THE SUPREME COURT OF APPEAL OF SOUTH AFRICA

JUDGMENT

REPORTABLE
Case No 1066/2013

In the matter between:

BAYER PHARMA AG (FORMERLY BAYER SCHERING PHARMA AG) **APPELLANT**

and

PHARMA DYNAMICS (PTY) LTD **RESPONDENT**

Neutral citation:	*Bayer Pharma AG v Pharma Dynamics (Pty) Ltd* (1066/2013) [2014] ZASCA 201 (28 November 2014).
Coram:	Brand, Lewis, Theron JJA and Schoeman and Dambuza AJJA
Heard:	**19 November 2014**
Delivered:	**28 November 2014**

Summary: Application for amendment of registered patent in terms of s 51 of Patents Act 57 of 1978 – objection that proposed amendment will render claim 1 of the patent unclear – further opposition on the basis that, in any event, the application should be refused for reasons of 'undue delay' and 'reprehensible conduct' on the part of the patentee.

ORDER

On appeal from: The court of the Commissioner of Patents of South Africa (Potterill J, sitting as Commissioner of Patents):

1 The appeal is upheld with costs, including the costs of two counsel.
2 The order of the Commissioner of Patents is set aside and the following order is substituted:
'(a) The amendment to South African Patent 2002/1968 applied for by the applicant is granted.
(b) The respondent is ordered to pay the applicant's costs, including the costs of two counsel.'

JUDGMENT

Brand JA (Lewis, Theron JJA and Schoeman and Dambuza AJJA concurring):

[1] This is an appeal against the judgment and order of Potterill J, sitting as the Commissioner of Patents. The appellant is a German company, Bayer Pharma Aktiengesellschaft (Bayer). It is the patentee of South African patent 2002/1968 (the 2002 patent or the patent in suit), which is for an invention entitled 'Pharmaceutical combination of ethinylestradiol (EE) and drospirenone (DSP) for use as a contraceptive'. The respondent, Pharma Dynamics (Pty) Ltd (Pharma), is a generic pharmaceutical company and the South African affiliate of Lupin Ltd, a transnational company based in India. The appeal originates from an application to amend the 2002 patent in terms of s 51(1) of the Patents Act 57 of 1978 (the Act). Pharma opposed the application which required the matter to be heard by the court a quo pursuant to s 51(3)(*b*) of the Act. In the event, Potterill J dismissed the application with costs, but afforded Bayer leave to bring an appeal to this court.

[2] As foreshadowed by the description in its title, the 2002 patent concerns a female oral contraceptive, containing the active pharmaceutical ingredients DSP and EE. It was filed in the South African Patent Office on 27 February 2002, but with the priority date of 31 August 1999, which it claimed from patent applications in Europe and the United States. In 2004 Bayer filed Patent 2004/4083 (the 2004 patent) in terms of s 37 of the Act as a so-called 'divisional patent' based on the 2002 patent as its 'parent patent'.

[3] In March 2011, Pharma obtained approval from the Medical Control Council to import and sell an oral contraceptive called Ruby. This product is the generic equivalent of the Yasmin product sold by Bayer under its 2002 and 2004 patents. Alleging that Ruby constituted an infringement of both its 2002 and 2004 patents, Bayer brought an application in the court a quo for an interim interdict. In due course Bayer also instituted an action for a final interdict prohibiting Pharma from infringing the claims of the 2002 and 2004 patents. The litigation between the parties which ensued proceeded along a rather tortuous route. Since the amendment application under consideration formed part of that process, it becomes necessary to traverse at least part of that route.

[4] Although Bayer initially founded its case on both the 2002 and the 2004 patents, it soon abandoned reliance on the 2002 patent in both the interim interdict application as well as the action proceedings. As a further step Bayer applied for the amendment of the 2004 patent. That application was heard together with the application for the interim interdict, which by then had been confined to the 2004 patent. Despite opposition by Pharma to both these applications, Bayer was successful in that on 14 November 2011 Vorster AJ granted the interim interdict and the amendment to the 2004 patent sought. That judgment has since been reported as *Bayer Schering Pharma AG & another v Pharma Dynamics (Pty) Ltd & another* 2011 BIP 73 (CP).

[5] In the action for a permanent interdict that followed, Pharma not only denied that it infringed the 2004 patent, but counterclaimed for the revocation of that patent on various grounds. Eventually Pretorius J, sitting as the Commissioner of Patents held, however, that the patent was valid and that Ruby had infringed it. In

consequence Pretorius J granted the relief sought by Bayer and dismissed the counterclaim. The appeal by Pharma against that judgment was recently dismissed by this court (see *Pharma Dynamics (Pty) Ltd v Bayer Pharma AG* (468/130) [2014] ZASCA 123 (19 September 2014).

[6] After achieving success before Vorster AJ in November 2011, but before the judgment by Pretorius J, Bayer brought its application to amend the 2002 patent, which eventually gave rise to this appeal. The amendments sought by Bayer are quite extensive in particularity and not uncomplicated in content. Broadly speaking, however, Bayer sought to (a) delete a number of paragraphs from the body of the patent specification; (b) delete all of the claims of the 2002 patent, except claim 1; (c) limit claim 1 by: (i) including certain extra features or integers which do not form part of the claim in its unamended form; (ii) by limiting the dosage ranges in the claim; and (iii) adding the words 'and in a rapid dissolution form' as a further limitation to the claim.

[7] Initially Pharma's opposition to the amendment relied on various grounds. Those remaining on appeal are, however, limited to the following three contentions:

(a) First, that claim 1 of the 2002 patent would, after amendment, be invalid for lack of clarity as contemplated by s 61(1)(*f*)(i) of the Act;

(b) Secondly, that there has been culpable delay on the part of Bayer in bringing the amendment application;

(c) Thirdly, that Bayer was guilty of 'reprehensible conduct' prior to the application to amend.

[8] In its judgment the court a quo upheld Pharma's first objection based on the proposed amendment's lack of clarity. In consequence the court found it unnecessary to consider the discretionary grounds of 'culpable delay' and 'reprehensible conduct'. In similar fashion, I shall deal with the lack of clarity-ground first.

Lack of clarity

[9] The principle is well-established that any ground for revocation of a patent may be advanced in opposition to a proposed amendment. The underlying consideration, as formulated in *Bendz Ltd & another v South African Lead Works Ltd* 1963 (3) SA 797 (A) at 803E, seems to be that no purpose can be served by allowing an amendment which will set the patent up for revocation. One such ground for revocation, contained in s 61(1)(*f*)(i) of the Act, is 'that the claims of the complete specification concerned are not – clear'. In determining whether or not a claim is sufficiently clear for purposes of this provision, I find guidance in the principles established by this court in a number of cases, such as *Letraset Ltd v Helios Ltd* 1972 (3) SA 245 (A) 249H-251B; *Roman Roller CC & another v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405 (A) 419B-G; *Ausplow (Pty) Ltd v North Park Trading 3 (Pty) Ltd & others* [2011] 4 All SA 221 (SCA) para 20. Included amongst these principles are the following, which are pertinent:

(a) It is the duty of a patentee to state clearly and distinctly the nature and limits of its claim so as to define its monopoly and so that others know exactly what they may and may not do. The degree of clarity required is that which leads to reasonable certainty. 'Absolutism does not perch happily on the banners of our law' (per Holmes JA in *Letraset* 250B).

(b) The court must view the patent through the eyes of the skilled addressee in the relevant art. In doing so the court may take into account that the addressee is expected to use reasonable skill and intelligence in interpreting the language of the patent. The addressee is not required to struggle unduly with it, but must make the best of it and not adopt an attitude of studied obtuseness.

(c) The court may also accept that the skilled person, when considering a claim, should rule out interpretations which are illogical or which do not make technical sense. The addressee should try to arrive at an interpretation which is technically sensible and takes into account the whole disclosure of the patent; that the patent will be construed with a mind willing to understand rather than to misunderstand.

(d) If words or expressions in a claim are defined by what is said in the body of the specification, the language of the claim must be construed accordingly.

(e) In determining whether the limits of the monopoly are sufficiently defined, technical terms are to be interpreted in the light of evidence given by witnesses skilled in the art. But words which have no special technical meaning are to be

interpreted by the court and are to be given their natural and ordinary meaning as read in their context.

[10] The lack of clarity objection is aimed, as I have said, at claim 1 as it will read in its proposed amended form. In its unamended form, claim 1 reads as follows:

'A pharmaceutical composition comprising;

as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the composition, of from about 2 mg to 4 mg, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of from about 0.01 mg to 0.05 mg, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in micronised form.'

After the proposed amendment, claim 1 will read as follows (with the additions and other changes emphasised for convenience):

'A pharmaceutical composition in **an oral form and in the form of a tablet, a pill or a capsule** comprising:

as a first active agent drospirenone in an amount corresponding to a daily dosage, on administration of the composition, of **3 mg**, and as a second active agent, ethinylestradiol in an amount corresponding to a daily dosage of **0.015 mg to 0.03 mg**, together with one or more pharmaceutically acceptable carriers or excipients, wherein said drospirenone is in micronised form **and in a rapid dissolution form**.'

[11] Pharma's contention, which found favour with the court a quo, is that the introduction of the words 'in a rapid dissolution form' will render the claim unclear. In this regard it is evident from the way in which the objection was formulated, that it was not aimed at the phrase itself. In other words, it was not contended that the meaning of 'in rapid dissolution form' is unclear. Any contention to that effect would be met by the fact that the expression 'rapid dissolution' is defined in the body of the specification to mean 'the dissolution of at least 70% over about 30 minutes, in particular at least 80% over about 20 minutes, of drospirenone from a tablet preparation containing 3mg of drospirenone in 900ml of water at 37ºC determined by the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at 50 rpm.'

[12] The ambiguity will result, so Pharma's objection went, from introducing this phrase in conjunction with the integer that the DSP is provided in micronised form. In evaluating this objection the court a quo started out from the premise that 'this is a

product claim and I need not understand how the product is manufactured'. In addition the court accepted that the term 'micronised' is not technical in that it means nothing more than 'to break up into very small particles' and that, while 'rapid dissolution form' is technical, it is specifically defined in the specification.

[13] Setting out from these points of departure, the court a quo's reasoning as to why the clarity objection should be upheld, went along the following lines:

(a) According to the specification of the patent in suit the inventor had found that the rapid dissolution rate as defined can be achieved by providing the DSP in micronised form or, alternatively, by dissolving the DSP in a suitable solvent, eg methanol, and to spray the solution on the surface of inert carrier particles followed by incorporation of these particles in the pharmaceutical composition.

(b) It follows that the rapid dissolution is the result of the micronisation of the DSP. Conversely, that the purpose of micronisation is to achieve rapid dissolution.

(c) By introducing the additional integer that the micronised DSP must also be 'in rapid dissolution form', the claim becomes unclear, because it raises the question whether a further step must be taken to render the DSP in a rapid dissolution form and what that step would be.

Or, as summarised in the words of the court a quo:

'. . . [I]n the body of the specification of the patent any reference to rapid dissolution is only in context of the result of micronisation or the "spraying on" of the drospirenone. No further alternative methods of achieving "rapid dissolution" are described in the specification and the question arises whether a further step must be taken to render the drospirenone "in a rapid dissolution form" or what this step would be. Whereas the dissolution rate was a result of the process of the micronisation of drospirenone it is now not clear whether it is an added or different requirement and not only a result of the micronisation.'

[14] Before us it was common cause that the starting point of the court a quo's reasoning, namely that this is a product claim as opposed to a method claim, cannot be faulted. But if this is so, it follows, in my view, that the potential infringer need not concern itself – and neither need the court – with how the product is manufactured. The question whether 'further 'steps' need to be taken in the process of manufacturing the product of claim 1, is of no consequence. All that requires consideration are the constituent elements and properties of the allegedly infringing

product in its final form. This follows from the test for determining infringement as formulated, eg in *Letraset v Helios Ltd supra* at 274G-H, namely that it involves a comparison between the allegedly infringing product and the words of the patent claim. If the product falls within the ambit of the claim an infringement had been established, otherwise it had not. *Cadit quaestio*.

[15] Moreover, it was common cause in argument before us that the court a quo was right in accepting (a) that micronisation is not a technical term and (b) that, while rapid dissolution may be technical, it is defined in the specification of the patent. In this light, I believe it should therefore create no problem for the potential infringer to establish whether or not (a) the DSP in its composition is micronised and (b) the dissolution profile of the DSP in its composition falls within the scope of 'rapidly dissolving' as defined in the patent specification. If the infringer's pharmaceutical product satisfies both of these tests, then the product infringes the claim of the 2002 patent. Conversely, if the infringer's product does not satisfy both of these requirements, then it does not. I can find nothing unclear about this.

[16] Formulating the same proposition somewhat differently, counsel for Pharma argued before us that inasmuch as it is unclear whether rapid dissolution is merely a result of micronisation or whether something additional is required, the potential infringer will be confused as to whether further steps need to be taken in order to constitute an infringement. But despite the different formulation, I remain unpersuaded by the argument. Even assuming that, in accordance with the specification of the patent in suit, micronising DSP will result in the composition of claim 1 being rapidly dissolving, this does not render the patent unclear. A potential infringer does not need to know whether a further step needs to be taken in the preparation of the pharmaceutical composition to render DSP both micronised and rapid dissolving. The forbidden field of claim 1, as sought to be amended (even if found to be tautologous), is clearly defined. All infringers would know exactly what they may and may not do.

[17] What is more, I believe that an enquiry at a somewhat more sophisticated level leads to the same conclusion. The starting point of this enquiry relies on the crystallised principle of patent interpretation, that it must be read through the eyes of

a person skilled in the art. This being so, it must follow, in line with common experience, that even non-technical words may, in the context of a patent, have a meaning to a person skilled in the art which is different from the one conveyed by the literal meaning of the words to the layperson. Ergo, even a conclusion that the literal words convey a meaning to the layperson which is unclear, would call for an enquiry at a more sophisticated level before the claim can be held to be invalid for lack of clarity. That enquiry is: do these words in the context of the patent, convey a meaning to a person skilled in the art, which is unclear?

[18] The evidence by Bayer's expert – which stands uncontradicted by any expert on behalf of Pharma – was that the dissolution rate of micronised DSP from a tablet preparation may be slowed down through the use of techniques well-known to those skilled in the art. For example, by applying an enteric coat to the tablet. Carriers or excipients that retard rather than promote dissolution (which are expressly contemplated in the patent) would be another example of doing so. Where a potential infringer therefore uses an enteric coat or an inert carrier in its composition that slows down the dissolution rate of micronised DSP to a degree that it no longer dissolves at the rate defined in the patent, that product will not infringe the patent. In this light the court a quo's finding that, post amendment, the claim may require 'a further step' to be taken in respect of the DSP in order to achieve the rapid rate of dissolution, is in my view unwarranted. As the skilled person would understand the claim, a potential infringement can be avoided by slowing down the dissolution rate of the micronised DSP contained in the tablet to below the level of 'rapid dissolution'.

[19] For these reasons I do not agree with the court a quo's conclusion that the proposed amendment will render claim 1 of the patent unclear. It follows that in my view the refusal of the amendment application on that basis cannot be sustained. That, however, is not the end of the matter. It is settled law that, although an amendment may satisfy all substantive requirements, the Commissioner nonetheless has a discretion to refuse it. As we know, Pharma advanced two grounds as to why the Commissioner should exercise that discretion adverse to Bayer, namely that Bayer was guilty of 'culpable delay' and 'reprehensible conduct'. Unlike the Commissioner, we now have to consider these contentions in the light of our contrary finding that the amended patent would not be unclear. Yet, in considering

the two grounds relied upon by Pharma separately, the overall approach in the exercise of this discretion, as directed by authority, starts out from the premise that amendments will ordinarily be granted, unless the conduct of the patentee was blameworthy to an extent that warrants refusal, despite compliance with substantive requirements (see eg *Interfelt Products (Pty) Ltd v Feltex Ltd* [1972] 3 All SA 299 (T) at 303).

Culpable delay

[20] Underlying Pharma's charge of culpable delay is its contention that Bayer must have known that the 2002 patent was invalid for a number of years prior to the amendment application. As the factual basis for its contention Pharma relied on the proposition that the 2002 patent in its unamended form includes within its scope non-oral, non-solid pharmaceutical combinations and that the patent is invalid in this form for lack of an inventive step. This basis in turn derives from two passages in the specification of the patent in suit – which Bayer now seeks to delete – relating to non-oral, non-solid types of composition.

[21] As a matter of law, an objection on the ground of culpable delay needs to satisfy a number of requirements. The two of these that I find most pertinent appear from the following dicta by Nicolas AJA in *South African Druggists Ltd v Bayer AG* 1989 (4) SA 103 (A) 107I-108F:

'The legal position on the question of delay on the part of a patentee in applying for amendments has been considered in a number of cases. A deliberate intention to delay knowing full well that some of the claims are invalid can in some circumstances be a bar to amendment. Even though a patentee never attempted to enforce them he has created an area which prevented competitors from freely entering it.'

And:

'Mere delay without actual or potential prejudice is unlikely to result in an amendment being refused.'

(See also eg *Barmac Associates Ltd v SA Dynamics* 1991 BP 16 (CP) 20G; *Denton Engineering (Pty) Ltd & another v J P McKelvey & others* 1997 BIP 113 (CP) 121-122.)

[22] I propose to deal with the requirement of prejudice first, because as I see it, the reliance on culpable delay should founder on this basis alone. I say that for the reasons that follow. Pharma made no allegation whatsoever that it has been prejudiced by the delay in the bringing of the application. Indeed, Bayer's expert says the following in her answering affidavit, which has not been denied or even dealt with in any way on behalf of Pharma in reply:

'It is important, firstly, under this heading to note that it is highly improbable that any third party (including the respondent) will have been prejudiced by the fact that the claims of the 2002 patent prior to the amendment covered non-oral, non-solid dosage forms. As far as I am aware, no one has ever registered or produced a non-oral, non-solid pharmaceutical composition falling within the scope of the claims of the 2002 patent.

It should also be borne in mind that generics companies such as the respondent seek to replicate innovator medicines which are already on the market. To the best of the patentee's knowledge no one other than the patentee's licensee and the respondent have registered products in South Africa which relate to the Bayer products. As the patentee has never commercialised a non-oral, non-solid pharmaceutical dosage form, it would be most unlikely that any generics companies would ever seek to market such a formulation as to do so would require extensive investment on their part in obtaining regulatory approval.'

[23] Nonetheless, to complete the picture, I shall also deal with Pharma's contention that Bayer must have known for a number of years that the 2002 patent was invalid, but intentionally delayed the amendment application. The factual basis for the contention, as we know, derives from two passages in the patent specification, which Bayer now seeks to delete, which relate to non-oral, non-solid types of composition. However, according to Bayer's answering affidavit, its experts always thought that despite these passages in the specification, the invention protected by the patent in suit was clearly confined to solid oral formulations and that no skilled addressee would understand it differently. This statement is supported by the evidence of an independent expert, Prof Martyn Davies, during the trial action for a final interdict. When confronted in cross-examination on behalf of Pharma with the passages in the specification referring to non-oral and non-solid compositions, Prof Davies' response was that, despite these references, 'I never thought the 2002 or the 2004 patent could be used for anything other than oral administration'. The direct evidence on behalf of Bayer was that it only became aware of the averment that the claims of the 2002 patent were not limited to solid oral dosage formulations in June

2011, when the issue was raised in Europe for the first time. In all the circumstances, I do not believe that an implied finding of dishonesty in rejecting this statement, is warranted. For these reasons I find that the objection based on culpable delay cannot be sustained.

Reprehensible conduct

[24] Pharma's first charge of reprehensible conduct on the part of Bayer relies on the allegation that 'the timing of the interim interdict application and the institution of the action displayed abuse of the procedure of this honourable court'. I find this complaint misplaced. Firstly, Bayer was successful in both the interim interdict and the action proceedings. If its conduct in those proceedings indeed amounted to an abuse, that relief would hardly have been granted. Secondly, if Bayer's conduct was in any way inappropriate in those proceedings, it should have been dealt with there and then, perhaps by way of a special costs order. But it has no bearing on these amendment proceedings.

[25] Pharma's second charge under this heading is that Bayer sought to enforce the 2002 patent in circumstances when it knew (a) that the patent was invalid and (b) that, in any event, Pharma's Ruby product did not constitute an infringement. I have already found the contention resting on Bayer's alleged knowledge of invalidity unsustainable. All that needs to be added in this regard is that Bayer launched both the interim interdict and the final interdict proceedings before the allegations of invalidity came to its notice in June 2011. Shortly thereafter it withdrew its reliance on the 2002 patent and sought an amendment to the 2004 patent so as to remove the offending passages from the specification. With regard to the allegation that Ruby did not infringe the 2002 patent because it does not contain DSP in micronised form, Bayer's answer is that it is still not convinced that this is so. This answer appears to be supported by the inherent probabilities. If Bayer indeed knew that the DSP contained in Ruby is not in micronised form, it would mean that Bayer embarked on litigation without any hope of success, which is hardly likely.

[26] Finally, Pharma contended that Bayer has abused the patent system in South Africa by obtaining 'two patents for the same invention'. All I need to say in this regard is that a similar argument was advanced by Pharma and dismissed by this

court in the previous litigation between the parties (see *Pharma Dynamics (Pty) Ltd v Bayer Pharma AG* (468/2013) [2014] ZASCA 123 (19 September 2014) paras 42-45). For these reasons I find that the objection based on the reprehensible conduct on the part of Bayer, must also fail.

Costs

[27] What remains are issues of costs. The reason for these issues arising is the contention by Pharma that, even if the amendment application were to be successful, Bayer should be ordered to pay the costs occasioned by the opposition, at least in the court a quo. In support of this contention Pharma argued that Bayer had sought an indulgence and that the grounds of objection raised against the application were 'fair, reasonable and not vexatious'. As authority for this argument Pharma relied on the general approach with regard to matters involving the amendment of pleadings. I do not believe, however, that the considerations underlying the approach to applications for the amendment of pleadings can be transposed without qualification to the amendment of patents. Especially where the amendments are aimed in the main at limiting the claims of the patent, I believe it to be in the public interest that a patentee should not be discouraged through apprehension of an adverse costs order to seek those amendments. In addition, Pharma also referred to decided cases involving amendments of patents where costs were awarded in favour of the unsuccessful objector. That is hardly surprising. The issue of costs is a matter that falls squarely within the discretion of the court and one can obviously think of cases where a costs order to that effect is warranted. But on the facts of this case, it is not one that falls within that category. In consequence, the costs order should, in my view, follow the event, both in this court and in the court a quo.

[28] For these reasons:

1 The appeal is upheld with costs, including the costs of two counsel.
2 The order of the Commissioner of Patents is set aside and the following order is substituted:
'(a) The amendment to South African Patent 2002/1968 applied for by the applicant is granted.

(b) The respondent is ordered to pay the applicant's costs, including the costs of two counsel.'

_____
F D J BRAND
JUDGE OF APPEAL

APPEARANCES:

For the Appellant:	P Ginsburg SC, G Marriot Instructed by: Adams & Adams Inc, Pretoria c/o Honey Attorneys Inc, Bloemfontein
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