IN COURT OF THE COMMISSIONER OF PATENTS
(REPUBLIC OF SOUTH AFRICA)

11/3/14

PATENT NO: 1998/10975

(1) REPORTABLE: YES / NO
(2) OF INTEREST TO OTHER JUDGES: YES / NO
(3) REVISED

11.03.14
DATE

SIGNATURE

In the matter between:

CIPLA AGRIMED (PTY) LTD **Applicant**

AND

MERCK SHARP DOHME GROUP

MERIAL LLC **Joint Patentees**

JUDGEMENT

TEFFO, J:

[1] The applicant seeks an order for the revocation of the South African Patent Number 1998/10975 ("the 1998 patent") held by the joint patentees ("the respondents herein").

[2] The application is based on the ground that the invention as specified in claims 1 to 29 of the 1998 patent, is not patentable in terms of section 25 of Act 57 of 1978 ("the Patents Act"). Further that the invention lacks novelty in that it was not new as at the priority date of its invention.

[3] The applicant contends that claims 1 to 29 of the 1998 patent is disclosed in, and therefore anticipated by, the specification of patent number 92/7457 ("the 1992 patent"), which was made available to the public on 30 March 1993 in terms of sections 43(1) and 43 (3) of the Patent Act.

[4] The application is opposed.

[5] Claim 1 of the 1998 patent provides as follows:

"A long – acting injectable formulation comprising:

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

(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 acid, triglycerides, or a combination thereof."

[6] It is common cause between the parties that integers (a) and (b) referred to *supra* are disclosed in the 1992 patent.

[7] It is also common cause between the parties that the 1998 patent has the priority dates of 3 December 1997 and 7 May 1998. Further that the 1992 patent was made available to the public before the relevant priority dates of the claims.

[8] The respondents deny that the invention claimed in claims 1 to 29 did not involve an incentive step and that the invention would have been obvious to a person skilled in the art of having regard to the specification of the 1992 patent in the light of the knowledge of the skilled addressee immediately before the relevant priority dates. They also seek

certification in terms of section 74(1) of the Patents Act that each of the claims of the 1998 patent is valid.

[9] The issue for determination is whether the particular combination of hydrophobic carriers claimed in integer (c) of claim 1 of the 1998 patent is disclosed in the 1992 patent and whether the 1992 patent anticipates the claims of the patent under review.

[10] The following parts of section 61 and 25 of the Patents Act are relevant to the relief sought:

Section 61 (1) (c) reads as follows:

"Grounds for application for revocation of patent

"(1) Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely:-

(c) that the invention concerned is not patentable under section 25;

(3) The commissioner shall decide whether the patent shall be revoked or whether and, if so, subject to what amendments, if any, of the specification or claims thereof, the patent shall be upheld: Provided that the commissioner shall not allow any amendment which is in conflict with the provisions of section 51(6) or (7): Provided further that the commissioner may in the exercise of his discretion as to costs take into consideration the conduct of the patentee in framing his specification and claims and permitting them to remain as so framed."

Section 25 reads:

"Patentable inventions

(1) A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.

(5) An invention shall be deemed to be new if it does not form part of the state of art immediately before the priority date of any claim to that invention.

(6) The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.

(7) The state of the art shall also comprise matter contained in an application, open to public inspection, for a patent, notwithstanding that that application was lodged at the patent office and became open to public inspection on or after the priority date of the relevant invention, if:-

(a) that matter was contained in that application both as lodged and as open to public inspection, and

(b) the priority date of that matter is easier than that of the invention.

(10) Subject to the provisions of section 39(6), an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art by virtue only of subsection (6) and disregarding subsections (7) and (8)."

[10] The rules for interpreting a patent were confirmed by Harms JA in *Monsanto Co v MDB Animal Health (Pty) Ltd (Formerly MB Biologics CC) 2001 (2) SA 887 (SCA)* as follows at p891 para 8 et seq:

"[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 614 A- 616 D may be emphasised:

(a) a specification should be construed like any other document, subject to the interpreter being mindful of the object 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 specifications 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."

[11] In Ensign-Bickford (South Africa) (Pty) Ltd and others v AECI Explosives and Chemicals Ltd 1999 (1) SA 70 SCA, Plewman JA made the following remarks with regard to interpretation:

" It will, I think, suffice to say that nothing contained in the body of the specification in this regard purports to provide a dictionary for the claims or even (in a more limited sense) to affect the wording of the claims. To construe the claims in this way would offend against a fundamental principle of patent law, namely that found in the famous dictum of Lord Russell in the case of Electrical and Musical Industries v Lissen [1939] 56 RPC 23 at 39 ([1938] 4 All ER 221 at 224H-225A and 227 C-D). It is a rule adopted by this court in the

([1938] 4 All ER 221 at 224H-225A and 227 C-D). It is a rule adopted by this court in the case of Power Steel Construction Co (Pty) Ltd v African Batignolles Contructions (Pty) Ltd 1955 (4) SA 215 (A) at 224 D-F. The dictum reads: '.... The claims must undoubtedly be read as part of the entire document, and not as a separate document; but the forbidden field must be found in the language of the claims, and not elsewhere. It is not permissible, in my opinion, by reference to some language used in the earlier part of the specification to change a claim for one subject matter into a claim for another and a different subject matter, which is what you do when you alter the boundaries of the forbidden territory ...

A claim is a portion of the specification which fulfils a separate and distinct function. It and it alone, defines the monopoly; and the patentee is under a statutory obligation to state in the claims clearly and distinctly what is the invention which he desires to protect."

[12] In the Gentiruco AG matter referred to *supra* it was held that an objection of anticipation relates to the claims and not the description of the invention in the body of the specification. Further to this the following was said:

"*Hence the particular claim must be construed to ascertain its essential constituent elements or integers...The two documents are then compared to ascertain whether the prior patent was granted for, or the prior printed publication 'described', the same process, etc., as that claimed. Prior patenting will be dealt with later. In regard to a prior publication, the ordinary meaning of 'describe' means to set forth in words or recite the characteristics of (concise Oxford English dictionary). Hence for it to 'describe' the invented process ,etc., it must be 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.*

'Substantially the same means practically the same, or, to use Lord Westbury's phrase adopted by WESSELS, J.A in Veasey's case, p.269, the same 'for the purposes of practical utility", i.e., substance and not form must be regarded. Consequently, if on the comparison of the two documents it appears that the same or substantially the same process, etc., is described in the above sense in both, the claim has been anticipated and is not novel; conversely, the description in the prior document differs, even in small respect, provided it is a real difference, such as the non-recital of a single essential

[13] In RG Murray v Vodacom (Pty) Ltd and another 2008 BP 31 (CP) 57 Murphy J said:

"The courts in interpreting patent claims should have recourse to the full context and background of a specification in order to decide what the skilled addressee would have understood the claims to mean - Vari-Deals 101 (Pty) Ltd v Sunsmart products (Pty) Ltd 2007 SCA 123 (RSA) at para 11."

[14] In support of its case the applicant relies on the expert evidence of Wentzel and Cromarty while the respondent relies on the evidence of Witchey-Lakshamanan and Swan. This evidence will only serve as a guide to the various integers which require comparison.

[15] The applicant contends that the respondents' witnesses cannot be regarded as independent in that Lakshamanan was previoulsly employed in the laboratory in which the 1998 patent was conceived and he was involved in the formulations containing ivermectin at that time while Swan was an employee of Merck Sharp and Dohme in South Africa.

[16] After comparing the wording of the 1992 and 1998 patents, Cromarty concluded that claim 1 of the 1998 patent has been anticipated by the 1992 patent for the following reasons:-

16.1 That the 1992 patent discloses a long acting injectable formulation;

a) a hydrogenated castor oil;

b) the avermectin compound (parasiticide); in

c) a hydrophobic physiologically acceptable solvent comprising in combination:

i) glyceryl triacetate (Triacetin); or

ii) distilled acetylated monoglycerides (Myvacet); or a combination of such carriers.

ii) distilled acetylated monoglycerides (Myvacet); or a combination of such carriers.

16.2 The 1992 patent thus discloses a list of ingredients for the formulation and specifies, expressly, that one of the combinations will contain both glyceryl triacetate and distilled acetylated monoglyceride. It discloses a formulation which includes an antioxidant, of which several are disclosed in the specification and it also states that the preferred compound is ivermectin. The formulation of claim 1 of the 1998 patent specification includes a combination of hydrogenated castor oil, a parasiticide (avermectin) in solution in a hydrophobic carrier consisting of triacetin and acetylated monoglycerides. The 1992 patent provides directions to produce what claim 1 of the 1998 patent claims as an invention.

[17] Counsel for the applicant submitted that it is apparent that the 1992 patent describes the 1998 patent's essential integers in such a way that the same or substantially the same formulation is identified and made known. The same product, the formulation defined in class 1 of 1998 patent, can be made from the description of the formulation contained in the 1992 patent specification. The paragraph found at page 7 lines 25 to 29 of the 1992 patent reveals that it discloses the formulation referred to it in the 1998 patent. The alleged inventive formulations set out in claim 1 of the 1998 patent are therefore nothing more than a repetition of the disclosure in the 1992 patent. The subject matter of claims 2,5,6,7,18,19,20,21,22,23 and 25 are disclosed in the 1992 patent.

[18] Counsel for the respondent submitted that the teaching of the 1992 patent in so far hydrophobic carriers is concerned, is extremely limited. It provides, vaguely, that "any physiologically and pharmaceutically acceptable carrier... so long as avermectin is soluble therein" may be used in the formulation disclosed in the 1992 patent. The patent carriers on to list examples of such carriers as being glyceryl triacetate (Triacetin) distilled acetylated monoglycerides (Myvacet), miglyol 812, safflower oil and the like, or a combination of such carriers. It is clear from the words used " and the like" that any carrier can be used in the formulation of the 1992 patent. The 1992 patent teaches the use of a single hydrophobic carrier, namely Triacetin, and does not disclose any particular combination of hydrophobic carriers. In support of this submission, claim 12 has been referred to in that it is specifically limited to Triacetin. It is contended that the 1992 patent considered that Triacetin, alone, constituted the preferred hydrophobic carrier for the

triacetin, benzyl benzoate or ethyl oleate or a combination thereof; and on the other hand, acetylated monoglycerides, propyl dicaprylates/ dicaprates, caprylic/ capric acid triglycerides or a combination thereof. The particular combinations of specific hydrophobic carriers claimed in the patent have not been specifically identified in the prior art. All what the 1992 patent teaches is that the skilled person can use any hydrophobic carrier in which avermectin is soluble.

[19] He further submitted that while particular specific examples are given in the 1992 patent, there is no suggestion or teaching that any of them, have any utility or advantage over other hydrophobic carriers or combinations of carriers. Save for the throw- away reference to these hydrophobic carries (which, interestingly, was deleted in the patent as it was granted) there is no teaching at all in relation to the properties or benefits of these carriers in a formulation containing avermectin. The teaching of the 1992 patent is, therefore of the sort which can be described as "purely intellectual content" and which does not amount to a teaching of the "technical action" which was later achieved using the specific combinations of hydrophobic carriers disclosed in the patent in suit. The 1992 patent teaches that the formulation of that patent will be efficacious up to 42 days. By contrast, by using the specific combinations of hydrophobic carriers of the patent in suit, efficacy of up to 180 days can be achieved. There is no teaching of the very significant advantage ("technical action) which arise from this longer duration of activity in practice and which are obtained through the use of the particular hydrophobic carriers disclosed in the patent in suit. 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 1992 patent and his or her "general technical knowledge". Instead the skilled person would (even armed with the 1992 patent and with the significant knowledge that the Merck scientists had regarding the active pharmaceutical ingredient) have to apply 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 signification technical advance which those specific combinations represent over the disclosure of the 1992 patent.

[20] As regards the submission by the applicant's Counsel that the expert witnesses of the respondents cannot be regarded as independent for the reason that one was employed by the respondent (Merck Sharpe & Dohme) and the other was employed at the laboratory where the 1998 patent was conceived, the respondents submitted that that

argument was absurd and referred to a number cases where such expert witnesses who were former parties' employees' evidence was preferred as against that of the independent expert witnesses.

[21] It is important to note that the meaning to be given to a claim, and whether the claim has been anticipated by prior disclosure, are not matters for expert opinion, but are matters for the court to decide, albeit that a court, in deciding those questions will often need to be guided by experts on the state of the art (Gentiruco AG v Firestone SA (Pty) Ltd referred to *supra)*. It is therefore immaterial whether the expert evidence is that of an independent witness or whatsoever, but at the end of the day the decision lies with the court. The argument by the applicant has therefore no merit in this regard.

[22] It is clear that the formulation of claim1 of the 1998 patent specification as referred to in para 5 *supra* includes the combination of hydrogenated castor oil, a parasiticide (avermectin) in solution in a hydrophobic carrier consisting of triacetin and acetylated monoglycerides.

[23] The 1992 patent discloses a long acting injectable formulation which comprises of:- a hydrogenated castor oil; the avermectin compound (parasticide); in a hydrophobic physiologically acceptable solvent comprising in combination: glyceryl triacetate (Tricetin); or distilled acetylated monoglycerides (Myvacet); or a combination of such carriers.

[24] The formulation referred to above in para 22 *supra* for the 1998 patent is expressly disclosed in the 1992 specification referred to in para 23 *supra.*

[25] I do not agree that there is no limitation in the 1992 patent as to the hydrophobic carrier which is to be used in the formulation of that patent. Reference is also made to both triacetin and acetylated monoglyceride in the 1992 specification as possible carriers that could be used. It can therefore not be said that the 1992 patent teaches that the most preferable formulation is one which includes only triacetin as the hydrophobic carrier in the formulation while the other carriers, e.g., acetylated monoglycerides, miglyol 812, safflower seed oil or mixtures thereof are also mentioned.

[26] It is therefore my view after comparing the 1992 and 1998 specifcations that the 1992 patent describes the essential integers in such a way that the same or substantially

the same; process is identifiable and made known. I agree that the formulations set out in the 1998 patent are nothing more than a repetition of the disclosure in the 1992 patent. For the reasons advanced above claims 1 to 29 of 1998 patent are invalid and fall to be revoked. Claims 1 to 29 of the 1998 patent are therefore anticipated in the 1992 patent. The 1998 patent fails to comply with section 25 of the Act.

[27] In the result I make the following order:

27.1 The application succeeds with costs including the costs of two counsels.

TEFFO J
JUDGE OF THE NORTH
GAUTENG HIGH COURT

COUNSELS FOR THE APPLICANT	:	CEDRIC PUCKRIN SC & MARK SEALE
INSTRUCTED BY	:	BRIAN BACON & ASSOCIATES INC
COUNSELS FOR THE RESPONDENT	:	LIONEL BOWMAN SC & GAVIN MARRIOT
INSTRUCTED BY	:	DM KISCH INC