THE SUPREME COURT OF APPEAL OF SOUTH AFRICA

JUDGMENT

Reportable

Case no: 20282/2014

In the matter between:

MERCK SHARPE DOHME GROUP **APPELLANTS**

MERIAL LLC

and

CIPLA AGRIMED (PTY) LTD **RESPONDENT**

Neutral citation: *Merck Sharpe Dohme Group v Cipla Agrimed (Pty) Ltd* (20282/2014) [2015] ZASCA 175 (27 November 2015)

Bench: Ponnan, Theron, Wallis, Petse and Willis JJA

Heard: 10 November 2015

Delivered: 27 November 2015

Summary: Patent – alleged lack of novelty – requirements of disclosure and enablement – selection patent – conditions for validity of.

ORDER

On appeal from Court of the Commissioner of Patents (Teffo J, sitting as court of first instance):

1. The appeal is upheld with costs, including the costs of two counsel.
2. The order of the court below is replaced with the following:
   ‘(a) The application for revocation of South African Patent Number 1998/10975 is dismissed.
   (b) Each of the claims of South African Patent Number 1998/10975 is certified as being valid in terms of section 74 of the Patents Act No 57 of 1978.
   (c) Costs are awarded to the joint patentees, including the costs of two counsel.’

JUDGMENT

Ponnan JA (Theron, Wallis, Petse and Willis JJA concurring):

[1] ‘An old question and answer runs as a follows: "Where does a wise man hide a leaf? In a forest." It is, at least faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves. The contention has no logical stopping place. . . .’ That excerpt from *Dr Reddy’s Laboratories (UK) Ltd v Eli Lilly and Company Ltd* [2009] EWCA Civ 1362 para 26 and 27 appears particularly apt when considering the issue raised by this appeal, which is whether or not, and the extent to which, a generalised description in a prior art document discloses and enables a specific matter falling within

that broad description for the purpose of anticipation. The issue arises for determination in this context: The appellants, Merck Sharpe Dohme Corp and Merial LLC, the joint patentees of South African Patent 98/10975, appeal against an order of the Commissioner of Patents (Teffo J) revoking their patent. The patent (the 98 patent) was revoked at the instance of the respondent, Cipla Agrimed (Pty) Ltd, on the basis that it was invalid for lack of novelty in terms of s 61(1)(c) read with s 25(1) of the Patents Act 57 of 1978 (the Act).

[2] A patent represents a *quid pro quo* (per Viscount Dunedin in the UK Privy Council case of *Pope Applicance Corporation v Spanish River Pulp and Paper Mills Ltd* [1929] AC 269 at 281). The *quid* is the monopoly conferred upon the patentee for a number of years and the *quo* is the new knowledge presented to the public, and which, after the expiry of the patent, will be available for general utilisation. 'Hence the function of the claim is to inform prospective rivals of the limits of the field denied to them while the patent lasts; and the function of the body of the specification is to instruct the public how to carry out the invention when the field is eventually open' (*Letraset Ltd v Helios Ltd* 1972 (3) SA 245 (A) at 249 F-G). Under the Act a patent may be granted for an invention only if, amongst other things, the invention is new and involves an inventive step (s 25(1)). It follows that a patent granted for an invention that does not meet those criteria may be revoked (s 61(1)(c)). In terms of s 25(5) an invention is deemed to be new if it does not form part of the state of the art immediately before the priority date of any claim to the invention.

[3] The rules relating to the interpretation of patents are well-settled.[1] The onus of proving anticipation (or lack of novelty) in this case was on the respondent as the

[1] Harms JA put it thus in *Monsanto Co v MDB Animal Health (Pty) Ltd (formerly MD Biologics CC)*) [2001] ZASCA 4; (2) SA 887 SCA para 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) at 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, ie 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)*

applicant for revocation.[2] The general principles relevant to the determination of the novelty of the claims of a patent were recently restated in *Standard Bank of SA v 3MFuture Africa (Pty) Ltd* (47/2013) [2013] ZASCA 157. As Nugent JA put it (para 9):

'The classic formulation of the test to be applied when asking whether an invention has been anticipated (whether the invention is "novel" or "new") is that expressed by Trollip JA in *Gentiruco AG v Firestone SA (Pty) Ltd* [1972 (1) SA 589 (A)] . . . in which the learned judge said the following:

"[The objection of anticipation] relates to the claims and not the description of the invention in the body of the specification. . . . Hence the particular claim must be construed to ascertain its essential constituent elements or integers. For the purpose of this objection the claim so construed is assumed to be inventive. . . . The prior printed publication or patent alleged to be anticipatory is then construed. . . . The two documents are then compared to ascertain whether . . . the prior printed publication "describes", the same process, etc., as that claimed. . . . In regard to a prior publication, the ordinary meaning of "describe" means "to set forth in words or recite the characteristics of" . . . Hence for it to "describe" the invented process etc., it must set forth or recite at least its essential integers in such a way that the same or substantially the same process is identifiable or perceptible and hence made known, or the same or substantially the same thing can be made, from that description."'

[4] Accordingly, the scope of each of the claims of the patent in suit must be construed[3] and then compared with the prior art document upon which the attack is based.[4] Moreover, the disclosure must be found in one document as the mosaicing of more than one prior art document is not permitted.[5] It is important to appreciate that a finding of anticipation requires more than a throw-away reference to the same subject

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technical words of the art or science involved in the invention must also be given their ordinary meaning, ie 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.'

[2] *Netlon v Pacnet* 1977 (3) SA 840 (A) at 861E-F.

[3] See *Monsanto* (above) paras 8 and 9.

[4] *Gentiruco AG* (above) at 646B-647B.

[5] *Letraset Ltd v Helios Ltd* (above) at 264D-F.

matter in a prior art document. In this regard, the subject matter must be taught in the prior art document in a way which enables the skilled person, on reading the prior document, to appreciate the import of, and implement, its teaching. (See *Synthon BV v SmithKline Beecham plc* [2005] UKHL 59; [2006] 1 All ER 685 para 14.)[6]

[5] The House of Lords (per Lord Hoffmann) explained in *Synthon* that there are two requirements for anticipation: prior disclosure and enablement. 'Disclosure', stated Lord Hoffmann (para 20), has been explained in what he described as two judgments of unquestionable authority - *Hill v Evans* (1862) 31 LJ (NS) 457[7] and *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457.[8] Lord Hoffmann summarised the effect of those two judgments thus (para 22):

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[6] Referred to with approval in *Sunsmart Products (Pty) Ltd v Flag and Flagpole Industries (Pty) Ltd t/a National Flags* [2007] ZASCA 50; BIP 44 (SCA) para 22.

[7] In *Hill v Evans* (1862) 31 LJ (NS) 457 at 463 Lord Westbury LC stated:

'I apprehend the principle is correctly thus expressed: the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful. If something remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent.'

[8] In *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457 at 485–486 the Court of Appeal (Sachs, Buckley and Orr LJJ) stated:

'To determine whether a patentee's claim has been anticipated by an earlier publication it is necessary to compare the earlier publication with the patentee's claim. . . . If the earlier publication . . . discloses the same device as the device which the patentee by his claim . . . asserts that he has invented, the patentee's claim has been anticipated, but not otherwise. . . .

When the prior inventor's publication and the patentee's claim have respectively been construed by the court in the light of all properly admissible evidence as to technical matters, the meaning of words and expressions used in the art and so forth, the question whether the patentee's claim is new . . . falls to be decided as a question of fact. If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty. . . . The prior inventor, however, and the patentee may have approached the same device from different starting points and may for this reason, or it may be for other reasons, have so described their devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which, if the patentee's claim were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated.

If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakable directions to do what the patentee claims to have invented . . . A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee.'

'. . . the matter relied upon as prior art must disclose subject matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing: "Whether or not a person is working [an] invention is an objective fact independent of what he knows or thinks about what he is doing" (see *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* (1995) 33 BMLR 201 at 213, [1996] RPC 76 at 90). It follows that, whether or not it would be apparent to anyone at the time, whenever subject matter described in the prior disclosure is capable of being performed and is such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so.'

'Enablement', according to Lord Hoffmann (para 26), 'means that the ordinary skilled person would have been able to perform the invention which satisfies the requirement of disclosure.' He added (para 28):

'As Laddie J said in relation to sufficiency in *University of Southampton's Applications* [2005] RPC 220, 236:

"In my view, devising an invention and providing enabling disclosure are two quite different things. Although both may be necessary to secure valid protection, as section 14 of the [UK Patents Act, 1977] Act shows, they relate to different aspects of the law of patents. It is very possible to make a good invention but to lose one's patent for failure to make an enabling disclosure. The requirement to include an enabling disclosure is concerned with teaching the public how the invention works, not with devising the invention in the first place".'

[6] In *Synthon* (para 30) Lord Hoffmann emphasised that it is important to keep in mind that disclosure and enablement are distinct concepts - each of which has its own function and rules and each of which has to be satisfied.[9] And, that in deciding whether

[9] Significantly, in the context of anticipation, the Supreme Court of Canada in *Apotex Inc v Sanofi-Synthelabo Canada Inc* [2008] 3 SCR 265 para 49, relying heavily on jurisprudence from the United Kingdom, adopted the two-step approach of disclosure and enablement. That represented a refinement of the approach set out in *Beloit Canada Ltd v Valmet OY* (1986) 8 CPR (3d) 289 (FCA). As the Supreme Court put it (para28), 'the *Beloit* decision by which the applications judge rightly felt bound dealt with only one aspect of anticipation, that is, whether or not the invention in a patent had been disclosed in a single prior publication or patent.'

there has been anticipation, there is a serious risk of confusion if the two requirements are not kept distinct. As Lord Walker of Gestingthorpe observed in a separate concurrence in *Synthon* (para 64):

'The practical importance of keeping the two requirements distinct will vary with the factual situation. In the case of the low-tech invention . . . the simple disclosure of the invention will probably be enough to enable the skilled person to perform it. By contrast in the case of a high-tech invention in the field of pharmaceutical science the bald assertion of the existence of the invention may have to be accompanied by detailed disclosure enabling the skilled person to perform it. But in testing the adequacy of the enablement it may be assumed that the skilled person will have to use his skill, and may have to learn by his mistakes . . .'

[7] Thus, in order to constitute anticipation, the prior disclosure must not only identify the subject matter of the claim in the latter patent, but must also do so in a way that enables the skilled person to make or obtain it.[10] Importantly, the test of enablement of a prior disclosure for the purpose of anticipation has been held to be the same as the test of enablement of the patent itself for the purpose of sufficiency (*Synthon* para 22). Equating the necessary test for enablement to that for sufficiency, 'produces a degree of symmetry in the law' (*Synthon* para 63). And, 'on the issue of sufficiency expert evidence is admissible as to whether or not the body of the specification, properly construed, affords adequate information to the skilled addressee about how to perform the invention or the particular embodiment of it' (*Netlon Ltd and Another v Pacnet (Pty) Ltd* 1977 (3) SA 840 (A) at 868 H).

[8] To round off the applicable legal principles, an issue of some moment between the parties to this appeal concerns the proper approach to be adopted when considering the validity of what has come to be described as a selection patent. Under pre-1977 law in the United Kingdom, disclosure of a class (typically a class of chemical compounds) prima facie amounted to disclosure of each and every member of that class. The general rule was that 'disclosure of the class prima facie deprives its members of novelty' and 'prima facie a general disclosure of a class is disclosure of all members of the class, however obscure and whatever the consequences' (*Dr Reddy's Laboratories*

[10] Simon Thorley et al *Terrell on the Law of Patents* 17ed (2006) para 7-33.

para 35). It was however possible to obtain a valid patent for a specific compound or subclass as a so-called 'selection patent' if it could be shown that the subclass possessed some special advantage which was enjoyed by the subclass as a whole but also peculiar to it. Those rules were famously formulated by Maugham J in *IG Farbenindustrie's Patents* (1930) 47 RPC 289 at 322-3*. B-M Group (Pty) Ltd v Beecham Group Ltd* 1980 (4) SA 536(A) at 558D-F summarises those rules thus:

'First, a selection patent to be valid must be based on some substantial advantage to be secured by the use of the selected members . . . Secondly, the whole of the selected members must possess the advantage in question. Thirdly, the selection must be in respect of a quality of a special character which can fairly be said to be peculiar to the selected group.'

[9] As is pointed out by Simon Thorley et al in *Terrell on the Law of Patents* 17ed (2006) para 11-61, the 'subsequent application of those rules (the *IG* rules) gave rise to problems in reconciling them with the statute and the other authorities on novelty, since there was nothing in the 1949 Act which recognised any special approach for selection patents as a special category'.[11] In *Dr Reddy's Laboratories*, the English Court of Appeal held that the pre-1977 jurisprudence including the *IG* rules were part of legal history not living law. The court took the view (para 104) that there was 'nothing in the 1977 Act (any more than there was in the 1949 Act) which recognises, or even implies, a special approach to, or even the existence of, selection patents as a special category of patent, which requires a different approach when determining validity from other patents'. Logic dictates, so held the court (para 30), the 'rejection of the argument that a disclosure of a large class is a disclosure of each and every member of it.' Following on *Dr Reddy's Laboratories*, selection patents are no longer to be treated as a special class forming an exception to the ordinary rules. They now fall to be treated in accordance with the general approach to patent validity.

[10] *Dr Reddy's Laboratories* rejected the broad proposition that the disclosure of a generalised class necessarily amounted to disclosure of each and every member of it. It pointed out (para 30): 'So what one must look for by way of anticipation is an

[11] *Terrell on the Law of Patents* (above) para 11-61.

“individualised description” of the later claimed compound or class of compounds’. The Court of Appeal illustrated the point thus (para 29):

‘Similarly it makes no sense to say that a generalised prior description discloses a specific matter falling within in. The Judge's example illustrates the point. A prior disclosure of "fixing means" is not a disclosure of a particular fixing means e.g. welding or riveting even though you could list out a whole number of ways of fixing things together which would include these means’.

The court did not deem it necessary (para 31) to go into what is sufficient to amount to an ‘individualised description’ because that obviously may partly be one of degree and other considerations may also come into that question. The court emphasised (para 32-33) that on this score its view of the law accorded with the decision of the House of Lords in *Synthon.* Moreover, it was at pains to point out that its approach was consistent with that of the European Patent Office and the German Courts.

[11] The court a quo appears not to have had any regard to the principles outlined in *Synthon* and *Dr Reddy’s Laboratories*. In my view, applying those principles ought to have led it to a contrary conclusion. Here, it is common cause that: (a) the 98 patent has the priority dates of 3 December 1997 and 7 May 98; (b) the prior art relied upon by the respondent is contained in the second appellant’s own earlier patent specification with number 92/7457 (the 92 patent); and (c) the 92 patent was made available to the public on 30 March 1993. The court below held that all of the claims of the 98 patent were anticipated by the disclosure of the 92 patent. Inasmuch as the respondent’s case had been that only some of the claims of the 98 patent had been disclosed in the prior art, it abandoned those parts of the judgment which held that claims 8 to 17, 25, 27 and 28 of the 98 patent were invalid.

[12] What the 92 patent discloses: By way of background, the 92 patent begins by describing the ‘avermectin series of compounds’ as ‘potent anthelmintic agents against internal and external parasites’. Reference is then made to an earlier named US Patent, in which the natural product avermectins are disclosed. Avermectin is an anti-parasitic theraupeutic agent (API). The 92 patent discloses an injectable formulation, which is described thus:

'This invention consists of an injectable formulation of a hydrogenated castor oil and an avermectin compound in a hydrophobic carrier which has been found to have a considerably prolonged duration of activity against internal and external parasites.'

Broadly stated the injectable formulation disclosed in the 92 patent specification comprises:-

(a) hydrogengenated castor oil;

(b) an avermectin compound; and

(c) a hydrophobic carrier.

In the specification of the 92 patent there is the following disclosure:

'The hydrogenated castor oil formulation contains the avermectin compound in a hydrophobic physiologically acceptable injection solvent in which the avermectin compound is readily soluble. Any physiologically and pharmaceutically acceptable carrier may be used so long as the avermectin compound is soluble therein. Examples of such carriers are glyceryl triacetate (Triacetin) distilled acetylated monoglycerides (Myvacet), miglyol 812, safflower seed oil and the like, or a combination of such carriers.'

[13] For the purposes of this appeal it is, in truth, only claim 1 of the 98 patent that needs be considered, for, if it is not anticipated none of the other (dependant) claims will be. Claim 1 provides:

'A long-acting injectable formulation comprising:

(a) a therapeutic agent selected from the group consisting of insecticides, acaricides, parasiticides, growth enhancers and oil-soluble NSAIDS,

(b) hydrogenated castor oil, and

(c) a hydrophobic carrier comprising:

    (i) triacetin, benzyl benzoate or ethyl oleate or a combination thereof; and

    (ii) acylated monoglycerides, propyl dicaprylates/dicaprates, caprylic/capric acids; triglycerides, or a combination thereof.'

There is little that requires interpretation in this claim. It simply lists the ingredients in the formulation of the claim.

[14] It is common ground that integers (a) and (b) are disclosed in the 92 patent. The only question therefore is whether the particular combination of hydrophobic carriers claimed in integer (c) of claim 1 of the 98 patent is disclosed in the 92 patent. In this

regard, as is clear from claim 1, the 98 patent contemplates the selection of a particular combination of specific compounds to make up the hydrophobic carrier including, on the one hand, triacetin, benzyl benzoate or ethyl oleate or a combination thereof and, on the other, acylated monoglycerides, propyl dicaprylates/dicaprates, caprylic/capric acid triglycerides, or a combination thereof. The 98 patent teaches that by using the specific combinations of hydrophobic carriers of the patent in suit results in a 'considerably' prolonged duration of activity, of up to 180 days, when compared to prior art formulations, including those disclosed in the 92 patent.

[15] The advantages, as is confirmed by the evidence, of such a long duration of action are plain. Professor Gerald Swan, one of the joint patentee's experts, explains:

'49. The increase in duration of action gives rise to very significant benefits in veterinary practice. Long acting anti-parasitic formulations that provide for an extended duration of efficacy achieve better control of parasites for a longer period. This in turn results in significantly improved productivity in production animals such as cattle because the harmful effects of parasites are avoided more effectively and for longer periods.

50. Furthermore, a longer acting formulation more comprehensively controls parasites. By way of explanation, in order to be effective against parasites, the API [active pharmaceutical ingredient] must be ingested by, or exposed to, the parasite in sufficient quantities to kill or paralyse the parasite. It is, in general, easier to kill adult parasites because they ingest more blood or body fluids and tissue from the host animal than immature parasites do. However, by using a long acting formulation, even immature parasites ingest or take up sufficient quantities of the API (over a particular period) to kill or paralyse them before they become adults. This is preferable, from a treatment perspective, to permitting the parasites to become adults before the treatment is effective.

51. Long acting formulations also ensure that re-infestation of the animal with parasites is prevented for longer periods. With conventional shorter acting formulations such re-infection would need to be retreated.

52. Finally, a wider spectrum of activity against parasites, particularly against ticks, may also be achieved using a formulation with an activity beyond 42 days. Certain ticks are "multi-host" (two- or three host) parasites. This means that they require a number of hosts in order to complete their life cycles and only infest the final host (e.g. cattle) as adults. By maintaining the minimal effective concentration of the API in the animal's blood over an extended period, the

formulation could achieve control of these tick species as all new tick infestation will be controlled for the duration of long action. A short acting formulation would only potentially affect ticks on the animal at the time of treatment and will not be effective against any new infestation.'

[16] On the question of the hydrophobic carriers, the 92 patent discloses that '[a]ny physiologically and pharmaceutically acceptable carrier may be used so long as the avermectin compound is soluble therein'. It goes on to list examples of such carriers as being 'glyceryl triacetate (Triacetin), distilled acetylated monoglycerides (Myvacet), miglyol 812, safflower seed oil and the like, or a combination of such carriers.' The 92 patent teaches in the 'example of the invention' the use of a single hydrophobic carrier, namely Triacetin. In line with this, claim 12, which is the only claim in the 92 patent directed at preferred hydrophobic carriers, claims the use of Triacetin alone as the hydrophobic carrier. The teaching of the 92 patent is therefore that *any* carrier can be used in the formulation of the 92 patent.

[17] The only 'individualised description' in the 92 patent of a hydrophobic carrier is that of Triacetin (alone). Both Dr Leonore Witchey-Lakshmanan (another of the joint-patentee's experts) and Professor Swan make this plain. The former stated:

'The 92 patent teaches in the examples of the specification (like the EP patent) that triacetin is to be preferred. Additionally, in the claims of the 92 patent only triacetin is singled out as a potential vehicle (see claim 12). The 92 patent teaches that triacetin is the preferred hydrophobic carrier but, as I have said, is not limited in this respect.'

And, the latter added:

'42. The 92 patent does however suggest possible hydrophobic carriers which might be used. These include glyceryl triacetate (triacetin), distilled acetylated monoglycerides (Myvacet), miglyol 812, safflower seed oil and the like, or a combination of such carriers. . . . The example given on page 9 of the 92 patent pertains to a single hydrophobic carrier namely triacetin, and does not disclose any particular combination of hydrophobic carriers.

43. In line with this teaching, claim 1 of the 92 patent is not limited to a particular type of hydrophobic carrier. Claim 1 makes clear that any carrier can be used. Claim 11 of the 92 patent is limited to the particular carriers referred to in the paragraph above. Importantly, however, claim 12 is limited specifically to triacetin, in line with the only example in the 92 patent. Thus, the 92 patent, consistent with the EP patent, again teaches that the most

preferable formulation is one which includes only triacetin as the hydrophobic carrier in the formulation.'

[18] Indeed, as Professor Swan further explains:

'44. It is clear from the disclosure of the specification as a whole that the inventors of the '92 patent placed no significance on the choice of hydrophobic carrier, stating expressly that *any* carrier could be used. This is accepted by Dr Cromarty in paragraph 20 of his affidavit where he states that the inventors of the '92 patent equated triacetin and monoglyceride – which have very different properties as hydrophobic carriers. Reading the '92 patent as a whole, it is clear that the important addition to the formulation of the '92 patent (particularly when regard is had to the EP patent) was that of hydrogenated castor oil in the formulation. The '92 patent teaches only that a hydrophobic carrier must be added – the nature and characteristics of that carrier would be understood by the reader of the patent not to be prescriptive.

45. A person skilled in the art of the '92 patent would have therefore understood from reading it that any hydrophobic carrier could be used in the formulation provided avermectin was soluble in that carrier.'

[19] Furthermore, while specific examples are given in the 92 patent, there is no suggestion or teaching that any of them, or any combination of them, have any utility or advantage over other hydrophobic carriers or combinations of carriers. By contrast the 92 patent is specific in requiring a combination of hydrophobic carriers selected from two clearly identified groups of such carriers. The possibility of a combination of carriers is no longer a random matter but a carefully delineated requirement.

Indeed, save for the reference to these hydrophobic carriers there is no teaching at all in relation to the properties or benefits of these carriers in a formulation containing avermectin. Moreover, the 92 patent teaches that the formulation of that patent will be efficacious up to 42 days. There is no teaching of the very significant advantages (up to 180 days of efficacy) which arise from the selection of the particular hydrophobic carriers disclosed in the 98 patent.

[20] In that regard as Professor Swan points out:

'48.2. the formulation claimed in the patent in issue allows for the API to remain active for up to 140 days as the patent in issue explains:

"While the previously reported avermectin formulation containing hydrogenated castor oil in triacetin did produce prolonged plasma level compared to a formulation without hydrogenated castor oil, it did not achieve a plasma level efficacious against all relevant parasitic species at the 42 day target. In contrast the present formulation using avermectins or milbemycins surprisingly provides a significantly higher plasma [sic: level] at day 42 and beyond. The present formulation is also efficacious against ticks and Dermatobia hominis for up to 75 and 140 days, respectively."

Thus, the formulation of the patent in issue provides significantly higher blood plasma concentration levels of the API at day 42 than the formulation of the '92 patent . . . and provides significantly longer protection than the formulation of the '92 patent (and the EP patent).'

[21] Finally, Dr Witchey-Lakshmanan and Professor Swan both make clear that the skilled person could not, armed only with the 92 patent, arrive at the combinations of hydrophobic carriers disclosed in the patent in suit without a significant amount of ingenuity and experimentation. This is because the elements of the formulation, including the active pharmaceutical ingredient, react with each other and in the animal body (*in vivo*) in wholly unpredictable ways. This evidence is not disputed by Dr Allan Cromarty, the respondent's expert. If anything, both of the respondent's witnesses effectively concede that the 98 patent is not anticipated by the disclosure in the 92 patent. Mr Jan Wentzel, the respondent's general manager, stated in reply:

'The 92 patent specification, as explained by Dr Cromarty, clearly discloses most of the subject matter of the 98 patent. Where the subject matter is not fully disclosed only experimentation, not invention, would be needed to obtain the specific formulation claimed.'

Whilst, in answer to Prof Swan's assertion that '. . . a further difference between a number of subsidiary claims and the prior art is the specific limitation to particular proportions of hydrophobic carrier of the patent in issue', Dr Cromarty stated the following:

'. . . suffice it to say here that where the proportions are not fully disclosed in the 92 specification, experimental work, and not invention, would be needed to achieve these proportions.'

[22] Critically, for the present appeal, if something remains to be ascertained which is necessary for the useful application of the discovery, there is sufficient room for another

valid patent.[12] To anticipate the patentee's claim the prior publication must therefore contain clear and unmistakable directions to do what the patentee claims to have invented.[13] The Federal Court of Australia (per Middleton J) in *Eli Lilly and Company Limited v Apotex (Pty) Ltd* [2013] FCA 214 para 272 and 273 put the position thus:

'The view I have reached in this proceeding is that even if the prior art theoretically includes all of the integers of the invention (among other possible combinations), this is *not necessarily* to anticipate a later patent. Such a view is particularly apt where the prior art discloses a class of chemical compounds, often by way of generic formula, as in the present case. Everything will depend upon the extent of disclosure in the prior art document, and the context in which that disclosure appears. It will be necessary to consider the disclosure in its entirety to determine what it clearly and unmistakably discloses. It is true to say as a matter of logic that a very generalised prior description in a prior art document does not necessarily disclose a specific item falling within that generalised description.

Undoubtedly, a prior document may disclose more than one thing. It may disclose many things, and in doing so, anticipate a later invention. However, a prior disclosure of many things must still provide "clear and unmistakable directions" to the claimed invention.'

[23] The 92 patent does not 'plant the flag at the precise destination' of the claims of the 98 patent. Rather, it appears to do no more than offer a 'signpost' on the road to the invention. But even if the flag had been planted, it still remains to be considered whether the skilled person would have been enabled by it. On the respondent's own version, armed with the 92 patent, the skilled person would still have to conduct further experiments and gain further information regarding the hydrophobic carriers broadly discussed in the 98 patent before he or she would appreciate the import of the very substantial advantages which flow from the invention of 98 patent. Even with the benefit of the 92 patent, therefore, 'something' (namely, the knowledge that particular selections of hydrophobic carriers will lengthen the duration of activity considerably) 'remains to be ascertained which is necessary for the useful application' of the formulation of the 92 patent. In these circumstances, as *Synthon* makes clear, there is sufficient room for another valid patent.

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[12] *Synthon* (above) para 20 quoting *Hill v Evans* (above) at 463.
[13] *Synthon* (above) para 21 quoting *General Tire and Rubber CO v Firestone Tyre and Rubber Co* (above) at 485-486.

[24] Carrying out the 92 patent would not necessarily result in an infringement of the 98 patent. For example, using Triacetin alone as the hydrophobic carrier in a formulation which includes integers (a) and (b) of claim 1 of the 98 patent would not be an infringement of any of the claims of the 98 patent. Similarly using 'any physiologically and pharmaceutically acceptable carrier . . . so long as avermectin is soluble therein' not specifically claimed in the 98 patent would not infringe any of the claims of the 98 patent. As such, again on the authority of *Synthon*, the 98 patent is not anticipated by the disclosure in the 92 patent.

[25] Moreover, applying *Dr Reddy's Laboratories*, there is no individualised description of the specific combinations of hydrophobic carriers of claim 1 of the 98 patent, and the advantages which flow from using them in combination in the 92 patent. The 92 patent teaches that any hydrophobic carrier will do; and where preference is expressed it is for Triacetin alone. The skilled person is not therefore able to produce the invention of claim 1 of the patent in suit on the basis of the 'indication' in the 92 patent and his or her 'general technical knowledge'. Instead, the skilled person would have had to have applied a significant amount of ingenuity and undertaken an extensive amount of pharmacokinetic and efficacy testing to arrive at the specific combination of hydrophobic carriers disclosed in the patent in suit, and the significant technical advance which those specific combinations represent over the disclosure of the 92 patent.

[26] There is thus no merit in the attack on the patent in suit. It follows that the revocation application should have been dismissed with costs, including the costs of two counsel, and a certificate of validity in terms of s 74 of the Act given.

[27] In the result:

1. The appeal is upheld with costs, including the costs of two counsel.
2. The order of the court below is replaced with the following:

‘(a) The application for revocation of South African Patent Number 1998/10975 is dismissed.

(b) Each of the claims of South African Patent Number 1998/10975 is certified as being valid in terms of section 74 of the Patents Act, 57 of 1978.

(c) Costs are awarded to the joint patentees, including the costs of two counsel.’

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V M Ponnan

Judge of Appeal

APPEARANCES:

For Appellants:	L Bowman SC (with him G Marriott) Instructed by: DM Kisch Inc., Pretoria Phatshoane Henney Attorneys, Bloemfontein
For Respondent:	C E Puckrin SC (with him M Seale and H Worthington) Instructed by: Brian Bacon Inc., Cape Town Webbers, Bloemfontein