IN THE COURT FOR THE COMMISSIONER OF PATENTS FOR THE REPUBLIC OF SOUTH AFRICA

Date: 2008-06-20

Case Number: 89/4476

In the matter between:

H LUNDBECK A/S LUNDBECK SA (PTY) LTD First Applicant Second Applicant

and

CIPLA MEDPRO (PTY) LTD

Respondent

JUDGMENT

SOUTHWOOD J

- This is an urgent application in which the applicant seeks the following relief –
 - Correction of the errors in claims 6 and 7 of South African
 Patent No 89/4476 ('the patent') in accordance with section 50 of the Patents Act 57 of 1978 ('the Act'); and

- (2) an order interdicting and restraining the respondent from infringing the claims of the patent by making, disposing or offering to dispose of, or importing Escitalopram falling within any of the claims of the patent pending the final completion of an action to be instituted by the applicants against the respondent within 20 days of the grant of this order;
- (3) costs of suit including the costs consequent upon the employment of two counsel.
- [2] The first applicant is a Danish corporation which carries on business internationally in the research, development, production, marketing and sale of drugs for the treatment of psychiatric or neurological disorders including depression, schizophrenia, Alzheimers disease and Parkinsons disease. The second applicant is the first applicant's wholly owned South African subsidiary which carries on business as a distributor of the first applicant's products in South Africa. The applicants allege that the second applicant is licensed under the patent by the first applicant to distribute, promote, market and sell an antidepressant drug known as Escitalopram under the trade mark CIPRALEX. The respondent is a South African company which carries on business in South Africa as a distributor of generic drugs.
- [3] The first applicant is the patentee under the patent which was granted on 25 April 1990, with priority date 14 June 1988, and which expires on

13 June 2009. The title of the invention is 'Enantiomers and their Isolation' and the patent is concerned with an antidepressant drug called Escitalopram and in particular with the (+) enantiomers of the antidepressant drug, citalopram, and salts thereof and methods of preparing this enantiomer. As already mentioned the applicants promote, market and sell escitalopram under the name CIPRALEX. There is no evidence that the validity of the patent has been questioned in the 18 years of its existence.

[4] This application was precipitated by the following letter dated 11
 February 2008 from the respondent's attorney, Brian Bacon & Associates Inc ('Bacon'), to the second applicant:

South African Patent Portfolio – Lundbeck – Our ref: 61247

- We act on behalf of Cipla Medpro (Proprietary) Ltd. We are advised that Mr Ben Cristen telephoned Mr Jerome Smith of Cipla Medpro regarding the patents which Mr Cristen said protected Lundbeck's rights in respect of escitalopram.
- As Mr Smith explained, Cipla Medpro respects patents which it is advised are valid but it does not, however, feel constrained to respect patents which it is advised are invalid.
- 3. It is the intention of Cipla to place a generic of escitalopram on the market as soon as it has a MCC

registration and it has been advised that there are no valid patents that will be infringed.

- 4. At this time we are only aware of patent 89/4476 which has claims covering the S enantiomer which Cipla intends to launch into the market. The United Kingdom patent corresponding to patent 89/4476 was, correctly in our view, declared invalid by the High Court of Justice in the United Kingdom. We have advised Cipla Medpro that the South African patent is invalid on the grounds that it claims as an invention an enantiomer which was already in the public domain having been disclosed in the specification of United States patent number 4, 136, 193. This is admitted in the specification of patent 89/4476. Additionally claim 7 is incomprehensible as it stands and hence invalid. An amendment is required to validate claim 7.
- 5. As a consequence of the above we have advised Cipla Medpro that patent 89/4476 is invalid and unenforceable.
- 6. Should you believe that there are other patents which could be infringed upon Cipla Medpro marketing the S enantiomer of citalopram, and which should consequently be considered by Cipla Medpro before launching its escitalopram generic, we call upon you to provide a list of those further patents. In the absence of such further patents Cipla Medpro will feel free to launch its escitalopram generic as soon as it can after the MCC registration procedure has been completed.
- 7. We await your urgent response to the matter raised in paragraph 6.'

It is clear from this letter that the respondent's generic drug falls within the scope of the product claims of the patent. Accordingly the distribution, marketing and selling of the respondent's generic drug will infringe the patent. It is also clear from the letter that the respondent wishes to enter the market before the patent expires and thereby gain an advantage over other generic companies. As soon as the respondent has obtained registration of its product, it intends to market and promote its infringing product in competition with the applicants' CIPRALEX product. The respondent states that it intends to market and sell its products at a lower price than that of the second applicant.

- [5] It will be noted that Bacon alleged only two grounds of invalidity: (1) that the patent was anticipated by US patent number 4, 136, 193 and (2) that claim 7 is incomprehensible.
- [6] Informed by this letter that the respondent would infringe the patent the applicants launched this urgent application on 17 March 2008, seeking in the notice of motion correction of the errors alternatively amendment of the patent by making changes to claim 7 and an interim interdict for infringement. The founding papers are relatively modest in extent, consisting of 184 pages. In answer the respondent filed a compendious 629 page opposing affidavit. This necessitated a lengthy reply by the applicant in a 640 page replying affidavit. Shortly before the hearing the respondent filed a fourth set of affidavits and at the hearing the applicant filed a fifth set of affidavits. The parties agreed, subject to the court's discretion, that both additional sets of affidavits should be filed. I ruled that the parties should address the court on all the affidavits, including the fourth and fifth sets of affidavits, and that I

would decide at the end of argument whether the two sets of affidavits should be received. In dealing with these new affidavits the respondent's counsel states that the respondent does not wish to rely on the affidavit of one of the witnesses, Haralambos Parolis. After hearing argument my ruling is that the fourth and fifth sets of affidavits will be received.

- [7] In its answering affidavit the respondent's stance regarding the validity of the patent is somewhat different from that in Bacon's letter of 11 February 2008. Dr De Jongh, the respondent's medical director, contends that the patent is invalid for the following reasons:
 - (1) Claims 1, 3, 5 and 9 are not fairly based on the matter disclosed in the specification;
 - (2) The invention claimed in claim 1 is not patentable under section25 of the Act in that the claim's subject matter:
 - (i) was not new over the US patent number 4, 136, 193;
 - (ii) was not new over DF Smith, Neurosci. Biobehav. Rev. 10(1)37-46, 1986;
 - (3) Claim 1 is not clear, in that the determination as to whether an enantiomer of citalopram is the (+) or the (-) –enantiomer is

dependent on the conditions of testing, and is not a fixed characteristic of the substance itself;

- (4) Claim 6 is not fairly based on the matter disclosed in the specification, in that the specification describes an inversion of the stereochemistry from the intermediate to citalopram itself, whereas claim 6 claims a process in which the stereochemistry of the intermediate is maintained;
- (5) The invention claimed in claim 7 is not capable of being performed, in that the Variable "R" recited in the claim cannot be 'hydrogen of F, a labile ester;
- (6) The invention claimed in claim 8 is not patentable under section
 25, in that it was not new at the priority date, having been disclosed in US patent number 4, 650, 884;
- (7) Claim 8 is not fairly based on the matter disclosed in the specification;
- (8) Claim 9 is not clear.
- [8] With regard to the UK patent and the High Court of Justice's decision the present case has been overtaken by events in the UK. In the

Chancery Division Patent Court the learned judge described the attack on the patent in the following terms:

- '3. The challenges to the validity of the Patent are founded upon the prior art drug called Citalopram. This was first synthesised by Lundbeck in 1972 and launched as an antidepressant in Denmark in 1989. Citalopram is a racemate and so comprises (+) enantiomers and (-) enantiomers, as I shall explain. Escitalopram, on the other hand, comprises the pure (+) enantiomer. The Patent has seven claims of which claims 1, 3 and 6 are alleged by Lundbeck to have independent validity. Claim 1 is a product claim and is directed to the (+) enantiomer and salts thereof. Claim 3 is to a pharmaceutical composition in unit dosage form containing the compound of claim 1. Claim 6 is to a method of preparing the compound of claim 1 which comprises converting the (-) enantiomer of an intermediate made during the synthesis of citalopram to the (+) enantiomer, which is isolated as such or as a salt.
- 4. The attacks on the Patent can be summarised as follows:
 - Claims 1 and 3 are alleged to be invalid for lack of novelty over:
 - a) US patent number 4, 136, 193 ('193');
 - b) US patent number 4, 650, 884 ('884');

The lack of novelty attack turns upon a question of construction: does the claim exclude the (+) enantiomer in the racemate mixture? Lundbeck

has met this allegation with a conditional application to amend, which is opposed.

- Claims 1, 3 and 6 are alleged to be invalid for obviousness in the light of the 193 and 884 patents and common general knowledge;
- iii) Claims 1 and 3 are alleged to be invalid for insufficiency. It is said that the inventive concept disclosed by the Patent was not the idea of resolving citalopram. The scope of the invention lay, and lay only, in devising a way to obtain it. Claims 1 and 3 therefore extend beyond any possible inventive contribution of the Patent in that they monopolised all ways of arriving at (+) citalopram.'

On 4 May 2007 the Patent Court found that claims 1 and 3 of the patent are invalid for insufficiency but that the other grounds of invalidity could not be upheld. The court found claim 6 to be valid. The first applicant, the patentee, appealed against the finding and order of the Patent Court and the claimants for revocation cross-appealed. On 10 April 2008 the Court of Appeal of the Supreme Court of Judicature, upheld the patentee's appeal and dismissed the cross-appeal. Obviously this was not known to the parties when this application was launched and the respondent's opposing affidavits filed. The UK patent has therefore not been found to be invalid. Although I accept that the law of the UK is not the same as South African law the limited nature of the attack on the UK patent and the findings of the two courts

are significant. The claims of the patent and the UK patent are for all practical purposes identical.

- [9] The applicants' case is straightforward. Firstly, it is an application for the correction of clerical errors in the patent in terms of section 50 of the Act and secondly, it is an application for an interim interdict against the respondent. According to the argument, as registered patentee the applicant has at least a *prima facie* right and the respondent has clearly threatened an infringement of the patent. The applicants have no other satisfactory remedy and the balance of convenience clearly favours the applicants. They have an established market and, if launched, the respondent's product will make inroads into that market whereas the respondent has not launched its product and has not built up any market for its product.
- [10] According to the respondent the case is anything but straightforward. The respondent raises two main defences in its affidavits and heads of argument. Firstly, the respondent contends that without the correction of the clerical errors or the amendments, the patent is not valid and no relief can be granted on the patent. The respondent contends for a number of reasons that the corrections/amendments cannot be granted. Secondly, the respondent contends that even if the corrections/alterations are granted, the applicants have failed to make out a case for interim relief. In particular the respondent contends that

the validity of the claims in the patent are extremely doubtful in view of the evidence.

- [11] It is common cause that if a claim in the patent is invalid no interim relief may be granted on the patent. It is accepted by the parties that the statements to this effect in *Deton Engineering (Pty) Ltd and Another v John Paul McKelvey* 1995 BP 228 (CP) at 236E-239B are correct. See also the comment by the court to this effect in *Medpro Ontwikkelingsmaatskappy (Bpk) v Allan Maskew (Pty) Ltd* 1991 BP 138 (CP) at 152. Despite the obiter comments in *Pfizer Ltd and Another v Cipla Medpro (Pty) Ltd and Others* 2005 BIP 1 (CP) questioning the correctness of the statements in the *Deton Engineering* case the applicants' counsel did not seek to persuade this court that the statements are clearly wrong. It is therefore accepted that they are correct and that an invalid claim in the patent, until corrected or amended, is an insurmountable obstacle to the grant of relief for infringement of the patent.
- [12] The respondent contends that the claims in the patent cannot be corrected or amended for the following reasons:
 - there has been a culpable delay on the part of the applicants in seeking the correction/amendment of the patent;

- (2) the applicants are not seeking to correct clerical errors in terms of section 50 of the Act, they are seeking amendments of the patent in terms of section 51 of the Act.
- (3) this court has no jurisdiction to hear the application for amendment of the patent because there are no proceedings pending in respect of the patent;
- (4) the applicants have not made out a proper case for an amendment in terms of section 51 of the Act and they have not complied with the procedural requirements prescribed by the section;
- (5) the amendments of the patent sought in respect of claim 6 and 7 are in conflict with subsections 51(6) and (7) of the Act as they will either introduce a claim not fairly based on matter disclosed in the specification before amendment or not wholly within the scope of a claim included in the specification before amendment.

These issues will be dealt with in turn.

[13] The respondent contends that there has been a culpable delay on the part of the applicants in seeking to correct/amend the patent and that on this ground the court should refuse to grant the

corrections/amendments sought by the applicants. The applicants' counsel agree that culpable delay may be taken into account by the court and justify the refusal of both applications to correct clerical errors in terms of section 50 and applications for amendment in terms of section 51. However they argue that the evidence does not support a finding that there has been culpable delay.

[14] In Barmac Associates Ltd v SA Dynamics 1991 BP 16 (CP) at 20G

the Commissioner formulated the test for culpable delay as follows:

'A delay is culpable if there is a deliberate intention to delay knowing full well that some of the claims are invalid and there is proof that the patentee knowingly and deliberately maintained claims of unjustified width'.

In support of this test the Commissioner referred to **SA Druggists Ltd v Bayer AG 1989 (4) SA 103 (A)** at 107-8. There the Appellate Division approved of the following statements of the court *a quo*:

'The legal position on the question of delay on the part of the 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 these he has created an area which prevented competitors from freely entering it.'

The learned author of **Burrell's** *South African Patent and Design Law* **3 ed** comments in paragraph 8.15.3:

'A delay on the part of a patentee in bringing an application to amend the patent specification can found the basis of opposition to the grant of the application but such a delay should only disentitle the patentee of an amendment if the patentee had endeavoured to misuse the patent, for instance by seeking to rely on it knowing full well of its inutility; delay without prejudice to someone cannot be relied upon.'

[15] The facts:

(1) In its founding affidavit deposed to by John Meidahl Pedersen, the first applicant's divisional director of corporate patents, the first applicant does not explain the delay between the grant of the patent in 1990 and the launch of this application in 2008. The respondent attached to its answering affidavit a copy of the first applicant's declaration filed in the US Patent Office in support of the first applicant's application for the reissue of US Patent No 4, 943, 590 which corresponds to the patent. The first applicant sought the reissue of the US patent because of errors in the patent, including claims 11 and 12, which correspond with claims 6 and 7 of the patent. The declaration said:

'The errors above identified first came to light shortly before April 27, 1993, when our in-house Danish Patent

Agent, John Meidahl Pedersen studied the corresponding Canadian Application in connection with the preparation of instructions to be given to our United State's attorney, Gordon W. Hueschen, to be transmitted to his Canadian associate for a response to an outstanding office action in the said corresponding Canadian Application. Upon further search, the errors involved were found to exist in all of the applications filed in this family of patents throughout the world.'

(2) The in-house Danish Patent Agent who discovered the errors is the same John Meidahl Pedersen who is the applicants' main deponent. In his reply Pedersen attempts to explain the failure to rectify the errors in the patent. He says that although the first applicant learned about the errors in about 1992 and 1993, the fact that the errors had not been corrected in claim 7 was only discovered in February 2008. Mr Pedersen goes on to say:

> 'In preparing an urgent application for a temporary interdict, the first applicant considered the alleged grounds of invalidity raised by the respondent in the fax. It was at this time that the first applicant realised that there were errors in claim 7 of the LUNDBECK patent. These errors had been corrected in other jurisdictions during prosecution and I was surprised to see that the errors had not been corrected in the LUNDBECK patent. This is because around 1993 and 1994, after these errors had been corrected in the United States of America I had reviewed all of the corresponding applications at the time and had effected corresponding corrections. However, in February 2008, while preparing the present application, I

noted that the LUNDBECK patent had proceeded to grant on 25 April 1990, and that around 1993 and 1994 when I had conducted my review of the corresponding patent applications, the LUNDBECK patent had already proceeded to grant. I realised then, i.e. in February 2008, that the granted LUNDBECK patent had not been included in my review of the corresponding pending patent application.'

- (3) Despite the unambiguous statements in the declaration Mr Pedersen attempts to draw a distinction between the corresponding patent application and the corresponding patents which had already been granted.
- (4) The respondent's counsel rightly criticised Mr Pedersen's evidence on the issue of delay. Despite being involved in the discovery of the errors and their correction he does not directly explain the first applicant's failure to rectify the errors before launching this application in 2008, a delay of about 15 years. I find his evidence disingenuous and unconvincing. It also appears to be contradicted by the error in the patent granted in Portugal on 12 May 1994.
- (5) If the first applicant discovered the errors in the patent in 1992/1993 it obviously did not seek to remedy them until the respondent announced that it intended to launch a competing product in South Africa and thereby infringe the patent. The inference is unavoidable that the first applicant decided to do

nothing to rectify the errors in the patent well knowing that they affected the validity of the patent, until it was challenged. Although the respondent has not demonstrated any prejudice the existence of the patent created an area which prevented competitors from freely entering there. That would seem to be good reason for refusing the correction of the errors or the amendment of the patent.

- [16] With regard to the correction of the clerical errors or amendment of the patent the applicant seeks final relief on notice of motion. Obviously, if the facts are not in dispute, the relief may be granted if the facts justify the grant of such relief. However where the facts are in dispute the rules set out in *Plascon-Evans Paints Ltd v Van Riebeeck Paints* (*Pty*) *Ltd* 1984 (3) SA 623 (A) at 634D-635D must be applied. Accordingly, where neither party seeks leave to cross-examine any witness, final relief can be granted only where the facts alleged by the respondent together with the facts alleged by the applicant and admitted by the respondent justify the grant of the relief.
- [17] As different considerations apply to corrections of clerical errors and amendments it is important for the applicants to establish that they in fact seek to correct clerical errors. The importance of the distinction lies in the relief which may be granted. In terms of section 50 of the Act a correction of a clerical error in a patent may be permitted which would materially alter the scope of the patent whereas subsections

51(6) and (7) expressly prohibit the amendment of a patent specification if the amended specification 'would include any claim not fairly based on matter disclosed in the specification before amendment' or 'will include any claim not wholly within the scope of a claim included in the specification before amendment'. In the present case there is little or no evidence to show how the errors occurred.

[18] In paragraph 28 of the applicants' founding affidavit Mr Pedersen explained the errors in claim 7 as follows:

> 'I submit the aforementioned errors arose by mistake, inadvertently and unintentionally. I can only assume that the errors arose because of a shortcoming in the communications between the inventor and the First Applicant's draftsman or due to an error in the transcription of the instructions by the draftsman. The draftsman was the first applicant's previous inhouse counsel, Mr Holden Nielsen. Mr Nielsen retired in 1990, and has subsequently passed away.'

The use of the words 'submit' and 'assume' show that Mr Pedersen has no personal knowledge of the facts. Although personally involved when the errors in the patents were discovered it is striking that he does not state how the errors occurred. It is also striking that he does not set out any facts to justify his assumption or inference. He also does not attach the instructions which must have been given to the draftsman of the patent in South Africa. Nor does he attach any final document containing the correct claims to demonstrate how the claims would have read if the instructions had been properly executed. The explanation is so vague it is difficult to make sense of it.

[19] The respondent also does not have direct evidence to explain how the errors occurred. The respondent relies on the declaration already referred to. The first applicant applied for the reissue of the US patent because it contained errors which affected its validity, including errors in the claims corresponding with claims 6 and 7 of the patent. The declaration explains these errors as follows:

'That such errors and/or omissions arose by accident, inadvertence, and mistake and without any deceptive intent, and apparently arose because of an unfamiliarity with or poor choice of the nomenclature relating to the involved compounds by our prior in-house patent agent, or because of some shortcoming in the communications between the inventors and P. Holden Nielsen, and is otherwise inexplicable.'

Clearly this is not a statement of fact. The use of the word 'apparently' indicates that the facts had not been established and that an assumption had been made or an inference drawn. Significantly, three possibilities are referred to: (1) an unfamiliarity with or poor choice of the relevant nomenclature on the part of the patent agent; (2) a shortcoming in the communication between the inventors and the patent agent; (3) they are otherwise inexplicable.

The respondent rightly contends that possibilities (1) and (2) are amendable errors and not clerical errors. See *McCauley Corporation Ltd v Brickor Precast (Pty) Ltd* 1989 BP 314 (CP) at 331G-332F: *Hokuriku Pharmaceutical Co Ltd v Cipla-Medpro (Pty) Ltd* 1999 BIP 384 (CP) at 385C-387A.

[20] It is striking that even at that stage when the facts were fresh in everyone's minds the first applicant could not provide accurate factual information relating to the manner in which the errors arose. Obviously, not even the two inventors who were available (they signed the declaration) could explain where things had gone wrong.

This unsatisfactory explanation relates to the errors which occurred in all the first applicant's patents corresponding with the patent. According to the declaration 'the errors involved were found to exist in all of the applications filed in this family of patents throughout the world.'

[21] The respondent correctly points out that the explanation for the errors in the declaration does not tally with that in the founding affidavit. In 2008, some 14 years later, Mr Pedersen states that the errors arose 'due to an error in the transcription of the instructions by the drafstman'. He now does not refer to the 'unfamiliarity with or poor choice of nomenclature' by the patent agent. The similarity in the wording of the declaration and the founding affidavit indicates that Mr Pedersen had the declaration available when he made his affidavit.

[22] In the first applicant's replying affidavit Mr Pedersen still provides no facts. He says –

'I specifically deny that the errors arose as a consequence of a deliberate intention on the part of the draftsman, as alleged, and submit that I believe the errors arose through carelessness in the drafting in the patent specification. With reference to what is stated in the founding affidavit of Prof. Stephen Davies, i.e. paragraphs 52-61 it is submitted that, if the drafter of the specification of the LUNDBECK PATENT, Mr Holden Nielsen, checked the patent specification carefully before filing, he would have noted the clerical errors in claim 7.'

- [23] The applicants rely heavily on the evidence of the expert witnesses to establish that the errors are clerical errors. This evidence is opinion evidence that the claims contain errors which must be ignored if sense is to be made of the claims. They do not explain how the errors occurred. That is a factual issue. In my view there are no facts to justify a finding that the errors are in fact clerical errors. The applicants have therefore not established that the errors are clerical errors and the application must be considered as an application for amendment in terms of section 51 of the Act.
- [24] If the application is an application for amendment in terms of section 51 of the Act the respondent contends that the court does not have

jurisdiction to hear the application because of the provisions of section 51(9) of the Act. The subsection reads:

'Where any proceedings relating to an application for a patent or a patent which are pending in any court, an application for the amendment of the relevant specification shall be made to that court, which may deal with such application for amendment as it thinks fit but subject to the provisions of subsections (5), (6) and (7), or may stay such pending proceedings and remit such application for amendment to the Registrar to be dealt with in accordance with subsections (2), (3) and (4).'

[25] The argument focuses on the word 'pending' in subsection 51(9). The crux of the argument is that the use of the participle makes it clear that the proceedings must be extant when the application for amendment is made to the court. The respondent contends that when the application for amendment was launched there were no proceedings pending relating to the patent. The applicant seeks firstly to amend the patent and secondly to obtain an interim interdict and the combination of the application for amendment and the application for the temporary interdict is clearly designed to circumvent the clear provisions of section 51 which require a full explanation to the Registrar, advertisement and an opportunity for opposition. The applicants contend that the use of the word 'pending' does not preclude the procedure adopted of applying for an amendment together with an interim interdict.

[26] In my view the use of the word 'pending' does not have the limited meaning contended for. The subsection refers to 'any proceedings relating to an application for a patent or a patent' which are pending in any court. As pointed out in *CIR v Ocean Manufacturing Ltd* 1990 (3) SA 610 (A) at 618H:

> "Any" is "a word of wide and unqualified generality. It may be restricted by the subject-matter or the context, but *prima facie* it is unlimited" (Per Innes CJ in *R v Hugo* 1926 AD 268 at 271.) "In its natural and ordinary sense, 'any' – unless restricted by the context – is an indefinite term which includes all the things to which it relates". (Per Innes JA in *Hayne & Co v Kaffrarian Steam Mill Co Ltd* 1914 AD 363 at 371)'

The moment proceedings relating to a patent are instituted in a court and until they have been concluded there are such proceedings pending. That is the ordinary meaning of the word 'pending' and it is appropriate in the context of subsection 51(9).

[27] The respondent contends that urgent relief in terms of section 51 of the Act is inappropriate as the applicant must satisfy all the requirements of the section regarding the full explanation to the Registrar, advertisement and furnishing an opportunity for interested parties to oppose. In my view there is no reason why urgent relief cannot be granted provided that there is no prejudice to interested parties. In my view the objection is largely dealt with in subsection 51(9). It provides expressly that the court to which the application for amendment is

made may stay the pending proceedings and remit the application for amendment to the Registrar to be dealt with in accordance with subsection (2), (3) and (4). The court therefore has a discretion to order that the normal procedure be followed. An urgent application for amendment will not exclude this discretion and may prevent the matter from being dealt with urgently. Obviously where the applicant applies to court for the amendment of a patent the application will disclose the nature of the amendment sought and the reasons for seeking it. In the present case the applicants have disclosed the nature of the amendments sought and their reasons for seeking them. However I am not persuaded that the normal procedure must be followed. This objection therefore cannot be upheld.

[28] Finally, the respondent contends that the amendments sought in respect of claims 6 and 7 will offend against subsection 51(7) as the claims as amended would not be wholly within the scope of a claim included in the specification before amendment. The limitations contained in sections (5), (6) and (7) of section 51 are fundamental to the scheme of the Act. Their purpose is to ensure that the patentee does not obtain a priority date to which it is not entitled and does not broaden its monopoly. See *Kimberly-Clark of South Africa v Proctor & Gamble SA (Pty) Ltd* 1998 BIP 228 (SCA) at 236C-G.

[29] The effect of the amendments will be as follows:

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(1) <u>Claim 6</u>

Claim 6 is a method claim which essentially claims the preparation of a (+) –citalopram by stereoselective conversion of the (+)-enantiomer of the specified intermediate (or a monoester thereof). The applicants seek to amend the claim by the inversion of the optical sign of the intermediate. This amendment would result in the claim covering a method whereby (+)-citalopram is produced by the (-) intermediate. This would cover a different process – the (-) intermediate to (+)-citalopram, rather than (+) intermediate to (+)-citalopram as it currently reads. The patent as amended would therefore include a claim not wholly within the scope of a claim before amendment;

(2) <u>Claim 7</u>

Claim 7 is a product claim to the (+)-enantiomers of compounds of the illustrated formula. The applicants seek to amend the claim firstly by deleting the phrase 'of F' and substituting it with the word 'or' and secondly by substituting '(+)' in the claim with '(-)'. The amendment of the optical sign would have the effect of claiming the (-)-intermediate, the opposite enantiomer to that presently claimed. The (-)-intermediate presently does not fall within the scope of any claim of the patent. The amendment would therefore result in the patent including a claim not wholly within the scope of a claim before amendment.

Both amendments would therefore offend against section 51(7) of the Act.

[30] In the absence of correction or amendment of the errors in the claims the patent is not wholly valid and no relief can be granted on it.

<u>Order</u>

- [31] (1) The application for correction/amendment of the patent is dismissed;
 - (2) The application for an interim interdict is dismissed;
 - (3) The applicants are ordered, jointly and severally, to pay the costs of the application, such costs to include the costs consequent upon the employment of two counsel.

B.R. SOUTHWOOD JUDGE OF THE HIGH COURT CASE NO: Patent 89/4476

HEARD ON: 22 May 2008 to 23 May 2008

FOR THE APPLICANT: ADV. J.W. LOUW SC ADV. C.J. VAN DER WESTHUIZEN

INSTRUCTED BY: Mr Whittaker of Spoor & Fischer Attorneys

FOR THE RESPONDENT: ADV. C.E. PUCKRIN SC ADV. R. MICHAU

INSTRUCTED BY: Mr Ball of Brian Bacon & Associates Inc.

DATE OF JUDGMENT: 20 June 2008