

NUGENT JA:

[1] ‘In law’ – remarked Lord Steyn in *R v Secretary of State for the Home Department, ex parte Daly*¹ - ‘context is everything.’ And so it is when it comes to construing the language used in documents, whether the document be a statute, or a contract, or, as in this case, a patent specification.

[2] Patent No. 87/2378, which is in issue in this appeal, relates to a pharmaceutical preparation containing omeprazole. Omeprazole is a potent inhibitor of gastric acid secretion, which makes it useful in the treatment of gastric and duodenal ulcers. It is relatively unstable, however, and degrades rapidly in the presence of acid solutions. If the drug is to be administered orally it must be prepared in a form that enables it to pass through the stomach without having contact with the acidic stomach fluids, so that it can

¹ [2001] 3 All ER 433 (HL) at 447a

be delivered intact to the proximal part of the small intestine where the environment is suitable for the drug to be dispersed.

[3] The first appellant is the patentee and the second appellant has been licensed to use the invention. The respondent imports and distributes a pharmaceutical preparation known as Ulzec, in 10g and 20g doses, which is alleged by the appellants to infringe the patent. The appellants applied to the Commissioner of Patents, as a matter of urgency, for interim relief aimed at restraining the respondent from distributing Ulzec pending the outcome of an action for final relief. Several issues were raised in those proceedings but the Commissioner (Southwood J) found it necessary to deal with only one of them - he found that Ulzec does not infringe the patent and on that ground alone the application was dismissed. Leave to appeal having been granted by the Commissioner this Court directed in terms of Rule 11 that the appeal would be confined to the issue of infringement and that if the appeal were to

succeed the application would be remitted to the Commissioner for the remaining issues to be dealt with.

[4] The aim of the invention, according to the patent specification, is to enable an oral dose of omeprazole to be delivered intact to the proximal part of the small intestine, there to be rapidly dispersed so that it can be absorbed through the wall of the intestine into the blood stream. In order for the drug to pass through the stomach without having contact with the acidic stomach fluids it is encapsulated in an enteric coating that is resistant to dissolution in the stomach but dissolves in the proximal part of the intestine. Enteric coatings that are in common use, however, are themselves acidic, which would ordinarily cause the drug to deteriorate while in storage, but the storage stability of the drug is enhanced if it is mixed with an alkaline compound. It was found that when such an alkaline core is enteric coated some diffusion of moisture through the coating occurs during the time that

the dosage resides in the stomach, which dissolves part of the core in the proximity of the coating with the result that an alkaline solution forms under the enteric coating and dissolves it from within. That problem is overcome, according to the invention, by coating the alkaline core with a substance that forms a barrier between the alkaline core and the outer enteric coating. It is the composition of that subcoating layer that lies at the centre of the present dispute.

[5] The invention is claimed as follows in claim 1 of the patent specification (some of the remaining claims are of secondary relevance to this appeal and I will return to them later in this judgment):

- '1. An oral, pharmaceutical preparation in the form of enteric coated tablets or pellets, containing omeprazole as the active ingredient characterized in that it is composed of:
 - (a) alkaline core material containing omeprazole together with an alkaline reacting compound, or an alkaline salt of omeprazole optionally together with an alkaline reacting compound, and

- (b) on said alkaline core material one or more inert reacting subcoating layers comprising tablet excipients which are soluble or rapidly disintegrating in water, or polymeric, water soluble, filmforming compounds, optionally containing pH-buffering, alkaline compounds between the alkaline core material and
- (c) an outer layer, which is an enteric coating.'

[6] The dispute falls within a narrow compass. Paragraph (b) of claim 1 envisages the active alkaline core of paragraph (a) being subcoated with one or more layers 'comprising tablet excipients which are soluble or rapidly disintegrating in water, or polymeric, water soluble, filmforming compounds'. The active alkaline core of respondent's product, Ulzec, is subcoated with a single compound (polyvinyl pyrrolidone, which is a water soluble, film-forming polymer). The respondent alleges that it is an essential element of the claim that the subcoating layer or layers should be constituted of more than one excipient or compound and that because the alkaline core of Ulzec is subcoated with a single compound the patent is not infringed.

[7] In *Letraset Ltd v Helios Ltd* 1972 (3) SA 245 (A) at 274G-H van Winsen JA, writing for the Court on that issue, described the nature of the enquiry into infringement as follows:

‘The determination of the question as to whether or not plaintiff has proved an infringement of his patent turns upon a comparison between the article or process, or both, involved in the alleged infringement and the words of the claims in the patent. If the article or process falls within the ambit of the claims, properly construed: an infringement is proved. But the article or process will not be regarded as falling outside the scope of the claims if such differences as the comparison may disclose are not matters of any substance. In making the comparison the law looks at the essence of what is contained in the claim and will not allow what is described as the “pith and marrow” of the protected invention to be pirated. The evaluation of what is the substance or essence of an invention is a matter for the “good sense” of the judicial tribunal seized with the enquiry.’

[8] While the enquiry into infringement requires the allegedly infringing article or process to be compared against the language of the claim, it appears from that *dictum*, and has subsequently been repeated by this Court, that the language of the claim must be construed purposively, so as to extract from it the essence, or the essential elements, of the invention (*Multotec Manufacturing (Pty) Ltd v Screenex Wire Weaving Manufacturers (Pty) Ltd*

1983 (1) SA 709 (AD) 722A-D; *Stauffer Chemical Co and Another v Safsan Marketing and Distribution Co (Pty) Ltd and Others* 1987 (2) SA 331 (A) 343A-344D; *Sappi Fine Papers (Pty) Ltd v ICI Canada Inc (Formerly CIL Inc)* 1992 (3) SA 306 (AD) 319I). For as pointed out by Lord Diplock in *Catnic Components Limited and another v Hill and Smith Limited* [1982] RPC 183 (HL) at 242, in a passage that was approved and adopted by this Court in the cases I have referred to:

‘... a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. “skilled in the art”), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is those novel features only that he claims to be essential that constitute the so-called “pith and marrow” of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that *any* variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.’

[9] In *Multotec Manufacturing, supra*, at 721C-E Corbett JA observed that a court should always guard against ‘too “textual” an approach’ in the interpretation of claims in a patent specification because by ‘peering too closely at the language of a claim the Court may overlook an infringement that takes the substance of the invention.’ While the claim must be construed to ascertain the intention of the inventor as conveyed by the language he has used (*Gentiruco A.G. v Firestone S.A. (Pty) Ltd* 1972 (1) SA 589 (A) 614B-C) what is sought by a purposive construction is to establish what were intended to be the essential elements, or the essence, of the invention, which is not to be found by viewing each word in isolation but rather by viewing them in the context of the invention as a whole. To the extent that it might have been suggested in an *obiter dictum* in *Nampak Products Ltd and Another v Man-Dirk (Pty) Ltd* 1999 (3) SA 708 (SCA) at 714A that it might be called in aid only to construe an ambiguous claim I do not think that is supported by the decisions of this Court and in my view it is

not correct. It is merely an approach to construction that is aimed at establishing what was meant in a particular context. As pointed out by Hefer JA in *Fundstrust (Pty) Ltd (in Liquidation) v Van Deventer* 1997 (1) SA 710 (A) at 726H-727B (in a passage that was adopted in relation to the construction of patent specifications in *Monsanto Co v MDB Animal Health (Pty) Ltd (formerly MD Biologics CC* 2001 (2) SA 887 (SCA) at 892B-C):

‘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.’

[10] The words ‘excipients’ and ‘compounds’ in paragraph (b) of the claim, expressed as they are in the plural, might indeed in literal terms mean at least two different excipients, or compounds, as the case may be (the literal meaning was adopted by the Commissioner). But when seen in the context of the invention as a whole, and also when seen in the context of one

of the remaining claims, in my view it is most doubtful that the inventor could have intended that to be essential.

[11] The purpose that is served by the subcoating layer or layers (for convenience I will refer hereafter to the subcoating layer or layers only in the singular) is merely to form an effective but water-soluble barrier between the alkaline core and the enteric coating. It is apparent from the claim itself that the chemical composition of the subcoating layer was considered by the inventor to be immaterial, provided only that it fulfilled the functional requirements specified in the claim, for the claim does not insist upon, or even specify, what its chemical composition should be. If the subcoating layer may consist of a mixture of any two excipients or compounds it must follow that its composition is immaterial (provided only that it has the functional characteristics specified in the claim) and there is then no apparent reason, nor could one be suggested, why it should not consist of

any one of those compounds alone. The fact alone that the inventor was indifferent to the composition of the subcoating layer (provided only that it had the characteristics described in the claim) makes it most doubtful that it was intended that two or more excipients or compounds were essential elements of the invention.

[12] Moreover, that doubt only increases when the words are read in the context of claims 3 and 4 (which indirectly incorporate all the elements of claim 1). Claims 3 and 4 provide as follows:

- ‘3. A preparation according to claim 1 wherein the subcoating comprises two or more sub-layers.
4. A preparation according to claim 3 wherein the subcoating comprises hydroxypropyl methylcellulose, hydroxypropyl cellulose or polyvinylpyrrolidone.’

[13] A preparation according to claim 4 will have a subcoating that comprises at least two layers, but those subcoating layers will nonetheless conform with paragraph (b) of claim 1. It will be a subcoating, however,

that might ‘comprise’ any one of the three compounds described in claim 4.

If the word ‘comprise’, as it is used in claim 4, was intended to mean ‘consists of’, then clearly claim 1 was not intended to exclude a subcoating consisting of only one compound, for otherwise the provisions of claim 4 would be internally inconsistent. It was submitted by the respondent, however, that the word ‘comprises’ in claim 4 is used as a synonym for ‘includes’ (which would not be inconsistent with modern usage - *Fowler’s Modern English Usage* 3rd ed by R.W. Burchfield – and is also the meaning that has been accepted in patent cases in the United States – see *In re Bertsch* 56 USPQ 379 at 384; *H.K. Porter Company, Inc v The Gates Rubber Company* 187 USPQ 692 at 715) and that claim 4 thus does no more than specify that the multiple compounds that are required by claim 1 are to include at least one of the compounds specified in claim 4. Whether the word ‘comprise’ is used in claim 4 synonymously with ‘includes’ is itself

questionable, for that would seem to be inconsistent with its use in claim 3, but it is not necessary for present purposes to decide whether that is so.

[14] In my view both those considerations, if not decisive of the meaning to be given to the words in the claim, at least raise considerable doubt that the inventor intended to exclude from the ambit of the claim preparations in which the subcoating layer consists of one compound, notwithstanding the use of the word in the plural. Where the words used in the claim are ambiguous, in the sense that when read in their proper context their meaning is doubtful or not reasonably clear, the body and title of the specification may be invoked to ascertain whether at least a reasonably certain meaning can be given to the claim (*Gentiruco A.G. v Firestone S.A. (Pty) Ltd* 1972 (1) SA 589 (A) at 615F-G).

[15] The description of the invention in the body of the specification contains no suggestion that the subcoating layer should consist of more than one excipient or compound: if anything it suggests the contrary. In describing the subcoating layer the specification says no more than that it 'consists of one or more water soluble inert layers, optionally containing pH-buffering compounds' and that the material for the subcoating layer 'is chosen among the pharmaceutically acceptable, water soluble, inert compounds or polymers used for film-coating applications.' Had it been thought essential that the subcoating layer should consist of more than one compound one would have expected something to that effect to have been said. What is decisive, however, is the composition of the subcoating layer in the various examples that are given in the specification of what are said to be 'the invention...described in detail.' In many cases the subcoating layer consists of a single compound (usually dissolved in distilled water or ethanol). That is entirely inconsistent with a construction of claim 1 that

confines the invention to preparations in which the subcoating layer consists of at least two different excipients or compounds.

[16] It is clear, when seen in that context, that the words in claim 1 were not intended to claim as an essential element of the invention a subcoating layer that consisted of more than one excipient or compound, and to exclude a subcoating layer that consisted of only one, notwithstanding that the words were used in the plural. In my view, the words were intended instead to refer merely to a quantity of excipient or compound rather than to excipients or compounds of more than one kind. In those circumstances the respondent's product infringes the patent and the application ought not to have been dismissed on that ground.

[17] Accordingly the appeal is upheld with costs, including the costs occasioned by the employment of two counsel, and the following orders are made:

- (a) The order of the Commissioner of Patents is set aside.
- (b) It is declared that the respondent, by importing, making, disposing of or offering to dispose of its Ulzec products infringes claim 1 of Patent No. 87/2378.
- (c) In accordance with the order made by this court on 17 May 2002 the application for the temporary interdict is remitted to the Commissioner of Patents.

R W NUGENT
JUDGE OF APPEAL

HEFER AP)
HARMS JA)
FARLAM JA)
NAVSA JA) CONCUR

