THE SUPREME COURT OF APPEAL OF SOUTH AFRICA

JUDGMENT

Reportable

Case No: 20772/2014

In the matter between:

MERIAL	**FIRST APPELLANT**
MERIAL LIMITED	**SECOND APPELLANT**
MERIAL SOUTH AFRICA (PTY) LTD	**THIRD APPELLANT**

and

CIPLA VET (PTY) LTD	**RESPONDENT**

Neutral Citation: *Merial v Cipla Vet* (20772/2014) [2016] ZASCA 57 (1 April 2016).

Coram: Navsa ADP, Leach, Petse & Dambuza JJA and Kathree-Setiloane AJA

Heard: 8 March 2016

Delivered: 1 April 2016

Summary: **Patents** – Validity – certainty of claim – compound consisting of a number of ingredients, each fulfilling a specific function – combination of potential ingredients to be selected accordingly – crystallisation inhibitor test to determine whether crystallisation inhibitor within scope of claim – whether dual functions of potential ingredients impact on clarity – interpretation of patent a process of construction by a mind willing to understand, not deconstruction by a mind desirous of

misunderstanding – skilled addressee capable of understanding ambit of claim, and only real challenge to clarity based on contrived or ‘mythical’ hypotheticals – patent not invalid for lack of clarity – infringement – held to have been proved.

ORDER

On appeal from: The Court of the Commissioner of Patents (Murphy J sitting as court of first instance).

The following order is made:

1. The appeal is upheld with costs including the costs of two counsel.
2. The order of the court below is set aside and substituted as follows:
    ‘1. The defendant is interdicted and restrained from infringing claims 1, 2, 3, 7 to 15 and 18 to 20 of the patent.
    2. The defendant is ordered to deliver up to the plaintiffs all infringing Fiprotec products in its possession or under its control.
    3. An inquiry is ordered in relation to the damages suffered by the plaintiffs as a consequence of the infringement of the patent by the defendant alternatively an inquiry into the reasonable royalty to which the plaintiffs are entitled.
    4. In the event of the parties being unable to reach an agreement as to the further pleadings to be filed, discovery, inspection or other matters of procedure relating to the inquiry, an order authorising any one of the parties to make application to the court for directions in regard thereto.
    5. Each of the claims referred to in para 1 above of South African Patent Number 1996/8057 is certified as being valid in terms of section 74 of the Patents Act 57 of 1978.
    6. The defendant is ordered to pay the plaintiffs’ costs of suit, including the costs of two counsel and the qualifying fees of the plaintiffs’ expert witnesses.’

JUDGMENT

Navsa ADP (Leach, Petse & Dambuza JJA and Kathree-Setiloane AJA concurring):

[1] This appeal concerns the correctness of the finding of the Court of the Commissioner of Patents (Murphy J) that the respondent, Cipla Vet (Pty) Ltd (Cipla), a South African company, did not infringe Patent No. 96/8057, entitled '*Anti-parasitic composition for the treatment and protection of pets*'. The first appellant, Merial, a company incorporated in France is the patentee and the second and third appellants, Merial Limited, a company incorporated in the UK, and Merial South Africa (Pty) Ltd, are licencees. The Commissioner held that the appellants had failed to discharge the onus upon them of proving that Cipla had infringed, and was continuing to infringe, claims 1, 2, 3, 7 to 15 and 18 to 20 of the patent. The Commissioner, however, also dismissed various other grounds of defence raised by Cipla in relation to the validity of the patent. I shall, in due course, allude to those. The appeal is before us with the leave of the Court below.

[2] Cipla has since 2008 made, used, sold, offered for sale and imported a composition in the form of a ready-to-use solution for the treatment and protection of domestic animals which are infested with parasites or are likely to be infested with them, under the trade mark 'Fiprotec', and continues to make, use, exercise, dispose or offer to dispose of and import the Fiprotec composition. Merial and the other appellants alleged that Cipla's conduct infringed the claims of the patent referred to in the preceding paragraph and that as a result of the infringement they have suffered damages in amounts which they are at present unable to quantify. In the event of their establishing infringement, the appellants sought an order that Cipla deliver up to them all infringing Fiprotec products in its possession and an order directing an inquiry into the damages suffered by the appellants as a consequence of the infringement.

[3] Like Merial's product, 'Frontline', which Cipla is accused of infringing, Fiprotec is a 'spot-on' composition used in the treatment and protection of domestic animals. The term 'spot-on' refers to a product which is applied locally to a limited area of the body of the animal but which, it is asserted, is effective over the entire body of the animal. The

specification of the patent in suit states that the invention relates to a composition for the treatment and protection of animals such as cats and dogs, which are infested with parasites such as fleas, ticks and galls.

[4] In response to Merial's claim of infringement in the court below, Cipla not only denied the infringement but challenged the validity of the patent on several grounds. Cipla did not, however, counterclaim for revocation of the patent as it was entitled to, in terms of s 65(4) of the Patents Act 57 of 1978 (the Act).[1] In challenging the validity of the patent Cipla raised its lack of clarity, insufficiency and inutility.

[5] All the claims listed above, other than claim 1, are dependant claims. As recorded by the court below, it was agreed by the parties that in the event of Merial having established an infringement of claim 1, it would be entitled to the relief claimed.

[6] Claim 1 of the patent reads as follows:

'Composition which is useful in particular for the treatment and protection of domestic animals which are infested with parasites or are likely to be infested with them, these compositions comprising in the form of a ready-to-use solution:

(a) 1-[4CF_3 2,6-Cl_2phenyl] 3-cyano 4-[CF_3-SO] 5-NH_2 pyrazole (hereinafter referred to as "fipronil");

(b) a crystallization inhibitor which satisfies the test according to which:

0.3ml of a solution A comprising 10% (W/V) of fipronil in the solvent defined in (c) below, and 10% of this inhibitor, are placed on a glass slide at 20°C for 24 hours, after which fewer than 10 crystals, preferably 0 crystals, are seen with the naked eye on the glass slide;

(c) an organic solvent having a dielectric constant of between 10 and 35, preferably of between 20 and 30;

(d) an organic co-solvent which is a drying promoter, having a boiling point below 100°C, preferably below 80°C, and a dielectric constant of between 10 and 40, preferably of between 20 and 30,

[1] That subsection provides:
'In any proceedings for infringement the defendant may counterclaim for the revocation of the patent and, by way of defence, rely upon any ground on which a patent may be revoked.'

wherein fipronil is present in a proportion of from 1 to 20% W/V in the composition.'

[7] As can be seen, claim 1 postulates a composition which includes four constituents, namely, fipronil, a solvent, a co-solvent and significantly for the invention, a crystallisation inhibitor. In relation to the last-mentioned the specification states the following:

'Yet another object of the invention is to provide such compositions which, when applied locally, will subsequently diffuse over the animal's entire body and then dry, while at the same time avoiding any phenomenon of crystallisation as far as possible.

Yet another object of the invention is to provide such compositions which, after drying, do not affect the appearance of the coat and in particular do not leave crystals and do not make the coat sticky.'

Fipronil itself was known at the priority date of the patent and appears to have been first used as an insecticide in crop science. It was also used in relation to parasites living externally on animals. So, the invention does not relate per se to the use of fipronil together with a solvent for topical applications on animals. What is claimed to be the invention is a composition which will minimize the phenomenon of crystallisation appearing on the skin of domestic animals such as dogs and cats. Simply put, the crystallisation inhibitor was intended to combat negative effects in relation to the possible appearance of crystals on the animal's coat.

[8] Importantly, claim 1, by virtue of integer b) provides a test to determine which constituents or combination of constituents, will result in a crystallisation inhibitor within the scope of the claim. The test requires that a solution be prepared containing (i) 10% (w/v)[2] of fipronil; and (ii) 10% of the crystallisation inhibitor of the allegedly infringing formulation (iii) both dissolved in the solvent present in the formulation in question. From this solution, 0.3ml is placed on a glass slide at 20°C for 24 hours. If, after 24 hours, fewer than 10 crystals are visible to the naked eye on the glass slide, then it follows that the crystallisation inhibitor will be within the scope of claim 1.

[2] W/v is an abbreviation for 'weight per volume'.

[9] The specification provides guidance on which types of solvents, co-solvents and crystallisation inhibitors are suitable for the claimed fipronil formulations. In this regard, the specification also provides preferred lists of chemicals for constituents of the formulation. Thus, the specification provides a list of potential and preferred organic solvents which may be used in preparations in accordance with the invention of the patent.

[10] It is important, both in relation to Cipla's challenge of invalidity on the basis of lack of clarity *and* the appellants' assertion of infringement by Cipla, to have regard to the detail of the patent specification concerning the preferred organic solvents, co-solvents and crystallization inhibitors. The following appears:

'As organic solvent c) which can be used in the invention, mention may be made in particular of: acetone, acetonitrile, benzyl alcohol, butyl diglycol, dimethylacetamide, dimethylformamide, dipropylene glycol n-butyl ether, ethanol, isopropanol, methanol, ethylene glycol monoethyl ether, ethylene glycol monomethyl ether, monomethylacetamide, dipropylene glycol monomethyl ether, liquid polyoxyethylene glycols, propylene glycol, 2-pyrrolidone, in particular N-methylpyrrolidone, diethylene glycol monoethyl ether, ethylene glycol, diethyl phthalate, or a mixture of at least two of these solvents.

The preferred solvents c) are the glycol ethers, in particular diethylene glycol monoethyl ether and dipropylene glycol monomethyl ether.

As crystallization inhibitor b) which can be used in the invention, mention may be made in particular of:

- polyvinylpyrrolidone, polyvinyl alcohols, copolymers of vinyl acetate and vinylpyrrolidone, polyethylene glycols, benzyl alcohol, mannitol, glycerol, sorbitol, polyoxyethylenated sorbitan esters; lecithin, sodium carboxymethylcellulose; acrylic derivatives such as methacrylates and the like. . . .' (my emphasis.)

[11] What follows in the specification as potential crystallisation inhibitors are lists of anionic surfactants,[3] cationic surfactants, amine salts, non-ionic surfactants and

[3] In *Chambers Dictionary of Science and Technology* (1974) 'surfactant' is explained as follows:
'An abbreviate form of *surface active agent*, ie a substance which has the effect of altering the interfacial tension of water and other liquids or solids, eg detergent or soap.'

amphoteric surfactants. It ends with the statement ‘or preferably a mixture of two of these crystallisation inhibitors’. The specification goes on to note the following:

‘In a particularly preferred manner, use will be made of a crystallisation inhibitor system, namely the combination of a film-forming agent of polymer type and a surfactant. These agents will be chosen in particular from the compounds mentioned as crystallisation inhibitor b).

Among the film-forming agents of polymer type, which are particularly advantageous, mention may be made of:

- the various grades of polyvinylpyrrolidone,
- polyvinyl alcohols, and
- copolymers of vinyl acetate and vinylpyrrolidone.

As regards the surfactants, mention will be made most particularly of non-ionic surfactants, preferably polyoxethylenated sorbitan esters and in particular the various grades of polysorbate, for example polysorbate 80.

The film-forming agent and the surfactant may in particular be incorporated in similar or identical amounts within the limit of the total amounts of crystallisation inhibitor which are mentioned elsewhere.’

[12] As can be seen (and as I have emphasised in the quote above) the potential organic solvents include propylene glycol (PG) and diethylene glycol monoethyl ether (DGME) (which is sold by one company under the trademark Transcutol® and is often referred to as such). The preferred organic solvents are said to be the glycol ethers, in particular DGME (and dipropylene glycol monomethyl ether (DPGMME)). The patent teaches that these solvents can be used on their own or as a mixture of at least two of the listed solvents.

[13] In respect of the co-solvent, the patent teaches that ethanol, isopropanol and methanol are suitable for use in the composition of the invention. The patent teaches that the organic co-solvent must be, in addition to being a co-solvent, a drying promoter. In simple terms, therefore, the co-solvent, being a ‘drying promoter’, ensures that the formulation does not remain ‘wet’ on the animal’s skin and elsewhere for a prolonged period. In line with this, claim 1 of the patent provides that the co-solvent must be a drying promoter and must have a boiling point below 100°C, preferably below 80°C.

[14] When what is set out in the preceding paragraphs is scrutinised, one will see that an item that appears as a contemplated organic solvent, is also envisaged as a crystallisation inhibitor. So, for example a preferred organic solvent in relation to integer b) is benzyl alcohol, which may also be a crystallization inhibitor. There is also an overlap between the items listed as potential solvents in terms of integer c) and the co-solvents in terms of integer d). In particular, the specification states that ethanol, isopropanol and methanol may be used as solvents in relation to integer c), all of which may also be used as co-solvents in relation to integer d).

[15] Further, as can be seen from what is set out above, the specification lists a number of potential crystallisation inhibitors, including several film forming agents of polymer type, and several surfactants. The list ends with the statement that the crystallisation inhibitor (ie. that of claim 1) should 'preferably [be] a mixture of at least two of these crystallization inhibitors'. The specification further explains that, in a particularly preferred embodiment of the invention, use will be made of a crystallisation inhibitor system, namely the combination of a film-forming agent of polymer type and a surfactant (the subject of claim 11). The specification identifies certain 'particularly advantageous' film forming polymers (including polyvinylpyrrolidone (PVP)) and surfactants (including Polysorbate 80/Tween 80[4]) which may be included in the composition of claim 1.

[16] Simply put, some of the contemplated constituent parts of the formulation envisaged in claim 1 may serve dual functionalities. It is those dual and interchangeable roles that Cipla finds objectionable. More will be said about this later.

[17] To enable a proper appreciation of the issues and the evidence discussed hereafter it is necessary, at this stage, to have regard to the constituent parts of Fiprotec. In Cipla's plea, it admitted that Fiprotec has the ingredients set out hereafter. Professor Barbour's expert summary indicated the relative weights or volumes of the

[4] Tween 80 appears to be a trade name.

ingredients. Para 11 of the judgment of the court below noted the constituent parts of Fiprotec. The list that appears hereunder contains that list together with the relative value:

(a) 9,7 % fipronil;

(b) 50 % diethylene glycol monoethyl ether (DGME);

(c) 27,7 % propylene glycol (PG);

(d) 1,40 % polyvinylpyrrolidone (PVP) which is a polymeric film-forming agent;

(e) 1 % polysorbate 80 (Tween 80) which is a non-ionic surfactant;

(f) 10 % ethanol; and

(g) 0,10 % butylated hydroxyanesole and 0,10% butylated hydroxytoluene which are antioxidants, as contemplated in claims 7, 8 and 19.

All of these ingredients are specifically mentioned as preferred ingredients in the patent in suit, albeit sometimes in alternate functions. However, Cipla denied that ethanol was a co-solvent in its Fiprotec product as envisaged in integer d). It did not accept that the mixture of DGME and PG served the function of the organic solvent provided for in integer c) of claim 1. It was also not accepted that polyvinylpyrrolidone and the polysorbate 80 operated together as crystallisation inhibitors within the meaning of integer b) of claim 1.

[18] Much of the proceedings in the court below involved evidence in relation to the integer b) test of claim 1. Both parties adduced evidence by respective experts in relation to the crystallisation inhibitor test set out in integer b). The experts reached opposite conclusions. Merial's expert, Dr Witchey-Lakshmanan (Dr Witchey) testified that she had successfully conducted the test set out in integer b). She concluded that the constituent parts of Fiprotec matched those of the patent and that Fiprotec satisfied the crystallization inhibitor test. As set out in the expert summary of Dr Witchey, she determined by way of integer b) 'that the use of the PVP and Tween 80 in a ratio of 1,4 to 1[5] as a crystallisation inhibitor in the crystallisation inhibitor test of claim 1 results in fewer than 10 crystals being seen with the naked eye on the glass slide used in the test'. Professor Barbour who testified on behalf of Cipla stated that he had conducted an

[5] The ratio appears from what is set out in the preceding paragraph.

experiment in line with integer b) using the actual ingredients of Fiprotec and that it had failed the crystallisation inhibitor test. He stated that when he conducted experiments using the method spelt out in the integer b) test, it resulted in heavy crystallisation beyond the parameters of that test.

[19] At this stage, it is important to note that the ingredients used by Dr Witchey to conduct the integer b) test were supplied by Merial and not by Cipla, and so were not the exact same components as those used in the manufacture of Fiprotec, more especially from Cipla's perspective, the fipronil. However, Dr Witchey, in conducting the integer b) test used the same concentrations of fipronil as employed by Professor Barbour. This aspect on which Cipla relied in challenging the validity of Dr Witchey's integer b) test will be discussed in due course. It is an aspect which the court below considered significant in holding that the appellants had failed to prove infringement.

[20] Whilst being critical of the test conducted by Professor Barbour, the court below reasoned and concluded as follows (para 55):

'55. The evidence of [Cipla] therefore does not conclusively establish that Fiprotec does *not* include a crystallization inhibitor that satisfies the test in integer b). But that does not resolve the question of infringement. The onus is on [Merial] to establish positively, on a balance of probabilities, that Fiprotec does indeed include a crystallization inhibitor that satisfies the test in integer b). The weaknesses in [Cipla's] case is not to my mind sufficient to warrant an inference that the combination of PVP K30 and Polysorbate 80 in a ratio of 1,4:1 (mixed in a solution of DGME, PG and/or ethanol) will operate to inhibit fipronil sourced from "GSP crop science" [the supplier to Cipla] from producing fewer than 10 crystals. There is no reliable test before me which adequately demonstrates that fact. [Merial's] evidence shows that the Fiprotec crystallization inhibitor system will achieve that result in relation to fipronil produced and/or supplied by Merial. Neither that fact nor the flawed results of the tests of the defendant provide sufficient evidence to conclude on the probabilities that the crystallization inhibitor system in Fiprotec achieves the same result in relation to the fipronil used in Fiprotec supplied by GSP. A test on the constituents of the patented product does not prove the constituents of the alleged infringing product actually infringe. To my mind it is impermissible, from the perspective of logic and fairness, to infer that because the crystallization inhibitor proved successful in inhibiting the Merial fipronil from producing crystals that it has equal success in so inhibiting the fipronil in

Fiprotec. The evidence is insufficient to reach that conclusion. While the different polymorphs[6] of fipronil may be insignificant once in solution, their existence in different polymorphic form points to different manufacturing processes that may or may not account for impurities which could impact upon the process of crystallization. Whether that is or is not so can only be established once the actual ingredients in Fiprotec have been subjected to a reliable integer b) test – something which has not happened in this case.

[21] The court below thus held that the appellants had failed to discharge the onus upon them to prove that Fiprotec infringes claim 1 of the patent.[7] Nevertheless, the court went on to discuss the other defences pleaded by Cipla.

[22] In dealing with Cipla's challenge to the validity of the patent on the basis of lack of certainty, the court below said the following (para 85):

'85. The lack of clarity attack, however, evolved somewhat during evidence and argument. A further contention was made that the claims lack clarity because the same chemical can serve different functions in the composition of claim 1 of the patent. In particular, benzyl alcohol can serve as the organic solvent in integer c) as well as being the crystallization inhibiter in integer b). Also, ethanol and isopropanol can serve as a solvent in integer c) and as the co-solvent in integer d). As mentioned earlier, this prompted counsel for the defendant to argue that the patent is unclear because "the skilled addressee is left to hazard a guess as to whether any particular composition may constitute an infringement".'

[23] On this aspect Murphy J concluded as follows (paras 86 – 87):

'86. I agree . . . that this attack goes to the issue of insufficiency not clarity in that it essentially alleges that the specification does not sufficiently describe the manner in which the invention is to be performed in order to enable the invention to be carried out by a person skilled in the art of the invention. The attack is not directed at the wording of claim 1. And, in any event, to the extent that any clarity issue arises on this basis it was never pleaded by the defendant and hence I am disinclined to entertain it.

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[6] Polymorphism is the property possessed by certain chemical compounds of crystallising in several forms which are structurally distinct. See *Chambers Dictionary* supra.
Professor Barbour explained the concept as follows:
'. . . [I]t is different crystalline forms of the same compound . . . the chemical bonding is different.'

[7] Para 57 of the judgment.

87. In consequence, the defendant has made out no case of lack of clarity upon which it may rely as a defence to the action for infringement.'

[24] The appellants, with the leave of the court below, appealed against the finding that they had failed to discharge the onus on them of proving that Cipla had infringed claims 1, 2, 3, 7 to 15 and 18 to 20 of the patent in suit and the consequent order dismissing the matter with costs, including the costs of two counsel. Murphy J had also rejected the defences raised by Cipla, set out in para 4 above. Before us Cipla's sole challenge to the validity of the patent was restricted to one based on a lack of clarity. Thus, in particular, it is worth noting that the defence of insufficiency was not persisted in. Since a decision in Cipla's favour on the clarity point would be dispositive of the appeal, it is to that issue that I now turn.

[25] It was submitted on behalf of Merial that this court should refuse to entertain an appeal on the clarity point, since it had not been properly pleaded as a ground of challenge by Cipla. An examination of the plea reveals that the attack based on lack of clarity was limited and related to the meaning of the words 'solvent', 'co-solvent', 'crystallization inhibitor' and 'fewer than 10 crystals, preferably 0 crystals, are seen with the naked eye'. Furthermore, it was pleaded that the crystallisation inhibitor test was not clear in that the objective physical results of that test may vary depending on the conditions under which the test is conducted, and that the observed results of that test may vary depending on the observer and the conditions under which they were observed. As can be seen, the ambit of Cipla's pleaded challenge to the validity of the patent was limited. Murphy J was correct, as noted above, when he recorded that the lack of clarity attack evolved during evidence and argument, and that in essence it was ultimately contended that the lack of clarity was brought about because of the dual role of constituent materials.[8] There is also some force in the submission on behalf of Merial that the attack on the validity of the patent as pleaded, more properly resides under the ground of insufficiency, ie on the basis that the complete specification does not fully describe and ascertain the invention and, where necessary, illustrate or exemplify the

[8] Para 85 of the judgment in the court below.

invention and the manner in which it is to be performed.[9] However, the question of the lack of clarity of the patent *was* explored fairly extensively when evidence was adduced in the court below and, in my view, consideration should therefore be given to Cipla's submissions on this aspect.

[26] Before dealing with Cipla's submissions and considering whether they have any merit, it is necessary to remind ourselves of what a patent represents, and why the monopoly claimed by way of the patent, has to be clearly and succinctly defined. In *Colgate-Palmolive Co v Unilever Ltd* 1981 BP 121 (CP) at 124F-125F, Nicholas J said the following:

'[A] patent represents a *quid pro quo* as it was aptly put by *Viscount Dunedin in Pope Alliance Corporation v Spanish River Pulp and Paper Mills Limited* [[1929] AC 46 RPC 23]. The *quid* is the monopoly conferred upon the patentee for a number of years; see sec 28(1) and 32 of the Act. The *quo* is the new knowledge which he presents 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 opened. As regards the claim, the legislature obviously intended that the monopoly must clearly and succinctly define the limits of the field closed to others, so that he who runs may read. As it was put by Galgut, J in *Transvaal and OFS Chamber of Mines v Hukki* [1964 BP 1 (T) at 212C-D]:

"The public who uses this art, the persons trained in the art, should not be left to hazard any guess as to what the forbidden field is."' (footnotes omitted.)

[27] It is necessary to consider the required degree of sufficiency and clarity of the claims of a patent. In T D Burrell *Burrell's South African Patent and Design Law* 3 ed (1999) para 4.37 at 197, the learned author, in dealing with the degree of clarity

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[9] See section 61(1)*(e)*(i) of the Act as a ground on which a patent may be revoked. It is well established that a challenge on the basis of insufficiency differs from that of a lack of clarity. The main ground of distinction is that the attack on lack of clarity is directed to the claims and not to the body of the specification, whereas in dealing with an objection based on insufficiency the whole specification must be considered. Essentially, the body of the specification (which goes to sufficiency) teaches how the invention works and/or how to operate it, while the claim (which goes to clarity) defines the limits of the monopoly claimed for the duration of the patent. Nevertheless, the evidence on lack of clarity may overlap with that on the question of insufficiency.See T D Burrell *Burrell's South African Patent and Design Law* 3 ed (1999) para 4.36 at 196 and the authorities there cited.

required, states that what is needed is ‘reasonable certainty’. He goes on to note, with reference, inter alia, to *Letraset Ltd v Helios Ltd* 1972 BP 243 (A) at 247D-E and *De Beers Industrial Diamond Division (Pty) Ltd v General Electric Company* [1988] ZASCA 82; 1988 BP 124 (A) at 142C, that ‘[a]bsolutism does not perch happily upon the banner of our law’. There is, however, a statutory obligation on a patentee to state in the claims clearly and distinctly what the invention is which it desires to protect.[10]

[28] Construing the meaning of the claims of the patent in the context of the rest of the specification is the first task the court must undertake. This was stated in *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 613F-H. At 614B of that case, which is still the leading case on the construction of patent specifications, the following appears:

‘Consequently, 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 his intention was as conveyed by the specification, properly construed . . . .’

[29] It was submitted on behalf of Cipla that when the words ‘solvent’, ‘co-solvent’ and ‘crystallisation inhibitor’ are read in conjunction with the body of the specification ‘great uncertainty arises’. The following appears in heads of argument on behalf of Cipla:

‘[W]hen read in the context of the specification, it is not possible from the meanings of these terms to determine the allocation of individual ingredients amongst the categories designated by the impugned terms, thus making it impossible to determine a definitive solution A, and thus perform the test for infringement.’

In short, it was submitted on behalf of Cipla that a contextual interpretation of the claims of the patent exhibits a glaring uncertainty. Cipla contended that when, in addition, regard is had to the evidence of Professor Barbour that the effect of the interchangeable roles of the constituent elements of the formulation is confusing, its case on this aspect was overwhelming.

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[10] See *Power Steel Construction Co (Pty) Ltd v African Batignolles Construction (Pty) Ltd* 1955 BP 155 (A) at 162.

[30] It was not suggested that the meaning of each of the words ‘solvent’, ‘co-solvent’, ‘crystallization inhibitor’ is unclear in the abstract. As recorded in para 82 of the judgment of the court below, those words have ordinary meanings. What was postulated on behalf of Cipla was that viewed contextually, more particularly in relation to the duality and inter-changeability of functions set out in the body of the specification, uncertainty unfolds.

[31] A reading of claim 1, in conjunction with the parts of the specification referred to above, does not, at least superficially, present any problems of comprehension. It is easy enough to understand the meaning of the words referred to above. Furthermore, as set out in para 7 above, when regard is had to claim 1 it is not difficult to understand that it postulates a composition which includes four constituents, namely fipronil, a solvent, a co-solvent and a crystallisation inhibitor. When the material parts of the specification on which Cipla relies are considered, one can see that some of the constituent parts may be used interchangeably, in combination, and can serve more than one constituent function. The question is whether it presents uncertainty from the perspective of the skilled addressee and in this regard the evidence of the respective experts is of assistance.

[32] As set out in para 29 above, Cipla placed reliance on the evidence of Professor Barbour. In addition, Cipla pointed to the difficulties allegedly experienced by Dr Witchey when she was confronted with hypothetical formulations which, so it was submitted, demonstrated that the patent was unclear. Reliance was placed on the evidence of Professor Barbour in relation to the alleged lack of clarity of the formulation in question, despite the limited field of his experience, namely, crystallography. In this regard, Cipla placed reliance on Dr Witchey’s acceptance that Professor Barbour was qualified to perform the crystallisation inhibitor test. Whilst it is true that Dr Witchey conceded that the patent is addressed to a team of professionals, as recorded by the court below, and that Professor Barbour was qualified to perform the crystallisation inhibitor test, she did not concede Professor Barbour’s expertise as a formulation scientist. Dr Witchey testified that the skilled addressee would constitute a professional team, including a

veterinary parasitologist and a formulation scientist. It is beyond doubt that Dr Witchey was a person skilled in the field of the invention of the patent with special knowledge in the area of formulating veterinary compositions for topical applications. She is a skilled formulation chemist whilst Professor Barbour is not. I shall deal with her evidence first and then consider whether Cipla's reliance on Professor Barbour's evidence is justified.

[33] Dr Witchey confirmed what appeared in her expert summary, namely, that the term 'co-solvent' is a chemical term referring to a solvent that is used in conjunction with another solvent to dissolve a solute and that co-solvent systems are routinely used in chemical and formulation systems. A co-solvent is simply a second solvent.

[34] Significantly, Dr Witchey testified that the patent presents the use of a variety of solvents, co-solvents and crystallisation inhibitors and that from the viewpoint of a formulator this was fairly typical. She went on to state:

'The lists of these materials are not overwhelming to a formulator because a formulator is used to these types of chemicals.'

Dr Witchey read claim 1 of the patent as comprising a formulation having four constituent elements and thus four areas of functionality. First, there is the active ingredient, fipronil. Second, a solvent is required; third, an additional solvent, which has to be a drying agent; and, fourthly and significantly, a crystallisation inhibitor.

[35] Later in her testimony Dr Witchey stated:

'. . . [A]s I have mentioned formulators will try to formulate with complements having multiple functions and so it does not bother me that a co-solvent and a solvent could be the same thing.'

In relation to percentage content in relation to what appears in claim 1, Dr Witchey indicated that one would have regard to the function served by a particular element.

[36] As to the suggestion that a formulator would, in relation to the teaching of the patent, be faced with an infinite number of permutations from an infinite number of ingredients, Dr Witchey responded by stating that one would look at the function of a particular ingredient and follow the teachings of the patent and would not include an

ingredient that does not serve the function that is required. Simply put, you would look at what the formula required and then select ingredients that would fulfil a particular function. It is necessary to repeat that the fact that one material might have more than one function did not trouble Dr Witchey.

[37] Dr Witchey also considered whether there were attendant difficulties with the specification, stating that the contemplated organic solvent could be a mixture of at least two of them. The same applied to crystallisation inhibitors. Dr Witchey took the view that a skilled formulator would have no problem with a constituent part consisting of two materials fulfilling the same function. She reiterated that, in making a formula based on the patent or in deciding what would not infringe the patent, a skilled formulator would explore the functions of each of the constituent materials.

[38] It was put to Dr Witchey that in terms of the patent, benzyl alcohol was envisaged as a potential organic solvent as well as a crystallisation inhibitor. She agreed that there were potential dual functions of constituent ingredients. A document was presented to Dr Witchey, which in counsel for Cipla's own words contained 'mythical' compositions. The hypotheticals presented by these compositions were put to Dr Witchey. The document contained a composition in line with the constituents of Fiprotec and then variations, which were intended to show that it would not be possible, if one were to have a mixture of certain crystallisation inhibitors and solvents, to conduct the crystallisation inhibitor test. The argument was that, when faced with these 'mythical' compositions, a skilled addressee would not be able to objectively determine which ingredients fell under which integer, and therefore would not be able to determine which ingredients must be included in the crystallisation inhibitor test as the solvent (integer c)), and which must be excluded as the co-solvent (integer d)).

[39] When the constituent parts of the hypotheticals were put to Dr Witchey, she was 'confused why someone would formulate this product in this way'. She was referring here to the substantial number of contemplated excipients.[11] She went on to state:

[11] In *Chambers Dictionary* supra, 'excipient' is defined as:
'The inert ingredient in a medicine which makes up and holds together the other ingredients.'

‘If the ingredients are present in the formula they serve some function within the formula. If they do not serve that function you do not put them in . . . . So my first question in looking at the formula is, why the formula is what it is. It does not make sense to me completely as a formulator.’

She testified that the hypotheticals presented to her showed a naivety on the part of the formulator. When confronted with the teaching of the patent that benzyl alcohol can be used both as a solvent and as a crystallisation inhibitor and that this would present problems if one were to conduct the crystallisation inhibitor test to see if a product infringes, Dr Witchey stated that a formulator would work towards an understanding of what ‘mechanisms each [ingredient] provides . . . within the formulation and as such . . . try to make an assessment as to what the appropriate test would be.’ She testified as follows:

‘A formulator prepares a series of different formulas before they even get to the integer b) test, to try and understand how the solution, the drug, how all of that interacts, how it behaves . . . .’

Later, Dr Witchey stated:

‘So I would hope by the time the formulator gets to the point of sale of a product . . . the formulator has established in some kind of scientific sense . . . [how] to make a better assessment as to what would be a co-solvent, what would be a solvent, and what would be both.’

Dr Witchey testified that in regard to Fiprotec there could be no confusion as to its constituent parts and as to the function of each element. She testified that in Fiprotec ethanol is the co-solvent, integer d) and that is why it was not included in the crystallisation test for Fiprotec. She pointed out that this was accepted by the parties to the litigation. On this she was essentially unchallenged. This is an aspect to which I will revert later, when I deal with the question of infringement.

Wikipedia defines ‘excipient’ as:
‘An excipient is a natural or synthetic substance formulated alongside the active ingredient of a medication, included for the purpose of long-term stabilization, bulking up solid formulations that contain potent active ingredients (thus often referred to as "bulking agents," "fillers," or "diluents"), or to confer a therapeutic enhancement on the active ingredient in the final dosage form, such as facilitating drug absorption, reducing viscosity, or enhancing solubility.’ Available at: *https://en.wikipedia.org/wiki/Excipient* accessed 30 March 2016.

[40] In explaining how to decide what functionality to ascribe to an ingredient and more particularly, determining what is to be a solvent and what is to be a co-solvent Dr Witchey said the following:

‘A person does not work in a vacuum. A person works to a systematic scientific method that offers that understanding and that is what I am trying to say about the function of the materials.’

[41] Dr Witchey went on to explain, in relation to claim 1, that the first information which a formulator would obtain would be the solubility of fipronil in the particular constituents. She postulated that there would be no problem with the solvent and insofar as the co-solvent was concerned, it was a solvent with a boiling point below 100°C and a dielectric constant between 10 and 40 which would serve as a drying promoter. As can be seen from the evidence of Dr Witchey a skilled formulator would have no difficulty in understanding the parameters of claim 1 and more particularly integer b).

[42] I now turn to the evidence of Professor Barbour. It is necessary to record that his expert summary, not unsurprisingly, given the initially limited nature of Cipla’s plea in relation to the patent’s alleged lack of clarity (referred to in para 22 above), does not deal with the multifunctional role of constituent elements of the formula as presenting a problem other than rendering the meaning of the words ‘solvent’ ‘co-solvent’ and crystallisation inhibitor” unclear. It undoubtedly did not deal with the propositions put to Dr Witchey or with the ‘mythical’ formulations presented to her. Professor Barbour’s limited area of expertise, referred to above, might well be an additional explanation for this omission in his expert summary.

[43] During his testimony in-chief, Professor Barbour stated that he found the various combinations and multiple potential functions of substances confusing. His testimony in this regard was brief. The ‘mythical’ permutations presented to Dr Witchey were never put to Professor Barbour. Under cross-examination, Professor Barbour appeared to limit his criticism in respect of the lack of clarity of the patent to the multiple possible identities of ingredients. Under cross-examination he was asked:

‘Where is the lack of clarity?’

His response was as follows:

‘The lack of clarity is in identifying a particular component listed as an example, that could be either part of the solvent or part of the crystallisation inhibitor or both.’

Professor Barbour was asked what he identified as a problem in relation to the crystallisation inhibitor test and his response is not entirely clear. He conceded that the simple procedure for conducting the integer b) test was not ambiguous but went on to state:

‘So the identification of the compounds that have to be used to make the formulation, in other words to formulate the test, I have already said could be ambiguous in terms of the identification of which has which identity and making the solution and dispensing a drop. That is the easy part. And then at the end, making an observation and making a judgment about whether things are crystals or not crystals and so on, and then whether they should be counted and whether it should be nine or ten, I believe that is somewhat unscientific and ambiguous also in terms of what you count as a crystal.’

[44] Professor Barbour was cross-examined further about his confusion concerning the dual identities of certain elements, more particularly in relation to the integer b) test. He stated that his problem was the dual identity of, for example, ethanol - being described both as a solvent and a co-solvent:

‘Let me elaborate on that. If ethanol is both the solvent and the co-solvent, what do we take from that? That means that some of the ethanol is the solvent and some of it is the co-solvent, So in other words, is it 60% of the ethanol is the solvent and 40% is the co-solvent?’

Referred to the specifics of the integer b) test Professor Barbour accepted that the problem did not arise in relation to it. He accepted that for the purpose of the test he would use ethanol as the solvent. In a subsequent exchange with counsel on behalf of the appellants, Professor Barbour once again suggested hypothetical difficulties that one might encounter with dual functionalities of constituent elements and the problems that might be encountered in attempting to identify constituent parts of a formulation.

[45] Cipla also relied on an affidavit by Professor Schuster, which was part of prior interdict proceedings. Dr Schuster appeared to have difficulty with the dual role of

ingredients. The content of that affidavit was put to Dr Witchey at the time that Cipla was pursuing the hypotheticals referred to above. According to the affidavit he had regard to the teaching of the patent that compounds like polyethelyne glycol can be the crystallisation inhibitor and also taught that PG and DGME can be solvents and that solvents can be used in combination. Thus the patent contemplated that combinations of PG and DGME can be present in a formulation of the invention. Counsel on behalf of Cipla put it to Dr Witchey that this presented a problem in relation to the integer b) test, namely, having DGME as crystallisation inhibitor but regarding ethanol either as a co-solvent on the one hand or as a solvent on the other and that the same would apply to isopropanol. Dr Witchey responded by stating that there was no basis to accept that Professor Schuster knew about the materials within Fiprotec at the time that the interdict was sought and there was no way of knowing what other information he had at his disposal. She stated the following:

'[L]et us say for the purposes of argument that DGME in this hypothetical formula also serves some function as a crystallisation inhibitor. You would not artificially remove, you would at least allow DGME to serve its other function as a solvent as well and that is not what is happening here.'

[46] Dr Witchey went on to state:

'As a formulator you try to understand what the functions are of each and try to apply your knowledge as best you can...[L]et us say for example that . . . fipronil were the active ingredient, PVP, benzyl alcohol and DGME were in fact the crystallisation inhibitor, ethanol and isopropanol were the co-solvents, what is left as the solvent? One has to address the solvent yet still. So certainly some assessment must be made to allow for a solvent but taking these step by step in this fashion gets to the point of not making sense to a formulator.'

Later she stated: 'I am saying that a formulator given this code, or a formulator having formulated, would have a better understanding of the functions or co-functions of each of these excipients'.

[47] Professor Schuster did not testify and we do not have the benefit of the content of his affidavit being subjected to further scrutiny. We are left to speculate about what was within his sphere of information.

[48] The alleged uncertainty in relation to observance by the naked eye of the number of crystals set as the outer limit of acceptability in terms of the crystallisation inhibitor test was, with good reason, not persisted in. As recorded by the court below Professor Barbour rightly conceded that he had no difficulty measuring the crystallisation when he conducted the integer b) test with ordinary vision which, in appropriate circumstances, could be corrected by spectacles and that the factors that might possibly impact on crystallisation could be controlled. As to variable environmental conditions that might impact crystallisation it appears to be uncontested that normal laboratory conditions would suffice. That part of Cipla's case was not persisted in before us.

[49] In *Integrated Mining Systems (Pty) Ltd v Chamber of Mines of South Africa* 1974 BP 281 (CP) at 310-311 the court said in relation to the assertion of insufficiency that courts will not find insufficiency simply because exceptional cases, or unlikely materials might come within the words of the specification and will not work. The same logic would apply to the hypotheticals presented in relation to the challenge based on lack of clarity.

[50] Counsel on behalf of Cipla submitted that given the dual and interchangeable functionalities of elements in the specification one would not be in a position to 'unscramble the egg'. It was suggested that one would not be able to deconstruct a formulation. That of course would not be a problem with an allegedly offending product. One could subject it to analysis. When, however, there is a challenge to the validity of a patent without an allegedly offending product, on the basis of lack of clarity, then the question that must be addressed is whether the patent is reasonably certain. In *Ausplow (Pty) Ltd v Northpark Trading 3 (Pty) Ltd & others* [2011] ZASCA 123; 2011 BIP 12 (SCA) Harms JA stated that patents are about construction and not deconstruction of the text.[12] In *Ausplow* this court referred (para 20 fn 10) to what was said in *Lister v Norton Brothers and Co* (1886) 3 RPC 199 (Ch D), namely, that 'a patent must be read by a mind willing to understand, not by a mind desirous of misunderstanding'. In my

[12] Para 20.

view the hypotheticals appear to have been employed with focused intent on misunderstanding.

[51] It was contended on behalf of Cipla that one would not find reported cases in which one could find pharmaceutical formulations in respect of which constituents may be selected from one or more pharmaceutical ingredients that may be part of an admixture. However, this is incorrect. In *Pharma Dynamics (Pty) Ltd v Bayer Pharma AG (formerly Bayer Schering Pharma AG) & another* [2014] ZASCA 201; [2014] 4 All SA 302 (SCA), at para 29 the following appears, taken from the detailed disclosure of the invention there in question:

'Bayer's case is that claim 1 protects the invention described by Prof Davies. The contrary position taken by Dr Rue and Pharma is that if there was indeed an invention as described by Prof Davies - which they denied – that is not the invention covered by claim 1. Although directly contradictory, each party found support for its interpretation in the body of the patent specification, which reads in relevant part, under the heading "Detailed disclosure of the invention":

"Drospirenone . . . is a sparingly soluble substance in water and aqueous buffers at various pH values. Furthermore, drospirenone is rearranged to an inactive isomer under acid conditions and hydrolysed under alkaline conditions. To ensure good bioavailability of the compound, it is therefore advantageously provided in a form that promotes rapid dissolution thereof.

It has surprisingly been found that when drospirenone is provided in micronized form . . . rapid dissolution of the active compound from the composition occurs in vitro *("rapid dissolution" is defined as the dissolution of at least 70% over about 30 minutes . . . of drospirenone from a tablet preparation containing 3 mg of drospirenone in 900 ml of water at 37ºC determined by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm).* Instead of providing the drospirenone in micronized form, it is possible to *dissolve it in a suitable solvent, e.g. methanol or ethyl acetate*, and spray it onto the surface of inert carrier particles followed by incorporation of the particles containing drospirenone on their surface in the composition. . .

The composition of the invention may be formulated in any manner known in the pharmaceutical art. In particular, as indicated above, the composition may be formulated by a method comprising providing drospirenone and, if desired, ethinylestradiol in micronized form in said unit dosage form, or sprayed from a solution onto particles of an inert carrier in admixture with one or more pharmaceutically acceptable excipients that promote dissolution of the

drospirenone and ethinylestradiol so as to promote rapid dissolution . . . on oral administration."' (my emphasis.)

[52] As can be seen, Professor Barbour's criticism of the patent was tentative, confusing, at times contradictory and on the whole rather diluted. The number of crystals and the test as to whether they are visible to the naked eye are aspects on which I will comment in due course. Cipla bore the onus to prove the invalidity of the patent. The evidence of Professor Barbour, for the reasons set out above, is of no assistance. The evidence of Dr Witchey, by contrast, is a formidable obstacle in the way of Cipla's case on invalidity.

[53] For all the reasons set out above Cipla's challenge to the patent in suit on the basis of lack of clarity must fail.

[54] It is now necessary to turn to the question whether the appellants had satisfied the onus of proving infringement of the patent. A determination of the question as to whether a plaintiff has proved an infringement of its 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.[13] It was accepted that in respect of the integer b) test, to which a substantial part of the proceedings in the court below was devoted, it was necessary to have regard to expert evidence. In the present case the principal actors were again Professor Barbour and Dr Witchey, whose evidence on this subject will be adverted to in due course.

[55] The issues concerning infringement were limited to the question whether ethanol is an organic co-solvent for the purposes of integer d) and whether the mixture of PVP and Tween 80 in Fiprotec is a crystallisation inhibitor for the purposes of integer b) and one which satisfies the test set out therein. In Dr Witchey's expert summary she matched the integers of the claims against the Fiprotec constituents and confirmed that DGME and PG is an organic solvent and that ethanol is a co-solvent in Fiprotec. She

[13] *Stauffer Chemical Co & another v Safsan Marketing and Distribution Co (Pty) Ltd & others* [1986] ZASCA 78; 1987 (2) 331 (A) at 342D-E.

persisted in this view, notwithstanding that the ethanol could also, in certain formulations, be the solvent. This aspect was dealt with during the cross-examination of Dr Witchey as referred to in the discussion above[14] in relation to the defence based on the lack of clarity. It will be recalled that Dr Witchey stated emphatically that in regard to Fiprotec there was no confusion as to its constituent parts and as to the function of each element and that it was accepted by the parties to the litigation that ethanol served as the co-solvent (integer d)). She was, as recorded above, essentially unchallenged in this as counsel on behalf of Cipla chose to move away from the discussion on the constituent parts of Fiprotec. Murphy J rightly recorded that Dr Witchey was unchallenged on this aspect.[15] As pointed out above, the hypothetical formulations put to Dr Witchey do not detract from her essentially unchallenged and persuasive evidence on this aspect.[16]

[56] Following on the conclusion set out in the preceding paragraph, the remaining issue relates to the question whether the mixture of PVP and Tween 80 in Fiprotec is a crystallisation inhibitor falling within integer b) and one which meets the requirements of that test. The answer to that question turns on the experiments carried out by the parties' respective experts.

[57] It is now necessary to consider the experiments conducted by Professor Barbour. His expert summary refers to three tests that he conducted in support of Cipla's case of non-infringement. He conducted tests B1, B2 and C. Cipla abandoned reliance on test C during the trial. As stated earlier, it is undisputed that Professor Barbour used the actual ingredients of Fiprotec and that the materials employed by Dr Witchey were supplied by the first appellant.

[58] As appears from his expert summary Professor Barbour's tests, B1 and B2, used DGME and PG present in Cipla's product as the organic solvent and the PVP and

[14] See para 39 above.
[15] Para 61 of the judgment in the court below.
[16] Professor Barbour in conducting his experiments in fact used ethanol as the co-solvent, even though he did this on the basis that Merial had advised it. He did not have any difficulty in conducting the integer b) test.

Tween 80 of Cipla's product, as the crystallisation inhibitor. These tests were carried out at concentrations which accord with the requirements in claim 1. In other words, fipronil has a concentration of 10% and PVP and Tween 80, together, have the same concentration. The same solution was used in both tests and both tests failed according to Professor Barbour.

[59] Murphy J took the view that Professor Barbour's tests were performed carelessly. In this regard, he accepted criticisms proffered by counsel on behalf of the appellants. In respect of test B1 Murphy J said the following (para 52):

'The principal reason for which I hesitate to accept the results of [Professor] Barbour's Test B1, as scientifically establishing the failure of the crystallisation inhibitor in Fiprotec, is that there is a distinct possibility, if not probability, that an etching on the slide used by [Professor] Barbour (caused by a microscope) contributed significantly to the formation of crystals. Instead of using a clean, new slide, [Professor] Barbour used a five year-old glass slide which he took from his microscope. The etching was caused by the pressure of the component of the microscope holding the slide in place. [Professor] Barbour conceded that any scratching on a glass slide could encourage crystallisation. The photographic evidence in relation to Test B1 reveals that the solution may have pooled against the edge of the etching. This alone makes Test B1 unreliable and the results must be disregarded.'

[60] In respect of test B2, Murphy J said the following (para 53):

'. . . I agree . . . that the results of Test B2, conducted by [Professor] Barbour, are not sufficiently credible to definitively exclude integer b). In this instance, crystallisation materialised after 13 minutes, whereas it took 5 hours in Test B1 despite using the same solution, in the same laboratory at the same temperature. Normally, before one would see crystallisation, at least part of the solution would have to reach the saturation point of the solute in the solvent. Dr Witchey estimated that some 45 % of the solution would have to evaporate before the concentration of fipronil reached a point where the crystallisation inhibitor is even needed. To accept the results of Test B2 it must be accepted that 45 % of a solvent system having boiling points of 200°C (DGME) and 185°C (PG) evaporated in 13 minutes. The probabilities point to an error of some kind, inexplicable in the evidence. [Professor] Barbour might have been prudent when confronted with the rapid rate of evaporation in this test to have conducted a third test.'

[61] As submitted on behalf of the appellants, it is true that Professor Barbour conducted his tests at relatively short notice and within time constraints. This was evidenced in the inconsistency between the results he obtained from tests B1 and B2.

[62] It is also correct that Professor Barbour conceded that he had made ‘a careless mistake’ in his summary when he spoke of a mixture of co-solvents. This amplifies the conclusion set out above in relation to his lack of expertise in relation to chemical formulations, but it is also true that his difficulty with dissolving the active ingredient was related to him not following the order in which the constituents were to be mixed. He was also rightly criticised for measuring the proportions of Tween 80 and DGME in v/v despite the facts that (i) Cipla’s own supplier measures these materials in w/v and (ii) it would mean that the percentages of the crystallisation inhibitor would not equal 10%. He also wrongly described propylene glycol as ‘polyethylene glycol’ (PG). All these factors point to a lack of application and conscientiousness.

[63] In relation to test B1, the criticisms noted by Murphy J are justified. Professor Barbour knew that there was an etching on the reverse side of the microscope slide brought about by the pressure of the microscope but ‘hoped’ that the drop in pursuance of the integer b) test would not spread beyond the etching. He accepted that scratching a glass slide was a well-known technique for encouraging crystallisation which for the purposes of the integer b) test had to be avoided. Professor Barbour’s ‘hope’ proved unfounded as the photographs show that the solution placed on the microscope’s slide pooled against the edge of the etching.

[64] In relation to test B2 Professor Barbour claimed that crystallisation manifested 13 minutes after the commencement of the trial. This differs vastly from the time of onset of crystallisation in relation to test B1. In relation to that test, crystallisation occurred after five hours. Professor Barbour used the same solution in the same laboratory at the same temperature. This was remarkable and ought to have given reason to pause.

[65] In the result, Murphy J was correct to reach the conclusion that one could not rely on Professor Barbour's integer b) tests.

[66] Murphy J, however, questioned the probative value of the tests conducted by Dr Witchey. He criticised her for not being able to offer any explanation as to why the results of her tests and those of Professor Barbour differed. This criticism discounts the Commissioner's own conclusions in relation to the reliability of the test conducted by Professor Barbour.

[67] The court below considered whether the divergent results might have been due to the fact that Dr Witchey conducted her test in a weighing cabinet which may have inhibited evaporation and thus the formation of crystals, but rightly in my view accepted her evidence that the use of the cabinet was legitimate as it avoided artificial means of enhancing evaporation such as would occur where a convector flux was allowed to push across the surface of a slide. Leaving the slide in an open laboratory would, if it was exposed to air handling systems, enhance evaporation. Dr Witchey was satisfied that the cabinet was of sufficient size and sufficient configuration to allow free evaporation.

[68] Continuing to explore the reason for divergent results, the court below considered that it might be due to the use by Dr Witchey, not of Cipla's own composition of fipronil, but of fipronil and PG sourced elsewhere. The Commissioner also noted that the DGME sourced by Dr Witchey was Transcutol V and not Transcutol P.

[69] Murphy J considered fipronil to be the most important ingredient in the test, particularly since it was the active pharmaceutical ingredient. He speculated that different processes in producing the ingredients used by Dr Witchey might have caused the divergent results. Whilst Dr Witchey did agree that it would have been optimum to have conducted the test with the exact constituents of the infringing product, she did not concede that the tests conducted by her were therefore invalid. Murphy J also theorised that the fipronil supplied by Merial may have been in a different polymorphic form to that

in Fiprotec. Having resorted to the speculation set out above, the court below found that there was no reliable test before it which adequately demonstrated that the crystallisation inhibitor system in Fiprotec (i.e. the combination of PVP K30 and Tween 80 (in a ratio of 1,4:1)) would inhibit fipronil sourced from GSP Crop Science (i.e. the fipronil used in Fiprotec) from producing fewer than 10 crystals in the crystallisation inhibitor test of claim 1.

[70] As correctly pointed out on behalf of the appellants, there was no evidence before the Commissioner on which it might be found that Cipla's fipronil was in a different polymorphic form. It appears from documents put to Dr Witchey when she was testifying that the fipronil used by Cipla and that used by Merial had the same chemical abstract number. Similarly, although Dr Witchey used a slightly different form of DMGE (Transcutol V and not Transcutol P), she explained that these two compounds were 'virtually identical' and this would not have materially affected the experiments. This was never seriously challenged.

[71] Furthermore, it is so that there was no evidence adduced that there were different processes employed in relation to manufacture of Merial's fipronil or Cipla's, or that Cipla's fipronil contained impurities which may have impacted on crystallisation.

[72] The most obvious cause for the discrepancies, as noted above, was the careless manner in which Professor Barbour conducted his tests as opposed to the more meticulous manner adopted by Dr Witchey. The high water mark of Professor Barbour's evidence was that fipronil from different sources might possibly have resulted in different impurities. The speculation referred to above discounted Professor Barbour using the same fipronil during the same series of tests but obtaining divergent results. I agree as submitted on behalf of the appellants that the impurities debate is a red herring.

[73] Despite having rejected Cipla's defences relating to the validity of the patent, Murphy J nevertheless held that Dr Witchey's view, that ethanol was the co-solvent in the formulation, was not persuasive. Although Murphy J found that Professor Barbour,

by using DGME and PG as the solvents, had, by implication, ‘arguably’ accepted that ethanol was in fact the co-solvent in Fiprotec, he thought it important that Professor Barbour had testified that he had found the teaching of the patent confusing because of the dual identity of ethanol. The court below held that Dr Witchey had experienced difficulty in dealing with the hypotheticals presented to her. He concluded that Dr Witchey had failed to prove that Fiprotec included integer d) by failing to persuade him that ethanol was indeed the co-solvent. This aspect has been dealt with in some detail in relation to Cipla’s challenge to the invalidity of the patent and I do not intend to repeat it, save to state that, for the reasons provided above, the court below erred in concluding as set out earlier in this paragraph.

[74] The contention on behalf of Cipla, that Dr Witchey was evasive and refused to make concessions which were called for and that her stock response was to retreat into her expertise as a formulator is unwarranted. As stated earlier, she was entitled to rely on her expertise as a formulator. She is a formulation chemist trained as a chemical engineer with 25 years of experience in pharmaceutical product development. She is, as recorded by the court below, indisputably a person skilled in the art and thus an addressee of the patent. As demonstrated above, she was an impressive witness. The submission on behalf of Cipla that Professor Barbour, by contrast, was an excellent witness is equally unjustified. The weaknesses in his testimony have been referred to earlier in this judgment.

[75] For completeness I record that Cipla presented evidence by a non-expert witness, a Mr Swiegers, that he had applied Fiprotec to a sample of dogs and that they all had crystals on their coats thereafter. In this regard there was countervailing evidence on behalf of the appellants. The court below disregarded Mr Swiegers’ evidence on the basis that claim 1 of the patent presented no degree of visibility of crystals on the coat of an animal. The evidence in relation to the actual application of Fiprotec to the coat of an animal was not relied upon before us and need not detain us.

[76] In my view the court below erred by not concluding that the appellants had proved on a balance of probabilities that there was an infringement of claim 1 and the other dependant claims.

[77] The following order is made:

1. The appeal is upheld with costs including the costs of two counsel.
2. The order of the court below is set aside and substituted as follows:

‘1. The defendant is interdicted and restrained from infringing claims 1, 2, 3, 7 to 15 and 18 to 20 of the patent.

2. The defendant is ordered to deliver up to the plaintiffs all infringing Fiprotec products in its possession or under its control.

3. An inquiry is ordered in relation to the damages suffered by the plaintiffs as a consequence of the infringement of the patent by the defendant alternatively an inquiry into the reasonable royalty to which the plaintiffs are entitled.

4. In the event of the parties being unable to reach an agreement as to the further pleadings to be filed, discovery, inspection or other matters of procedure relating to the inquiry, an order authorising any one of the parties to make application to the court for directions in regard thereto.

5. Each of the claims referred to in para 1 above of South African Patent Number 1996/8057 is certified as being valid in terms of section 74 of the Patents Act 57 of 1978.

6. The defendant is ordered to pay the plaintiffs’ costs of suit, including the costs of two counsel and the qualifying fees of the plaintiffs’ expert witnesses.’

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M S NAVSA

Acting Deputy President

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