

SOUTH AFRICA / JUDGMENT

Bayer Intellectual Property GMBH and Others v Dr Reddy's Laboratories (Pty) Ltd (22237/21; 2007/06238-5) [2022] ZACCP 1; 2022 BIP 291 (CP); [2022] HIPR 188 (CP) (1 March 2022)

[2022] ZACCP 1

COURT

Court of the Commissioner of Patents

BEFORE

R Keightley

CASE / FILE NUMBER

22237/21; 2007/06238-5

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REPUBLIC

OF SOUTH AFRICA

IN

THE COURT OF THE COMMISSIONER OF PATENTS

FOR

THE REPUBLIC OF SOUTH AFRICA

CASE

NO: 22237/21

2007/06238-5

REPORTABLE: NO

OF INTEREST TO OTHER

JUDGES: NO

REVISED.

1st/3/2022

In

the matter between:

BAYER
INTELLECTUAL PROPERTY GMBH
&
TWO
OTHERS
First to third applicants
(Respondents in
application for leave to appeal)
And
DR
REDDY'S LABORATORIES (PTY) LTD
Respondent
(Applicant in application
for leave to appeal)

JUDGMENT

IN APPLICATION FOR LEAVE TO APPEAL

KEIGHTLEY, J:

INTRODUCTION

1. The respondent in the main application, Dr Reddy's, seeks leave to appeal my judgment dated 15 December

2021. In that application I concluded that:

"... (the applicants) has satisfied all the requirements for the grant of an interim interdict protecting its rights under the patent-in-suit. I make the following order:

1. Pending the final determination of the patent infringement action which has been instituted by the applicants against the respondents in respect of South African Patent No. 2007/06238, the respondent is interdicted and restrained from infringing the claim of South African Patent No. 2007/06238 by using, disposing of or offering to dispose of the product RIVAXORED (or any other product falling within the scope of the claim of the patent) in the Republic and by importing any such product into the Republic.
2. The respondent is ordered to pay the costs of this application, including the costs of counsel and the qualifying fees of the applicant's expert witnesses."
2. Despite the express grant of the relief in the form of an interim interdict, Dr Reddy's contends that the judgment and order is appealable. The applicants in the main application, whom I shall refer to collectively as Bayer, contend otherwise.

3. Dr Reddy's does not dispute that the application in the interdict application was brought, and dealt with by both parties, on the basis that Bayer sought interim relief. Nor do they dispute that judgment dealt with the matter on the basis that interim relief was granted. However, they submit that the judgment was final in effect, that I made "several final findings"

in my order, and that for this reason it falls into that category of judgments that are susceptible to appeal. Alternatively, they contend that it is appealable based on the requirement of the interests of justice.

PRINCIPLES APPLICABLE TO THE QUESTION OF APPEALABILITY

4. It is trite that at common law interim interdicts generally are not appealable. As was stated in the still-applicable principles laid down in *Zweni*:

"A 'judgment or order' is a decision which, as a general principle, has three attributes, first, the decision must be final in effect and not susceptible of alteration by the Court of first instance; second, it must be definitive of the right of the parties; and third, it must have the effect of disposing of at least a substantial portion of the relief claimed in the mains

proceedings."^[1]

5. This is not a closed list of requirements.^[2] It is sometimes said that an order has "final effect" if it causes prejudice to the unsuccessful party. However, what is meant by "prejudice" in this context, is specific. It does not mean a generally disadvantageous outcome for that party. Instead, the question is whether the order is prejudicial because it "affects the final determination of an issue in the suit or stands in the way of an issue being determined at a later date."^[3] In other words, the guiding element of finality is that the order will not be reconsidered by the court that granted it.^[4]
6. The Constitutional Court has stressed that the test for appealability of interim orders must be developed and applied in line with constitutional requirements and, most importantly, the interests of justice. In *City of Tshwane Metropolitan Municipality v Afriforum and Another*, that Court explained that:

"The appealability of interim orders in terms of the common law depends on whether they are final in effect... The common law test for appealability has since been denuded of its somewhat inflexible nature. Unsurprisingly so because the common law is not on par with but subservient to the supreme law that prescribes the interests of justice as the only requirement to be met for the grant of leave to appeal. Unlike before, appealability no longer depends largely on whether the interim order appealed against has final effect or is dispositive of a substantial portion of the relief claimed in the main application. All this is now subsumed under the constitutional interests of justice standard. The over-arching role of interests of justice considerations has relativised the final effect of the order or the disposition of the substantial portion of what is pending before the review court, in determining appealability".^[5]

7. Despite this statement of law, the jurisprudence of the Constitutional Court makes it clear that the finality of the order remains an important requirement, albeit that it must be weighed with the interests of justice. This is evident, for example, in its dictum in *National Treasury and Others v Opposition to Urban Tolling Alliance and Others*:

“This court has granted leave to appeal in relation to interim orders before. It has made it clear that the operative standard is the “interests of justice”. To that end, it must have regard to and weigh carefully all germane circumstances. Whether an interim order has a final effect or disposes of a substantial portion of the relief sought in a pending review is a relevant and important consideration. Yet, it is not the only or always decisive consideration. It is just as important to assess whether the temporary restraining order has an immediate and substantial effect, including whether the harm that flows from it is serious, immediate, ongoing and irreparable.”[6]

FINALITY OF THE JUDGMENT AND ORDER

8. Dr Reddy’s contends that my judgment and order has final effect because, at paragraph 59 of my judgment, I stated, allegedly erroneously, that:

“Dr Reddy initially placed the issue of obviousness in dispute by contending that the patent did not involve an inventive step. However, at the hearing of the matter, counsel indicated that, insofar as the validity of the claim was concerned, it would only

persist in its submissions that the patent was an invalid Swiss form claim, and that it should be revoked on the basis of Bayer’s alleged misrepresentation at the time the patent was submitted for registration. It did not persist with its challenge based on obviousness.”

9. The submission seems to be that in effect I found that Dr Reddy’s had abandoned its attack based on obviousness for all intents and purposes. As such, so the submission continues, Dr Reddy’s will be precluded from relying on the obviousness attack in the pending revocation application and trial, as I have found it to have abandoned this attack, not only for the interim interdict application before me, but also for the pending litigation. Consequently, it concludes that my judgment has final effect on this

issue.

10. Read on its own this paragraph might perhaps support the submission. However, the paragraph was but one of many in a thirty-seven-page judgment. It is perfectly clear from a reading of my judgment as a whole that I did not find that Dr Reddy’s had abandoned its obviousness attack, and that, going forward and for the purposes of all pending litigation, that attack was a legal dead letter.

11. First, as the matter was dealt with by myself and the parties as an application for an interim interdict, I could not have made such a finding anyway: all of my findings were expressly stated to be of a prima facie nature. There are numerous markers in my judgment making this very clear.

12. In paragraph 5 of the judgment, I state that:

"It can be safely said that the present application is but the first step in what will not no doubt be extensive further litigation between the parties. However, it is important to bear in mind that in these proceedings I am concerned only with the application by Bayer for interim relief, and any findings I make on the broader issues in dispute will be on a prima facie basis."

13. In addition, the question of obviousness also arose for discussion in connection with the attack by Dr Reddy's on Swiss form claims, with which they persisted before me. During the course of analysing the relevant case law and evidence on this issue, I noted that obviousness seemed to me to be a relevant factor in assessing whether a dosage regimen was objectionable or not. In further discussion, at paragraphs 62 and 63 of my judgment, I stated that:

"Insofar as it may be necessary to reach a conclusion in this regard, bearing in mind that Dr Reddy's does not persist with its obviousness challenge, like Fourie J, on the evidence before me, I am also of the view that it is not likely that a challenge based on obviousness will prevail at trial It follows that in my view, this matter is one of those where a patent in respect of a dosage regimen in the form of a Swiss claim is not objectionable under the Act. The facts establish, at least at a prima facie level, that the patent clears the hurdle of obviousness. There is persuasive evidence that based on the state of the art at the time, a once daily dose of rivaroxaban in the form of a rapid release tablet was not predictable, and thus it would not have been obvious to try it out. "

14. Insofar as any finding was made in respect of the obviousness issue, it was patently prima facie. What is more, I expressly anticipated that the issue of obviousness was not dead for purposes of further proceedings and that it would be traversed at the trial. Further, I would not have had reason to traverse the issue of obviousness in the context of the attack on Swiss form claims if I had understood, and found, that Dr Reddy's had evinced an intention to abandon the attack going forward, rather than simply for purposes of the application before me.

15. It was perfectly clear to me and the parties that all Dr Reddy's had done was to inform Bayer's legal representative and the court that for purposes of the interim interdict application it did not persist with its obviousness attack. This is clear from the following extract from the transcript:

[...]. M'lady may I turn back to the case, if my learned friend would permit me? I have discussed the case with my learned friend ...[intervenes]

COURT: Yes.

MR PUCKRIN: Whom I might say is not only my learned, but my very good friend, and has acted as a gentleman throughout. I am going to make everyone's life much easier. If I might ask Your Ladyship to turn to our Heads of Argument ...[intervenes]

COURT: Yes?

MR PUCKRIN: I will give you the CaseLines reference ...[intervenes]

COURT: It is Q, I think. Q ...[intervenes]

MR PUCKRIN: Yes, Q28. This is the index.

COURT: Oh okay. Yes I am there.

MR PUCKRIN: Now M'ady you will see that the Bayer's patent is invalid, and stands to be revoked. We are going to argue (a) and (b).

COURT: Okay.

MR PUCKRIN: It is just claims which deal of course with section 25(9), 25(11), 67 and the like. We will deal with material misrepresentation.

COURT: Right.

MR PUCKRIN: M'ady I want to make it quite clear that we do not, in any way, abandon ... [intervenes]

MR PUCKRIN: Our attack on obviousness, [inutility], insufficiency, lack of fair basis and clarity for the purposes of the P20 proceedings ... [intervenes]

MR PUCKRIN: That are attached to the proceedings. I have had a bad experience before the Constitutional Court, where they split five all on here.

COURT: Okay. MR PUCKRIN: So I have told my learned friend ...[intervenes]

COURT: Am I understanding you correctly Mr Puckrin, for purposes of the interim interdict application, you will only speak to (a) and (b)?

MR PUCKRIN: Yes. COURT: But you are placing on record that when it comes to all the issues at trial, those remain on the table?

MR PUCKRIN: Absolutely.

COURT: Yes, I understand. (my emphasis)

16. In this context, it is inconceivable that paragraph 59 of my judgment could possibly reasonably be read to embody a final finding that Dr Reddy's had abandoned its obviousness attack for all intents and purposes going forward, including for purposes of the revocation application.

17. In addition to the submission that I made a final finding on the abandonment of the obviousness attack, Dr Reddy's submits that I also made a final finding in paragraph 20 of my judgment. There, I stated the following:

"I have used the applicants' formulation of the integers but I do not understand Dr Reddy's formulation of the integers to differ in any substantive respect from them. I should add that although both parties identified E as being an integer of the claim, Fourie J recently found in Bayer v Austell that the half-life feature was a property of the drug and not an essential feature of it. Mr Puckrin SC, who appeared for Dr Reddy's, appeared to accept this in his oral, and subsequent supplementary written, submissions to the court. Nothing much turns on the issue of whether E is an essential integer or not." (my emphasis)

18. Dr Reddy's assertion is that my "finding" that Mr Puckrin appeared to accept that the half-life feature was not

an essential feature has final effect. The remainder of the paragraph puts paid to this contention. My statement is in general terms and was clearly merely an observation of the stance Mr Puckrin had taken in argument on the broader issues. It is simply not a finding that would be appealable in any sense at all. Even if it could be categorised as such, as stated over and over in my judgment, it would have been no more than a finding on a prima facie basis.

19. Dr Reddy's final contention on the question of finality of my order and judgment (save on the issue of costs) is that it is final in effect because the patent-in-suit will expire in 2026 and that the revocation application and trial will not be completed by then. In other words, even though interim in form, the practical effect of the order is that it will last for the remainder of the life-time of the patent.
20. This is an issue that was considered at length in Cipla SCA. In the minority judgment (erroneously referred to as the majority judgment in Dr Reddy's heads of argument) Rogers AJA, as he then was, found some force in the approach adopted in BHT Water Treatment (Pty) Ltd v Leslie and Another,[7] involving a restraint of trade dispute. The court in BHT found that although the relevant interdict had been sought on an interim basis, it was in substance final because the pending action would not be determined within the 12-month restraint period remaining. As is noted in the judgment in Cipla SCA, other courts had found differently on this issue. Neither the minority nor majority judgments in Cipla SCA made findings on whether the approach to finality and appealability in BHT was correct. However, the minority judgment of Rogers AJA found it more persuasive, and proceeded on the assumption, without making a finding, that BHT was correct. Notwithstanding this, Rogers AJA cautioned that:

"On that assumption, there are two points to be made. Firstly, the BHT approach should be confined to cases where it is clear, at the time the court grants the interdict, that the matter will not be able to be finally determined before the interdict in any event expires. BHT and Reddy were cases of that kind. The trial court cannot be expected to engage in speculative crystal-ball-gazing. Second, the BHT approach is concerned with whether the trial court will have opportunity to decide the case finally, given the limited duration of the legal restraint. The fact that an appeal from the trial court's final decision could not be

finalised before the expiry of the legal restraint is, as Cronshaw shows, irrelevant. An interdict, interim in form, could only be regarded as a final order of the trial court if the trial court would not have the

opportunity, before the expiry of the legal restraint, of deciding the matter on a final basis.”[8] (my emphasis)

21. The majority in Cipla SCA found that the facts of the case before it was on par with the facts that were before the court in Cronshaw.[9] As in Cronshaw, the court a quo had been approached for relief on the basis of an application for an interim interdict pending an action that would finally determine the issues between the parties. The matter had been approached by the parties on the basis that interim relief was sought, and the court a quo expressly granted the order on the basis that the requirements for an interim interdict had been met. The majority in Cipla SCA concluded that:

“On the established principles in our law, the order granted was thus both in form and effect an interlocutory interdict and not

appealable.”

22. The facts in the present case are in line with those in Cronshaw and in Cipla SCA: the parties approached the matter on the basis that the relief sought was only interim, and my judgment made it quite clear that I considered the application and granted the relief on the same basis. It follows that, in accordance with the binding authority in Cipla SCA, my judgment and order are interim and not final in both form and effect.
23. But even if the minority judgment in Cipla SA were to be considered and applied to this case, it is clear that the requirements laid down by Rogers AJA are not met. It simply was not clear, at the time I granted the order, that the matter would not be finalised before the patent-in-suit expires. Indeed, there is no clarity even now that finality will not be reached by then. Dr Reddy’s asserts that the proceedings will take many years to reach finality, but in doing so, it engages in what both minority and majority judgments in Cipla SCA called speculative crystal-ball gazing. Submissions of this kind do not establish a proper basis on which to find that despite its patently interim nature, an order of court is final in effect. In any event, as Rogers AJA noted, the relevant time for determination is when the order was granted. Events that have occurred subsequently, and upon which Dr Reddy’s made much of, are irrelevant.
24. I conclude, for these reasons, that my judgment and order were interim in both form and effect.

INTERESTS OF JUSTICE

25. It was submitted on behalf of Dr Reddy’s that in this case the interests of justice render the judgment and order appealable. It was contended that this was because there is an urgent need for more accessible and cheaper direct-acting oral anticoagulants (DOACs), such as rivaroxaban, in South Africa, particularly in the public health sector. As such, so it was contended, Dr Reddy’s should be permitted to continue to sell its generic product in South

Africa sooner rather than later. In other words, it is not in the public interest to prolong the effect of the interdict for interim period until the trial and revocation application are determined. On this basis, despite the interim and not final nature of the order, it should be found to be appealable.

26. There was no evidence placed before me that established that Dr Reddy's was already supplying its generic product to the public health sector and that this sector would be jeopardised significantly by the operation of the interim interdict. It was challenged to do so in the application, but did not meet this challenge. There was also no hard and fast evidence to show as a matter of fact how the interim interdict against the continued distribution of Dr Reddy's product would impact on the private health service. The fact that in principle it would be better to have wider access to DOACs in the health system is not sufficient to establish a basis to find that the requisite interests of justice ought to render the order appealable.
27. I conclude, for the above reasons, that my order and judgment are not appealable. However, in the event that I may be incorrect in this finding, and as a matter of caution, I consider, nonetheless, whether a case has been made out for leave to appeal to be granted.

ALTERNATIVELY, SHOULD LEAVE BE GRANTED?

28. Under s17(1)(a) of the Superior Courts Act, leave to appeal may only be given where the Judge is of the opinion that the appeal
- (i) would have a reasonable prospect success or (ii) there is some other compelling reasons why the appeal should be heard, including

conflicting judgments on the matter under consideration. The test for granting leave under this section is well settled. The question is not whether the case is arguable or another court may come to a different conclusion.[10] Further, the use of the word "would" in s 17(1)(a)(i) imposes a more stringent and vigorous threshold test than that under the previous Supreme Courts Act,

1959. It indicates a measure of certainty that another court will differ.[11] The Mont Cheveaux test was endorsed by a Full Court of this Division in the unreported case of Zuma & Others v the Democratic Alliance & Others.[12]

29. As to the prospects of success, Dr Reddy's application for leave to appeal comprised a 52-page document that can hardly be described as a typical application for leave to appeal. Indeed, it reads like heads of argument, or possibly the draft of the

judgment

that Dr Reddy's would have preferred me to write. Essentially, and save for the order of costs which it seeks to appeal, in its application for leave to appeal, Dr Reddy's traverses all of the submissions it made before me when I heard the matter for the first time. There is nothing really new in substance. I have dealt fully with all the submissions in my original judgment.

There is always some prospect that another court might find differently. However, I am not persuaded that in this case there is a prospect that it would do so.

30. It was also submitted on Dr Reddy's behalf that leave to appeal was warranted on the basis that there were conflicting judgments in England on the issue of Swiss form claims. As discussed at length in my judgment, while English law has some relevance, it is South African law that prevails. Conflicting judgments in English law are thus hardly a compelling reason to grant leave to appeal in this case.

APPEAL AGAINST THE COSTS ORDER

31. In my order I granted costs in favour of Bayer. Dr Reddy's applies for leave to appeal that order on the basis that it is usual in matters of this nature that costs be costs in the cause. Although costs orders have final effect, appeals against costs

orders on their own are not generally permitted. In this regard, the Constitutional Court has noted that:

"Few appellate courts countenance appeals on costs alone, and indeed the statute regulating appeals from a High Court to a Full Court or the Supreme Court of Appeal has long provided that an appeal may be dismissed on the sole ground that the decision sought 'will

have no practical effect or result' and that, save under exceptional circumstances, the question whether there would be any

practical effect or result must be determined 'without reference to any consideration of costs'. The practical impact

of this provision is that appeals on costs alone are allowed very rarely indeed."

[13] The quotations in inverted commas in this paragraph of the judgment are from s 16(2)(a) of the Superior Courts Act.

32. This in itself is reason to refuse the application for leave to appeal against the costs order alone. In any event, it is accepted as a general principle that costs are always at the discretion of the court. An appeal court may only interfere unless the court a quo misdirected itself by reaching a decision which could not have reasonably been made if it had properly applied itself to the facts and principles.
33. It is not a hard and fast principle that costs in interim patent infringement applications should be reserved for determination at, or follow the result of, the trial. Recently, in a very similar matter involving Bayer and rivaroxaban, this Court granted an order of costs against the respondent.[14] Dr Reddy's identifies no misdirection on my part, save for my not having applied what it says is the usual approach. Bayer applied for an order of costs, alternatively an order that costs be reserved for determination at the trial. It never abandoned its primary prayer for costs to be granted in its favour in the event that I granted the interdict. Indeed, at the commencement of the hearing, as I noted in my original judgment, Dr Reddy's elected

not to proceed with a substantial portion of its defences for purposes of the application for the interim interdict. Bayer placed on record at that time that it had incurred substantial expense in preparing to oppose those portions of Dr Reddy's defences which were later abandoned. Bayer submitted that this should have implications for the issue of costs.

34. It is difficult to see, in these circumstances, that there are reasonable prospects that another court would find that I misdirected myself on the question of costs.

CONCLUSION, COSTS AND ORDER

35. I find that paragraph 1 of the order I granted is not appealable, alternatively, and if I am wrong in this regard, that there are no reasonable prospects of success on appeal or any other reason permitting a grant of leave to appeal under s 17(1)(a) of the Superior Courts Act. As to paragraph 2 of the order, dealing with costs, I find that there are also no reasonable prospects of success.
36. Bayer submitted that if the application for leave to appeal was dismissed a punitive costs order was warranted on the basis that there was clearly no merit in the application and that it was an abuse of the appeal process. While there are aspects of the application that in my view warrant criticism, such as the format and length of the notice of application for leave to appeal, and the fact

that Dr Reddy's filed an affidavit of almost 200 pages in support of its application, I am not persuaded that an attorney and clients cost order would be appropriate.

37. In the circumstances, I make the following order:

"The application for leave to appeal is dismissed with costs, such costs to include those of two counsel."

R KEIGHTLEY

JUDGE OF THE HIGH COURT

GAUTENG LOCAL DIVISION

This judgment was prepared and authored by the Judge whose name is reflected and is handed down electronically by circulation to the Parties/their legal representatives by email and by uploading it to the electronic file of this matter on CaseLines. The date for hand-down is deemed to be 01 March 2022.

Date Heard (Microsoft Teams): 17 February 2022

Date of Judgment:

1 March 1, 12022

On behalf of the Applicant:

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N NYEMBE

Instructed by:

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On behalf of the Respondent: CE PUCKRIN SC

LG KILMARTIN

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VON SEIDELS ATTORNEYS

[1] Zweni v Minister of Law and Order 1193

(1) SA 523 (A) at 533I)

[2] Cipla Agrimed (Pty) Ltd v Merck Sharp Dohme Corporation and Others 2018

(6) SA 440 (SCA) at para 37 (Cipla SCA)

[3] Cipla SCA, para 40

[4] Minister of Cogta v De Beer 2005

(3) SA 1 (SCA) at para 96

[5] [2016] ZACC 19 at paras 39 and 40

[6] [2012] ZACC 18 at para 25

[7] 1993

(1) SA 47 (W)

[8] Para 24

[9] Cronshaw and Another v Coin Security Group (Pty) Ltd 1996

(3) SA 686 (A)

[10] R v Nxumalo 1939 AD 580 at 588

[11] Mont Cheveaux Trust v Goosen [20014] SALCC 20 (3 November 2014); Notshokuvo v S [2016] ZASCA 112 (7 September 2016))

[12] Case no: 19577/09, dated 24 June 2016

[13] Tebeila Institute of Leadership, Education, Governance and Training v Limpopo College of Nursing and Another [2015] ZACC 4; 2015 (4) BCLR 396 (CC), para 13

[14] Bayer Intellectual Property GMBH and Others v Austell Pharmaceuticals (Pty) Ltd, Commissioner of Patents judgement ZA2007-06238-(20May 2021)

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