the respondent did not rely upon, and for that reason dismissed the appellant's claim.

[4] Oils have certain physical characteristics in common: they are liquid at ambient temperatures, they have a viscous consistency and a characteristic unctuous feel, they are lighter than water and insoluble in it, they are soluble in alcohol and ether, inflammable and they are chemically neutral. Fats differ from oils in one respect only. They are solid at room temperature. With this background the attention can now turn to the body of the specification because the respondent argues that it defines “oil” with reference to its chemical characteristics in such a way as to exclude Vitamin E from its ambit.

[5] The argument focussed on the following passage from the specification:

"As aforesaid, the compositions of this invention each contain, as a continuous phase thereof, a biocompatible oil, ie, an oil having no intolerable adverse effect on the polypeptide, the animal, or, in the case of animals whose products enter the food chain, the consumers of such products. Preferably such oils are of low acidity and essentially free from rancidity. As used herein, the term ‹oil' means a fatty oil or fat that is liquid at the body temperature of the animal. Thus, such an oil will melt or at least begin to melt below about 40° and preferably below about 35°. Oils that are liquid at about 25° may facilitate injection or other administration of some compositions of this invention. In some cases, polyunsaturated (eg partially hydrogenated) oils may be favoured for greater biocompatibility with the animal or other reasons.

In a preferred embodiment, the biocompatible oil is composed essentially of triglycerides, ie, long chain (generally C_8 - C_{24}, preferably C_{12} - C_{18} fatty acid esters of glycerol, or mixtures of triglycerides and such fatty acids (preferably in only minor proportions, eg less than about 10% free fatty acid). In some embodiments, other trihydroxy or polyhydroxy compounds can be substituted for the glycerol.

Especially preferred oils include vegetable oils such as olive, sesame seed, peanut, sunflower seed, soybean, cottonseed, corn, safflower, palm, rapeseed and mixtures of such oils. Sesame and peanut oils are highly preferred for many embodiments. Oils of animal or mineral origin or synthetic oils (including long chain fatty acid esters of glycerol or propylene glycol) can also be employed provided they are sufficiently biocompatible."

(Underlining added.)

[6] According to the argument, the underlined sentence defines the term "oil". In order to understand what an oil for the purposes of the specification is, one must determine what the chemical nature of a "fat" is. Generally a "fat" is defined in technical dictionaries as a glyceryl ester of higher fatty acids which forms a class of neutral organic compounds. Fatty oils, fats and oils are chemically the same. Since "oil" is defined in terms of "fat", the oils of the patent must likewise be glyceryl esters of higher fatty acids, something which Vitamin E is not. (It may already now be noted that for these propositions reference was made to the same

works that state that Vitamin E is an oil. So much for consistency in scientific dictionaries.)

[7] The use of the term “fatty oil” in the specification creates problems. No witness defined it, nor do the chemical dictionaries that form part of the exhibits. The evidence of one of the appellant's witnesses was that the adjective “fatty” does not add to the definition. This evidence was not gainsaid and appears to be plausible although the witness may have hovered on the border of inadmissible evidence, a common occurrence during the course of this trial. If there is no chemical difference between a fat and an oil, the term “fatty oil” must be a tautology. If I am wrong in this regard, the evidence of van Oudtshoorn establishes that what determines whether a compound is a fat or fatty is the presence of a long aliphatic hydrocarbon chain in the molecule, something present in Vitamin E. Although he tried to downplay this evidence by stating that the aliphatic hydrocarbon chain in Vitamin E forms but a small part of the molecule, he later had

to recant this qualification.

[8] The rules relating to the interpretation of patents have often been stated and do not need any reformulation. The problem lies in their sensible application in any given case. For present purposes the following rules as they appear in *Gentiruco AG v Firestone (SA) (Pty) Ltd* 1972 (1) SA 589 (A) 614A - 616D may be emphasised: (a) a specification should be construed like any other document subject to the interpreter being mindful of the objects of a specification and its several parts; (b) the rule of interpretation is to ascertain, not what the inventor or patentee may have had in mind, but what the language used in the specification means, i e, what the intention was as conveyed by the specification, properly construed; (c) to ascertain that meaning the words used must be read grammatically and in their ordinary sense; (d) technical words of the art or science involved in the invention must also be given their ordinary meaning, i e, as they are ordinarily understood in the particular art or science; (e) if it appears that a word

or expression is used, not in its ordinary sense, but with some special connotation, it must be given that meaning since the specification may occasionally define a particular word or expression with the intention that it should bear that meaning in its body or claims, thereby providing its own dictionary for its interpretation; (f) if a word or expression is susceptible of some flexibility in its ordinary connotation, it should be interpreted so as to conform with and not to be inconsistent with or repugnant to the rest of the specification; and (g) if it appears from reading the specification as a whole that certain words or expressions in the claims are affected or defined by what is said in the body of the specification, the language of the claims must then be construed accordingly.

[9] Two qualifications - if they are indeed qualifications - may be added. The first relates to the reference to the "ordinary meaning" of words. In *Fundstrust (Pty) Ltd (in liquidation) v Van Deventer* 1997 (1) SA 710 (A) 726H - 727B, Hefer JA said this:

"Recourse to authoritative dictionaries is, of course, a permissible and often helpful method available to the Courts to ascertain the ordinary meaning of words (*Association of Amusement and Novelty Machine Operators and Another v Minister of Justice and Another* 1980 (2) SA 636 (A) at 660F-G). But judicial interpretation cannot be undertaken, as Schreiner JA observed in *Jaga v Dönges NO and Another; Bhana v Dönges NO and Another* 1950 (4) SA 653 (A) at 664H, by 'excessive peering at the language to be interpreted without sufficient attention to the contextual scene'. The task of the interpreter is, after all, to ascertain the meaning of a word or expression in the particular context of the statute in which it appears (*Loryan (Pty) Ltd v Solarsh Tea and Coffee (Pty) Ltd* 1984 (3) SA 834 (W) at 846G *ad fin*). As a rule every word or expression must be given its ordinary meaning and in this regard lexical research is useful and at times indispensable. Occasionally, however, it is not."

Something similar was expressed in the context of the interpretation of a patent specification by the Full Court (per Nicholas J) in *De Beers Industrial Diamond Division (Pty) Ltd v Ishizuka* 1980 (2) SA 191 (T) 196E - F:

"A dictionary meaning of a word cannot govern the interpretation. It can only afford a guide. And,

where a word has more than one meaning, the dictionary does not, indeed it cannot, prescribe priorities of meaning. The question is what is the meaning applicable in the context of the particular document under consideration."

[10] The second qualification is that even definitions must be read in context. As said by the Master of the Rolls in *The Cleveland Graphite Bronze Company and Vandervell Products Ld v The Glacier Metal Coy Ld* [1949] RPC 157 (CA) 162 lines 31- 41:

"The vice of the Respondents' contention appears to me to lie in the fact that for the purpose of having recourse to the legitimate use of the body of the specification as a dictionary they have seized upon a definition therein contained and read it out of its context . . .. It is not right to seize upon one passage in the body of the specification and treat it as though it were an interpretation section in an Act of Parliament. In order to make proper use of the body of a specification for dictionary purposes the whole document must be considered: and even where a passage describes itself as a definition it must be read in its context."

[11] I do not agree with the respondent's submission that the underlined

sentence should be read in isolation or that it was intended to set out an all-embracing definition of the word "oil", and that the rest of the specification should be ignored. The two paragraphs quoted from the specification focus on bio-compatibility and to a lesser extent on an oil. The first paragraph is essentially concerned with the physical characteristics of oil. If the underlined sentence is read in context, it becomes clear that its intention is to extend the meaning of oil to include fats which are liquid (or oils) only at body temperatures, and not to limit it to oils at ambient temperatures (its ordinary meaning). In other words, the substance must be administrable at body temperatures. It does not purport to deal with the chemistry of oils, something the second paragraph does.

[12] Turning the attention to the second paragraph, the first sentence deals with the chemistry of the compatible oil in "a preferred embodiment": it describes the glyceryl esters of higher fatty acids. This is a clear indication that by using glyceryl esters of higher fatty acids as a *preferred* embodiment, the inventor could

hardly have intended to limit the invention to them. Then follows the statement that "in some embodiments, other trihydroxy or polyhydroxy compounds can be substituted for the glycerol." If the glycerol is substituted, the product is no longer a glyceryl ester. The concluding statement that "oils of animal or mineral origin or synthetic oils (including long chain fatty acid esters of glycerol or propylene glycol) can also be employed provided they are sufficiently biocompatible" is also significant. If the intention was to limit the oils to esters of glycerol, this sentence makes no sense because it *includes* those oils. Propylene glycol is also not an ester of glycerol.

[13] The inevitable conclusion is therefore that the specification did not intend to limit the term "oil" to esters of glycerol. The invention is concerned with the physical properties of the carrier and not its chemical composition. It is not there for its pharmaceutical properties. It must be hydrophobic in order to retard absorption and liquid at body temperature to be administered parenterally. As

mentioned, it must exist in a continuous phase with the hormone. The last sentence quoted makes it clear that all oils, even synthetic oils and irrespective of their chemical composition, are included provided they are bio-compatible. As stated, alpha tocopherol acetate is a synthetic oil.

[14] "Especially preferred" are vegetable oils, probably because they were at the date of the patent the oils in use as carriers as the examples show. But that does not justify the limiting of the term "oil" to vegetable oils as van Oudtshoorn would have it. His evidence was flawed. Apart from the fact that he had to recant on a number of statements, he had regard to extraneous irrelevant matter such as the inventor's notebook in interpreting the specification in order to arrive at the conclusion that the specification was limited to vegetable oils. In addition, because he regarded the use of Vitamin E by the respondent as a carrier to be inventive, he concluded that the specification did not include it within its terms. If one assumes that it was inventive, the respondent may have been entitled to a selection patent or

a dependent patent but that does not mean that the patent in suit does not cover its use.

[15] Having found that Vitamin E is an oil within the meaning of the term as used in the claims, it follows that the respondent is infringing claims 1, 2, 4 and 5 of the patent. (The last three claims have not been quoted because their wording does not add anything.) In the result the appeal should be upheld and the appellant is entitled to the usual orders of an interdict, delivery-up and an enquiry into damages. There is, however, a complication. The respondent relied on the invalidity of the patent as a defence to the claim for infringement and has a counterclaim for its revocation. During the course of the trial the parties entered into an agreement which was made an order of court. The counterclaim was postponed *sine die*. The respondent agreed to withdraw the counterclaim if it were successful in its defence on infringement. In the event of the patentee being successful on infringement, the respondent has the right to proceed with the

counterclaim and "the parties are agreed that such counterclaims shall proceed as expeditiously as possible." In the light of this, the appellant is only entitled to a declaratory order in respect of the infringement and the grant of effective relief must depend upon the outcome of the counterclaim.

[16] In the result the following order is made:

(a) The appeal succeeds with costs, including the costs of two counsel.

(b) The order of the court below is set aside and substituted with an order in the following terms -

(i) It is declared that the defendant, by importing and selling the product "Hilac", is infringing claims 1, 2, 4 and 5 of SA Patent 85/7642.

(ii) The defendant is to pay the costs of the action insofar as it relates to the plaintiff's claim, which costs include the costs of two counsel and the qualifying fees of Dr Palmer.

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L T C HARMS
JUDGE OF APPEAL

AGREE:

STREICHER JA
NAVSA JA
BRAND AJA
NUGENT AJA