

REPUBLIC OF SOUTH AFRICA



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

CASE / PATENT NO: 2007/06238-5

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

In the matter between:

BAYER INTELLECTUAL PROPERTY GMBH

First applicant

BAYER AG

Second applicant

BAYER (PTY) LTD

Third applicant

And

DR REDDY'S LABORATORIES (PTY) LTD

Respondent

J U D G M E N T

KEIGHTLEY, J:

INTRODUCTION

1. This is an application for an interim interdict restraining the respondent from infringing the claim of a South African patent by using, disposing of or offering to dispose of the anticoagulant medicament, Rivaxored in, or importing it into, the Republic, pending the final determination of a patent infringement action which has been instituted simultaneously by the applicants. The patent in question is South African Patent No. 2007/06238 (the patent or patent-in-suit): "*Prevention and Treatment of Thromboembolic Disorders.*" It relates to the manufacture of tablets marketed as Xarelto and iXarola, in which the active ingredient is rivaroxaban.
2. The applicants all form part of the corporate Bayer group of companies. The first applicant, Bayer Intellectual Property GmbH, is the registered proprietor of the patent-in-suit, and the second and third applicants are registered licensee's under it. For simplicity, I refer to the applicants collectively as Bayer.
3. The respondent is Dr Reddy's Laboratories (Pty) Ltd (Dr Reddy's), which is a company incorporated in South Africa. It is a wholly owned subsidiary of Dr Reddy's Laboratories Limited, which is a multinational pharmaceutical company located in Hyderabad, India. Dr Reddy's is a generic medicine supplier. It is common cause that Dr Reddy's launched its generic product, Rivaxored, which it imports from India, in South Africa on 31 March 2021. Bayer contends that this is an infringement of the patent-in-suit.
4. In the infringement action Bayer seeks a final interdict for the remaining life of the patent-in-suit, as well as damages. There is also ancillary litigation between the parties. On 1 April 2021, shortly prior to launching Rivaxored in South Africa, Dr Reddy's instituted an application to revoke Bayer's patent. Bayer filed its counter statement in that application, whereafter Dr Reddy's applied twice to amend its statement of particulars. As matters stood at the time the present application was

heard Dr Reddy's founding evidence in its revocation application had not yet been filed. Dr Reddy's has also filed a counterclaim in the infringement action in which they seek to set aside an amendment to the patent specification that was applied for and granted in August 2020 (the post-grant patent amendment).

5. It can safely be said that the present application is but the first step in what will 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.

TEST FOR INTERIM RELIEF

6. In order to succeed in an application for an interim interdict, an applicant must establish a *prima facie* right, though open to some doubt. It must satisfy the court that there is a well-grounded apprehension of irreparable harm if the interim relief is not granted and it ultimately succeeds in establishing its right. The balance of convenience must favour the applicant, and the applicant must have no other satisfactory remedy.¹
7. The test to be applied for purposes of determining whether, on the facts, the applicant has met these requirements is well established.

“The proper manner of approach I consider is to take the facts as set out by the applicant, together with any facts set out by the respondent which the applicant cannot dispute, and to consider whether, having regard to the inherent probabilities, the applicant could on those facts obtain relief at trial. The facts set up in contradiction by the respondent should then be considered. If serious doubt is thrown on the case of the applicant he could not succeed in obtaining temporary relief, for his right, *prima facie* established, may only be open to some doubt. But if there is mere contradiction, or an unconvincing explanation, the matter should be left to

¹ *L F Boshoff Investments (Pty) Ltd v Cape Town Municipality* 1969 (2) SA 256 (C) at 267

trial and the right be protected in the meanwhile, subject of course to the respective prejudice in the grant or refusal of interim relief.”²

8. This test was endorsed in *Gool*,³ subject to the clarification that the question is whether the applicant “should”, not “could”, on the applicant’s admitted facts obtain final relief at trial. In patent matters, where an interim interdict is sought, courts should refrain from making final findings, but nevertheless consider the relative strength of each party’s case. Each case must be decided on a basis of fairness, justice and common sense in relation to the whole of the issues⁴

9. Although other issues are placed in dispute, much of the present case turns on whether Bayer has established a *prima facie* right under the patent. Dr Reddy’s disputes that it has done so. It relies on its revocation application in which it has asserted that the invention claimed by Bayer under the patent is not patentable “*in that the invention claimed does involve an inventive step having regard to the matter made available to the public immediately prior to the priority date*”. As I discuss shortly, the claim in the patent is in what is commonly referred to as the Swiss form. Dr Reddy’s also contends that claims in this form are not permissible under South African law, alternatively, that the patent-in-suit is not a genuine Swiss form claim. It accepts that to succeed in its defence in the application it must place serious doubt on the validity of the patent.

2 *Webster v Mitchell* 1948 (1) SA 1186 (W) at 1189

3 *Gool v Minister of Justice and Another* 1955 (2) SA 682 (C) at 688 C-E

4 *Beecham Group Ltd v B-M Group (Pty) Ltd* 1977 (1) SA 50 (T)

THE PATENT-IN-SUIT

10. The patent-in-suit was filed in South Africa on 27 July 2007 as a national phase entry into South Africa from a Patent Co-Operation Treaty international application (PCT/EP2006/000431). It was granted on 26 November 2008. Its earliest priority date is 31 January 2005. The post-grant amendment of the patent was filed on 19 March 2020 and allowed on 3 August 2020. It is common cause that the patent-in-suit is in force and is due to expire on 19 January 2026. A copy of the complete specification and the register sheet of the patent is attached to the founding affidavit.
11. There is a single claim in the patent-in-suit demarcating the monopoly Bayer stakes out for itself. It is stated in the following terms:

“The use of the compound (rivaroxaban) for the manufacture of a medicament in an oral dosage form for the treatment of a thromboembolic disorders for administration no more than once daily for at least five consecutive days, where said compound has a plasma concentration half life of 10 hours or less when orally administered to a human patient, wherein the thromboembolic disorder is pulmonary embolism, deep vein thromboses or stroke, and wherein the oral dosage form is a rapid-release tablet.” (My emphasis)
12. Based on its claim, Bayer contends that the patent confers on it the exclusive right to manufacture oral, rapid-release rivaroxaban tablets which are to be taken no more than once a day for at least five days for use in the treatment of the identified thromboembolic disorders.
13. It is common cause that the underlined portion of the claim identifies that the claim is worded in the Swiss form. It is also common cause that until recently a separate patent held by Bayer was in force in respect of the compound, rivaroxaban. I refer to this as the compound patent. It expired in December 2020 and should not be

confused with the patent-in-suit. As later discussion highlights, one of Dr Reddy's complaints about the validity of the patent-in-suit is that it uses the same compound in respect of which an earlier patent was enjoyed.

14. The teaching of the patent-in-suit appears from the body of the specification. It instructs that the patent is concerned with the treatment of thromboembolic disorders, which are characterised by abnormal blood clotting. It explains that blood coagulation is a protective mechanism of the organism which helps to seal defects in the wall of the blood vessels quickly and reliably and thus to avoid blood loss. Maintenance of normal haemostasis, or the balance between bleeding and thrombosis (clotting), is subject to a complex regulatory mechanism. Uncontrolled activation of the coagulant system or defective inhibition of the activation processes may cause the formation of local thrombi or embolisms leading to serious thromboembolic disorders. These disorders are the most frequent cause of morbidity in most industrialised countries.
15. Certain anticoagulants were known from the state of the art at the priority date. These included vitamin K antagonists (like warfarin) and heparins. However, these anticoagulants were known from the prior art to have severe disadvantages. More recent approaches involved factor Xa inhibitors, like rivaroxaban, in the treatment of thromboembolic disorders. The compound patent was registered in respect of rivaroxaban in 2002, although rivaroxaban had not been approved for use as a medicament and was not sold commercially as at the priority date of the patent-in-suit.
16. The teaching of the patent recognises that oral and a less frequent dosage regime, preferably, once daily, is ideal due to patient compliance and convenience. However, this goal is sometimes difficult to achieve depending on the specific

behaviours and properties of the drug substance, especially its plasma concentration half-life. In other words, the time it takes for the plasma concentration of the drug in the body to be reduced by 50%. To avoid potential side effects, the drug substance must be applied in no more than a therapeutically effective amount. This means it must be given approximately every half life.

17. According to the teaching, the invention of the patent is explained as follows:

“Surprisingly, it has now been found in patients at frequent medication that once daily oral administration of a direct factor Xa inhibitor with a plasma concentration half life time of 10 hours or less demonstrated efficacy when compared to standard therapy and at the same time was as effective as after twice daily (bid) administration.”

18. In simple terms, Bayer says that the invention claimed in the patent is that because of what was known about the half-life of rivaroxaban at the priority date, while it was expected that at least a twice daily dosage would be the required regime to provide the balance between efficacy and patient safety, or less frequent dosage in the form of an extended release tablet, it had been found that a once daily dose in the form of a rapid release tablet had the same result.

19. In determining the validity and infringement of a patent (which is in issue here) a court must have regard to the essential integers or features of a claim.⁵ The features or integers of the claim in this case may be identified as being:

- A. The use of rivaroxaban in the manufacture of a medicament;
- B. The medicament being in the form of a rapid release tablet;
- C. The medicament being used for the treatment of pulmonary embolism, deep vein thromboses or stroke;

⁵ *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 646 (C)

D. For administration no more than once daily for at least five consecutive days;

E. Wherein the said compound has a plasma concentration half-life of 10 hours or less when orally administered to a human patient.

20. 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*⁶ 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.

21. It is common cause that integers A and C were known from the prior art at the priority date of the patent. In other words, that it was publicly known that rivaroxaban was a compound that could be used to treat thrombembolic disorders. Bayer also does not contest the fact that rapid release tablets were known from the prior art. It does contend, however, that the use of rapid release tablets (as opposed to extended release tablets) in this instance is an important element of its invention. What Bayer says is that its claim must be understood as a method of manufacture, or a process claim. In other words, a claim in which the novelty lies in a known substance being used in the manufacture of a medicament for a second medical use.⁷ As I mentioned earlier, claims of this nature are identified as

⁶ *Bayer Intellectual Property GMBH and Others v Austell Pharmaceuticals (Pty) Ltd*, unreported judgment of the Court of the Commissioner of Patents, under Case No 9026/2021, dated 20 May 2021, para 40

⁷ See the discussion of this type of claim in *Elan Transdermal Ltd v Ciba Geigy* 1994 BP 1, at 11D-12B

being claims to a process, or method of manufacture, as opposed to a product claim. It is this type of claim that is typically referred to as being in the Swiss form.

STATUTORY FRAMEWORK AND SWISS FORM CLAIMS

22. In order to understand Swiss form claims, it is necessary to have regard to s 25 of the Patents Act 25 of 1979 (the Act). Logically, one starts with s 25(11), which provides that:

“An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall be deemed not to be capable of being used or applied in trade or industry agriculture.”

23. In simple terms, the manner of treatment or diagnosis per se cannot be patented. For example, a surgeon could not patent a particular method of stitching she has devised in her surgical practice. However, s 25(12) establishes an exception to s 25(11) in that it states that:

“Subsection (11) shall not prevent a product consisting of a substance or composition being deemed to be capable of being used or applied in trade or industry or agriculture merely because it is invented for use in any such method.”

24. This means that products consisting of substances or compositions used in the treatment of humans and animals can be patented. Under s 25 (9):

“In the case of an invention consisting of a substance or composition for use in a method of treatment of a human or animal body by surgery or therapy or of a diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of any claim to the inventions shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.”

25. In *Elan Transdermal Ltd v Ciba Geigy*⁸ (*Transdermal*), as regards s 25(9), MacArthur J explained that:

“It is apparent from this sub-section that even if the substance is known but is being used for the medical treatment of, say a human body, such a claim would not be objectionable, provided it is the first time it has been used for a medical treatment. This follows from the use of the words in section 25(9) ‘in any such method’, which must refer back to the opening words in that subsection, namely ‘for use in a method of treatment of the human or animal body’.”⁹

26. In other words, s 25(9) permits what are usually referred to as first medical use claims. Bayer accepts that its patent is not a first medical use patent because at the priority date it was known that rivaroxaban was a compound that could be used for the treatment of thromboembolic disorders. In fact, Bayer had the compound patent to protect its rights in rivaroxaban at the time.
27. As the court explained in *Transdermal*, Swiss form claims were introduced in the United Kingdom because of the limitations placed on second medical use claims:

“It was in order to overcome the problem where the known substance was found on a subsequent occasion to be useful as a novel method of medical treatment that the Swiss-type of claim came to be introduced in the United Kingdom. ... It was held in the *John Wyeth* case at page 563 that a claim in the Swiss forms such as ‘the use of substance A in the manufacture of a medicament to treat disease B’ is in reality a claim to a method of manufacturing such a medicament by using substance A in its manufacture. Further, there was no objection to patenting in the Swiss form of claim of an invention directed to a second or subsequent medical use of a known pharmaceutical, if the statutory requirements of novelty could be met. Put another way, if the medicament made for the second medical use is novel and is not obvious the claims will be good.”¹⁰ (My underlining)

28. It is important to point out, as I will discuss in more depth later, that in *Transdermal* it was accepted by the parties that Swiss form claims were acceptable in South

8 Above n7
9 At 10D-E
10 At 11E-12B

African law. In this application, Mr Puckrin, who coincidentally represented one of the parties in *Transdermal*, advances the submission on behalf of his client that in fact this type of claim ought not to be permissible in our law.

29. Bayer's claim is drafted in the Swiss form: "*The use of the compound (rivaroxaban) for the manufacture of a medicament in an oral dosage form for the treatment of a thromboembolic disorders*" The first issue to consider is whether Bayer has established a *prima facie right* to the protection of its registered patent in light of Dr Reddy's contentions: first, that claims in the Swiss form are not permissible in our law and, second, that even if they are, Bayer's claim is not a true process, or Swiss form, claim. In particular, as regards the second defence advanced by Dr Reddy's, it says that the claim is an unlawful attempt to claim a patent over what is in effect no more than an unpatentable dosage regime.

PRIMA FACIE RIGHT: ARE SWISS CLAIM FORMS ACCEPTABLE IN OUR LAW?

30. Dr Reddy's principled objection to the validity of Swiss form claims in our law may be summarised as follows: *Transdermal* did not find that this form of claim was acceptable in our law; it did not consider the issue, as the parties had agreed that they were acceptable; no other case has ruled that Swiss form claims are valid under the Act; it is "*common knowledge*" that these types of claims "*were devised as a stratagem to avoid the prohibition against the patenting of 'second medical use' claims' and 'method of treatment claims'*"; they are aimed at extending the normal statutory monopoly "*under the guise that they are focussed on a process/method of manufacture*"; however, shorn of all adornment, they are nothing more than second medical use or method of treatment claims; hence, they fall foul of ss 25(9) and (11) of the Act.

31. In its answering affidavit, Dr Reddy's indicated that it "*wished to raise a constitutional point*". It did not seek to impugn any of the provisions of the Act. However, it averred that any: "*extension of the ambit of section 25(9) of the Patents Act ... to permit 'Swiss-type claims' would, in South African law, fail to give proper meaning to the provisions of sections 25(9) and 25(11) of the ... Act, particularly when viewed through the prism of the South African Constitution ... including the rights to life, dignity and access to healthcare facilities enshrined therein and having regard to sections 39(1) and 39(2) of the Constitution.*"
32. In developing this line of argument, Dr Reddy's submitted that context is everything. It pointed out that with the current Covid19 pandemic, more patients needed access to anticoagulant medication. Generic medications (like Rivaxored in this case) are generally much cheaper than the original drugs manufactured under a patent, in this case Xiralto, which is the commercial name of the drug manufactured by Bayer under the patent. Most South Africans are not covered by medical aid. This means that for most South Africans, safer anticoagulants, like Xiralto, are not affordable, leading to patients of necessity having to use less safe drugs, such as Clixane and Warfarin.
33. Dr Reddy's also referred to the concept of "*patent evergreening*" in terms of which it is alleged that pharmaceutical companies file a series of patents, often spaced apart in time, for various aspects of the same product. While the first patent filing is for a genuine innovation, those filed later are often for "*trivial changes*", such as new mixtures, formulations or delivery systems. Implicit in Dr Reddy's submission is that Swiss form claims are contrary to public policy and constitutional imperatives in that they permit pharmaceutical companies to extend their monopolies in pursuit of profits at the expense of public health and welfare.

34. It seems that the gist of Dr Reddy's argument is that these contextual factors bring into focus constitutional imperatives aimed at protecting the rights to life, dignity and access to healthcare facilities. In the submissions made on its behalf, Dr Reddy's relies on what it says is an open question in South African law as to the validity of Swiss form claims. Dr Reddy's appeared to accept that under English law these forms of claims are acceptable. It also recognised that in previous patent cases, or at least in *Transdermal*, the competing parties had worked on the assumption that they were viable under our law. The submission is that the constitutional context is an important factor that lends strong support to a change in the approach that seems up to now to have been the assumption in our law that there was nothing objectionable in Swiss form claims. Based on these considerations, Dr Reddy's advocates that a change of approach is required and that it should be determined that Swiss form claims are not valid.
35. Bayer takes issue with the absence of facts to support Dr Reddy's claims. For example, it points out that there is no evidence to support the assertion that Swiss form claims are well known to be a stratagem to avoid the prohibition against second medical use claims. Two academic articles were relied on by Dr Reddy's in support of its assertions. However, Bayer says that these are no more than opinions. It points to the fact that insofar as there may be policy considerations weighing against a liberal acceptance of Swiss form claims, there are equal policy considerations in continuing to regard them as legally valid. There is support for this submission. In *Actavis v Merck*, which involved a Swiss form claim for a dosage regime, the Court of Appeal in the United Kingdom, explained that:

“When Mr Thorley was asked what policy reason there should be for on the one hand allowing Swiss form second medical treatment claims for different diseases but not allowing them for the same disease, the only answer he could devise was that the treatment might cost more. Why, he said, should you pay more for a 1mg pill than for an out of patent 5 mg pill? The reason is

obvious - the 1mg pill has only come about because of expensive unpredictable research. Patented things often cost more. And the reason is because the monopoly has been given as a result of the research which led to it. Research into new and better dosage regimes is clearly desirable - and there is simply no policy reason why, if a novel non-obvious regime is invented, there should not be an appropriate patent reward. Such a reward cannot extend to covering the actual treatment but a Swiss form claim which specifies the new, inventive, regime is entirely in accordance with policy."¹¹

36. Dr Reddy's policy arguments overlooks that in order to be patentable, a Swiss form claim must comply with the requirement of novelty, innovation or inventiveness. Without this key element, the claim is not patentable. It is precisely this requirement that aligns Swiss form claims to, and makes them palatable with, policy considerations. If there is an absence of innovation, there can be no policy reason to warrant protection of a patent. However, if there is innovation, it cannot be said that there is a public policy reason not to reward a patentee in the interests of fostering research and development.
37. I am mindful of the fact that, these being interim interdict proceedings, I am not required, and indeed should avoid, making final findings on contested issues. For present purposes, I accept that it may be that a debate is to be had as to whether Swiss form claims are compatible with the Act, taking into account public policy (including constitutional) considerations. However, as the law stands at present, in other jurisdictions, such as in the United Kingdom, these forms of claims have been held to be acceptable. We are not the United Kingdom, of course, but it is well established that, save for more recent developments effected to bring about alignment with European law, South African patent law is closely modelled on that of the United Kingdom.

11 At para 29

38. In *Transdermal*, MacArthur J had no difficulty calling on English law to assist him in making a determination. Indeed, counsel for both parties before me in this matter referred to English law extensively in their submissions. The acceptance of Swiss form claims forms in that legal system is at least a relevant factor for me to consider. MacArthur J was not called on to decide whether Swiss form claims are acceptable under the Act. However, in my view, this is a neutral point. It does not mean that this issue is wide open in our law. On the contrary, it is arguable that the reason why counsel in that matter accepted the validity of Swiss form claims was precisely because it was an uncontentious issue. It is arguable, for the same reason, that this is why our courts have not been called on yet to make a specific ruling. Indeed, counsel for Dr Reddy's did not suggest that at present it is assumed that these types of claims are invalid in our law. He advocated for a change in the current legal approach to the issue.
39. On Bayer's version, Swiss form claims are valid under the Act. The question is whether Dr Reddy's evidence and accompanying submissions are sufficient to place serious doubt on Bayer's case in this regard. It follows from my discussion above that I am not persuaded that this is so. Much of the factual material relied on by Dr Reddy's is generalised, resulting in speculative conclusions. The opinions of the two academics relied on by Dr Reddy's are interesting and provide food for thought. However, they do not constitute evidence placing serious doubt on Bayer's case. Importantly, Dr Reddy's averments do not address the question of why the requirement of innovation or novelty (which is part and parcel of the patentability of a Swiss form claim) is not sufficient to warrant, in principle, acceptance of their validity from a policy, and constitutional, point of view. Dr Reddy's addresses the issue of novelty at length in its attack on the patentability of Bayer's particular claim, but not at the level of principle. I conclude, on a *prima*

facie basis that no serious doubt is placed on Bayer's case in this regard: in principle, Bayer has a *prima facie* right to protection of its claim regardless of the fact that it is in the Swiss form.

40. The next question raised by Dr Reddy's in its attack on the validity of Bayer's patent is whether the patent-in-suit is a genuine Swiss form claim.

PRIMA FACIE RIGHT: IS IT IN FACT A SWISS FORM CLAIM?

41. Bayer has a registered patent which, absent serious doubt being placed on its validity, must be determined to be *prima facie* worthy of legal protection. Dr Reddy's contends that although the patent may be drafted in the Swiss form, this does not mean that it genuinely falls within that category of patentable claims.

42. It is common cause that the invention claimed by Bayer in the patent is not directed at the compound rivaroxoban per se. The compound was known in the state of the art at the priority date of the patent and was protected under the separate compound patent. Bayer accepts that its patent is in respect of a dosage regimen. However, it says this does not render the invention unpatentable. Bayer's case is that its patent is an accepted claim in the Swiss form as it is aimed at the process or manufacture of the medicament described in it. It is thus covered by s 67(1) of the Act, which provides that:

"A claim in respect of a patent for a process or an apparatus for producing any product shall be construed as extending to such product when produced by the process or apparatus claimed."

43. Bayer says that the essence of the invention claimed in the patent lies in the use of a once-daily dosage regimen of a rapid release rivaroxaban tablet formulation to treat the identified disorders. In a nutshell, Bayer's case in this regard is that the

manufacture of this formulation is novel and inventive because it was contrary to the prior art at the time: all expectations derived from the prior art pointed away from a once daily dosage in the form of a rapid release tablet. The prior art indicated that, in order to balance the twin considerations of efficacy and patient safety, a more frequent dosage regimen of rivaroxaban in a rapid release tablet would be required. The expectation was that a once daily dosage regimen would only be safely effective in an extended release tablet. It was only through Bayer's research and development that the invention of a once daily rapid release tablet of rivaroxaban that was both efficient and safe came about.

44. Dr Reddy's says that a dosage regimen is not patentable in the Swiss form as a dosage regimen is not a process or method of manufacture. Such patents are effectively second medical use patents that fall foul of s 25(9) of the Act. Dr Reddy's contends that at best for Bayer, it could only claim a second medical use patent if it could prove a "*new technical effect*" which, says Dr Reddy's, it cannot. This latter contention is based on the decision of the Extended Board of Appeal in the *Abbott Respiratory* matter¹² (*Abbott Respiratory*). In this respect, Dr Reddy's highlights the fact that the patent is for the treatment of thromboembolic conditions, being the same medical conditions covered in the compound patent. It argues that Bayer simply cannot claim a permissible second medical use for the treatment by the same compound for the exact same condition.
45. Dr Reddy's recognises that in some cases from the United Kingdom, and in *Transdermal*, the patentability of claims directed at dosage regimens in the Swiss form have been accepted. It points to *Bristol Myers Squibb v Baker Norton*,¹³ (*BMS*), in which the Court of Appeal held that a claim to an improvement in a

12 G 02/08 Dosage regime/ABBOTT RESPIRATORY, dated 19 February 2010
13 [2001] RPC 1

method of administering an existing treatment was not patentable in that it did not define a new and inventive therapeutic purpose. It was held in that case that the claim was: “an unsuccessful attempt to monopolise a new method of treatment by drafting it along the lines of a Swiss-type claim”. Dr Reddy’s notes that the same principle was applied by the Hearing Officer in the *Advance Biofacturers’ Application*¹⁴ (*Advance Bio*), which stated that: “Thus it is not acceptable for Swiss-type claims to be distinguished from the prior art only by the mode of administration of the amount, timing or frequency of dosage.” This conclusion was followed by the Patents Court in *Merck and Co’s Patent*¹⁵ (*Merck*). The decision of the Patents Court was upheld by the Court of Appeal.

46. Implicit in Dr Reddy’s reliance on these cases is the submission that the patent-in-suit in this case falls within that category of dosage regimens that has been found to be unacceptable in the United Kingdom. As to *Transdermal*, Dr Reddy’s says it is to be distinguished from the present case. This is because, in the first place, as noted earlier, it was common cause between counsel that Swiss form claims are valid under our Act. Secondly, Dr Reddy’s says that the facts are entirely distinguishable in that the patent in *Transdermal* was a genuine Swiss form claim. This is because what counsel for Dr Reddy’s described as the entire centre of gravity of the claim in *Transdermal*, pointed to the process or method of manufacture. The submission is based on the consistory clause in the specification in that case which described the preparation for the administration of the compound in question, nicotine, as being in the form of nicotine patches. Dr Reddy’s submits that this is entirely different from the present case where the administration of the known compound, rivaroxaban, is in the form of a rapid release tablet, which is also known. Thus, unlike in *Transdermal*, says Dr

14 BL O/303/04

15 [2003] FSR 29, p1498

Reddy's, the patent-in-suit is simply for a non-novel dosage regimen, unrelated to a process or method of manufacture.

47. As Dr Reddy's appears to accept, depending on the nature of the invention, a claim to a dosage regimen may be patentable in the Swiss form. This is so in the United Kingdom in the cases cited by Dr Reddy's, but it was also accepted in *Transdermal*. In *Abbott's Respiratory*, it was concluded that the new use claimed in the Swiss form need not be the treatment of a new disease, but it could include a new and inventive dosage regimen, provided there was a new technical effect involved. In *Advance Bio*, a dosage regimen claim in the Swiss form was found to be both novel and inventive because the active ingredient was present at substantially higher concentration than that in the prior art. The Hearing Officer took into account that the person skilled in the art would have considered this higher concentration to have unacceptable side effects.
48. Dr Reddy's contends that the present case is different to these, and is aligned with the facts in *Merck*, which established, as Dr Reddy's puts it, that it is impermissible to "*have a 20 year patent for a tablet divided into two or three parts but then unlawfully extend it for another 5 years for a whole tablet*".
49. In *Merck*, the claim of the patent was for "*oral administration in a unit dosage form which comprises about 70mg of alendronic [acid] ... according to a continuous schedule having a dosing interval of once weekly*." The patent was revoked on the basis that it was for a dosage regimen that was not novel. The patentee had previously sold alendronate commercially as a 10mg daily dose. It was also marketed in 35mg, 40mg and 60mg tablets. The Court of Appeal found that the patent did not specify that the claim was to a 70mg tablet. In fact, the patentee conceded that the patent would not be infringed by the administration of a

combination of one 60mg and one 10mg tablet. On this basis the Court of Appeal found that the claim was not novel: "*There were in existence pills containing 10mg and other quantities. A 70mg pill could not be new in the sense required by s.2 Patents Act 1977.*"¹⁶

50. On these facts, I am not persuaded by the submission that the present case is aligned to the facts in *Merck*. In this case, rivaroxaban was not previously commercially available in tablet form in different quantities, as was the case in *Merck*. Accordingly, it is not correct that this case, like *Merck*, involves an unlawful extension of a patent as described by Dr Reddy's.

51. Further, Bayer draws attention to the fact that in *Merck* both the Patent Court and the Court of Appeal held themselves bound by the decision in *BMS*.¹⁷ However, subsequent to *Merck*, in *Actavis*, the Court of Appeal concluded that it was not satisfied that *Merck*: "... contains a clear ratio that a Swiss form claim lacks novelty if the only difference between it and the prior art is a new dosage regime for a known medical condition."¹⁸ It found further that it was: "...unlikely that *BMS* actually decided that a Swiss form claim whose difference from the prior art is only in the dosage regime lacks novelty."¹⁹ The Court of Appeal also agreed with the submission that a new dosage, even for treating a disease previously treated with the same substance in a different dosage, was novel. It said in this regard that: "A claim to a pill containing a 1mg dose of finasteride would be a claim to a new thing. No-one has made or proposed such a thing, so why should it not be novel?"²⁰

16 Para 58
17 Para 59
18 Para 71
19 Para 66
20 Para 23

52. As to the Patent Court's finding that the claim was to a method of treatment, and not a true Swiss form claim, the Court of Appeal in *Actavis* held that:

"(The Judge) accepted Mr Thorley's submission that the dosing regime was a matter of choice for the doctor and that as far as the prior art was concerned it would make no difference whether the patient was given five 1mg tables a day or one 5mg tablets per day. But that is not enough in our view to mean that the claim is in substance to (*sic*) a method of treatment. There is nowhere near the degree of involvement of medical personnel which turned the case in *BMS*. In its essence the claim here is to the use of finasteride for the preparation of a medicament of the specified dosages. It is not aimed at and does not touch the doctor - it is directed at the manufacturer. Putting it another way, even if *BMS* is right on this point, it cannot be extended to cover every case where novelty depends on a specified dosage regime. After all every prescription medicine must be prescribed - that does not mean they are all for methods of treatment."²¹

53. The Court of Appeal concluded that Swiss form claims were permissible where the novelty is conferred in the new dosage regimen or other form of administration of a substance. It cautioned, however, that:

"So holding is far from saying that in general just specifying a new dosage regime in a Swiss form claim can give rise to a valid patent. On the contrary nearly always such dosage regimes will be obvious - it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present ... could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim."²² (my emphasis)

54. There seems to be acceptance in the United Kingdom, then, that claims to a dosage regimen are lawfully patentable, provided that they overcome the inherent problem that they might be found to be obvious. While not bound by these authorities, they are persuasive, given the historic parallels between our patent regime and that of the United Kingdom.

55. In our jurisdiction, *Transdermal* accepted the validity of a dosage regimen patent in the form of a Swiss claim. It did so in the face of the same contention that is made

21 Para 75

22 Para 32

here, namely that a dosage regimen is not a true Swiss form claim and should properly be regarded as an impermissible method of treatment claim. The court found that:

“In my view the introduction of the additional features does not take it out of the Swiss form. The claims do have these limitations and there may be difficulties or criticisms levelled at them in considering, say, ambiguity; they do not however take away the main characteristic of the Swiss form of claim which in this case is making a medicament for the treatment of a condition by using a known substance in its manufacture.”²³

56. Dr Reddy's submitted that *Transdermal* was a claim in the true Swiss form because of the reference to the use of a dermal patch in the consistory clause. It says that in contrast, in the present case there is no process or method of manufacture described. This submission was made in counsel's supplementary heads of argument. If one reads *Transdermal*, there is no indication that MacArthur J placed any particular emphasis on the method of manufacture involving a dermal patch as the medium of dosage in reaching his conclusion. I am not persuaded that Dr Reddy's attempted distinction between *Transdermal* and the present case is sufficient to place serious doubt on the validity of Bayer's claim.
57. It seems to me that if one goes back to first principles, and taking into account the authorities discussed above, the real question in dosage regimen Swiss form patent claims lies in whether in each case the claim meets the test of novelty and avoids the pitfall of obviousness. *Actavis* suggests that the test for novelty in these types of cases is relatively easily satisfied: if no-one had thought of that dosage regimen before, it will be new even if, it would seem, the novelty lies in the quantity of the compound in the claim being different to what was previously in the

23 At p13G-14B

state of the art and on the market.²⁴ In this case, rivaroxaban was not previously marketed. Thus, the claim for its use in the manufacture of a medicament for a once daily dose would be a new claim: it is not suggested in this case that anyone had previously marketed a dose of this sort before.

58. Obviousness seems to me to be the higher hurdle, for the reasons stated in *Actavis*. However, if the dosage regimen patented under a Swiss form claim is not obvious on the facts, then *Actavis* and *Transdermal* support, at least *prima facie*, the validity of the claim, as do *Advance Bio* and *Abbott's Respiratory*.
59. 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.
60. The recent decision of this Court in *Bayer v Austell Pharmaceuticals* is relevant to the issue of obviousness. That case involved an application by Bayer for interim interdictory relief against the respondent in order to protect against an infringement of the same patent under consideration in this matter. The respondent challenged the validity of the patent on the basis that it would have been obvious to the skilled person at the priority date that a rapid release rivaroxaban tablet can be administered once daily to treat the identified thromboembolic disorders. Bayer relied on much the same evidence as it does here to establish a case that the claim involved an inventive step. Austell presented contrary evidence by its

24 Above n6

expert, Prof Greeff, to the effect that the patent would have been arrived at as a matter of routine during clinical trials. It was therefore submitted on the basis of this evidence that it would have been obvious to try this dosage regime.

61. Fourie J considered the evidence presented by both parties in broad outline. He noted that Prof Greeff had no experience in the field of haematology, thrombotic disorders or anticoagulation, and that he had never been personally involved in the design of a dosing regimen for an anticoagulant drug. For purposes of determining whether interim relief should be granted, he accepted that the evidence of Prof Weitz much more convincing.²⁵ He also concluded it would not have been obvious to the skilled person at the priority date that a rapid release tablet of rivaroxaban could be administered once daily for the treatment of the thromboembolic disorders. Consequently, he found that on the basis of the evidence presented, it was not likely to be shown at the trial that the patent-in-suit was invalid because it was obvious.²⁶

62. Prof Weitz has also given evidence for Bayer in this application. He was supported by the expert evidence of Dr Misselwitz who was involved in the clinical trials in question. As in the Austell matter, Dr Reddy also elected to use an expert, Prof Blockman, who has no specialised knowledge in the field of haematology, or actual involvement in trials aimed at determining dosage regimes for anticoagulants. I have considered the evidence presented by experts for both sides. 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.

25 Paras 49-58

26 Para 62

63. 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.
64. For these reasons I find no merit in Dr Reddy's contention that serious doubt is raised as to the validity of Bayer's patent which is framed as a Swiss form claim.
65. This is not the end of the validity and *prima facie* right issue, however, because Dr Reddy persists with its further contention that the patent is revocable because of material misrepresentations that were made by Bayer on the filing of its patent.

MISREPRESENTATION

66. Section 61(1)(g) of the Act provides that a patent may be revoked on the basis:
- “that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew to be false at the time when the statement or presentation was made.”
67. The prescribed declaration is contained in the PS Form. It reads: “*To the best of my / our knowledge and belief, if a patent is granted on the application, there will be no lawful ground for the revocation of the patent.*” It has been held that the misrepresentation must be assessed at the time when it was made.²⁷
68. Dr Reddy's says that when the patent-in-suit proceeded to grant it included wholly invalid claims that rendered it invalid and liable to be revoked. It says that the fact that that this was ameliorated by an *ex post facto* amendment by Bayer does not negate this.

²⁷ *Gallagher Group v IO Tech* 2014 (2) SA 157 at 164D-E

69. It is common cause that when the patent-in-suit was filed it was directed at a method of treatment. Prior to the grant of the patent, it was amended (the pre-grant amendment). Dr Reddy says that in terms of the pre-grant amendment, the claim was a second medical use claim. The patent was registered on the basis of the pre-grant amendment, which was accepted. As I indicated earlier, the patent was once again amended by way of the post-grant amendment in 2020, so that it now reads in its current form.
70. Dr Reddy's case, in the first place, is that the form of the patent -in-suit when it proceeded to registration was contrary to the second medical use prohibition in South African law. In other words, that contrary to the declaration made by the signatories of the PS Form (Dr Burkert and Dr Köhler) on 27 July 2007, a lawful ground for its revocation existed. This in itself does not amount to misrepresentation warranting revocation under s 61(1)(g), as revocation on this ground requires that the patentee knew that the declaration was false.
71. In this latter respect, in the answering affidavit deposed to by Ms Keyser, the country manager for Dr Reddy's, the deponent states that: *"I am advised that in or around 2005, Bayer (or their predecessors) were engaged in litigation against Pfizer, in which Bayer attacked the validity of Prizer's 'Viagra' patent on the ground that the claims in Pfizer's patent included 'second medical use' claims. Bayer's interpretation of South African patent law, so it argued, was that such 'second medical use' claims are not patentable in South Africa if the compound referred to was previously known to be used in a medical use of some sort."* Ms Keyser concludes from this is that the declaration in the PS Form was contrary to Bayer's own belief that a second medical use claim was liable to revocation.

72. In reply, Bayer correctly pointed out that Ms Keyser does not provide any evidence to support her central contention that the patentee, being the first applicant, advanced this position in the Pfizer litigation. Nor does Ms Keyser indicate the source of her information. The basis for the averment is thus speculative. Bayer searched for the original records of the South African Pfizer dispute and found some of them, including the amended revocation application. It notes that the first applicant, being the patentee, was not a party to that litigation. Further, that in the amended application for revocation, no reliance was placed on revocation on the grounds of second medical use.
73. This pleading was annexed to the replying affidavit. The grounds for revocation cited there were the general assertion that the claim wasn't patentable (without specifying a reason); lack of fair basis; lack of clarity and insufficient description of the invention. Bayer notes further that the dispute was settled confidentially, but that in terms of the settlement, the patent was not revoked. It submits that from this it must be inferred that the parties accepted that the patent was valid.
74. Bayer raises other obvious issues with Ms Keyser's contention that the first applicant knew at the time that its claim was revocable on the basis that it was an impermissible second medical use claim. These include the fact that it is unlikely that the signatories of the declaration would have known what Bayer may or may not have contended in the Pfizer litigation, as there is a clear division between the patent litigation and the patent prosecution departments in Bayer. Thus, there would have been no reason for a person prosecuting a patent relating to thromboembolic conditions to be aware of the Pfizer litigation involving Viagra.
75. Dr Reddy's makes further speculative assumptions about what it says should be inferred as the real reason for the amendments to the patent. The difficulty for Dr

Reddy's is that without evidence to back up its unsubstantiated assertion that the patentee in this case knew, because of alleged litigation assertions in unrelated litigation, that the patent was revocable because it was a patent for a second medical use, the inferences it seeks to draw lacks any foundation. The same holds true for the additional submissions advanced by Dr Reddy's in its heads of argument to the effect that Bayer ought to have known, because it was represented in South Africa by highly qualified patent lawyers, that there were lawful grounds to revoke the patent contrary to what was stated in the declaration. There is no evidence to support this.

76. For these reasons, and based on the evidence before me in these proceedings, I am not persuaded that the material misrepresentation challenge places serious doubt on the validity of Bayer's patent.

77. I conclude that Bayer has established that it has a *prima facie* in the form of the patent-in-suit, and it is accordingly entitled to seek to protect that right from infringement. The next question that arises is whether it has established an infringement by Dr Reddy's.

INFRINGEMENT

78. In determining whether a patent has been infringed it is necessary to make a comparison between the essential features of the patent, and the article or process involved in the alleged infringement.²⁸ An infringer who takes the "*pith and marrow*" of the invention commits an infringement even though he or she omits an inessential part of the claimed invention.²⁹

²⁸ *Stauffer Chemical Company and another v Safsan Marketing and Distribution Co (Pty) Ltd and others* 1987 (2) SA 331 (A), at 342 D-E

²⁹ P Ramsden *A Guide to Intellectual Property Law* at p329

79. Dr Reddy's raised four non-infringement defences in its answering affidavit. They were not pursued in the written or oral submissions or, at least, not with any vigour.
80. The first defence was that Bayer had not proven that Rivaroxared was formulated as a rapid release tablet. There is no merit in this contention on the evidence before me. It is common cause that Rivaroxared is a generic of Bayer's rivaroxaban medicament, Xiralto. It stands to reason, as Dr Chauke explained on behalf of Bayer in its founding papers, that it releases the active ingredient at the same rate as the original, in other words, as a rapid release tablet. In fact, Dr Reddy's does not explicitly deny that Rivaroxared is a rapid release tablet.
81. The second defence was that Bayer has not established that Rivaroxared infringes the half-life feature of the patent. In *Austell*, Fourie J found that the half-life feature was not an essential integer of the patent. Instead, it was an inherent property of the drug.³⁰ Dr Reddy's has not advanced any argument as to why I may be justified in departing from this finding on the basis that it is clearly wrong. The half-life defence thus falls by the wayside: whatever Dr Reddy's submissions may be on this feature, it is not an essential feature. As such, it is not relevant to determining whether Bayer has established an infringement.
82. The third defence is that because Rivaroxared is not manufactured in South Africa, there has been no patent infringement. This submission rests on the proposition that s 67(1) offers no protection to Bayer. If s 67(1) applies to the patent-in-suit, then it does not matter where the drug is manufactured: a claim directed to a process for producing a product extends to the product produced. Section 45 of the Act provides that the effect of a patent shall be to grant to the patentee in

30 At para 39

South Africa, the right to exclude other persons from, among others, disposing of, or importing the invention. As such, the sale of Rivaroxared, regardless of where it is manufactured, infringes the patent-in-suit. I have rejected Dr Reddy's contention that the patent is in effect a prohibited second medical use claim rather than a true claim in the Swiss form. Accordingly, it follows that its argument that s 67(1) does not provide protection to Bayer is ill-founded.

83. Finally, Dr Reddy relies on the existence of a tacit agreement or estoppel to defend against the contention that it has infringed the patent. This is based on the communications between the parties when Bayer first took issue with Dr Reddy's alleged infringement of its compound patent. The letter of demand issued by Bayer, and Dr Reddy's responding undertaking, expressly referred only to the compound patent and not the patent-in-suit. It is difficult to understand on this evidence how a case of either tacit agreement or estoppel can be well-founded. Estoppel and tacit agreement defences require particular evidence in their support. There is no such evidence on the affidavits before me. I am not persuaded, on *prima facie* basis, that this defence places doubt, let alone serious doubt on Bayer's claim that by its conduct Dr Reddy's infringed the patent-in-suit.

84. What is left to be considered are the remaining requirements for the grant of an interim interdict, namely, the alleged irreparable harm, absence of an alternative remedy, and the balance of convenience.

IRREPARABLE HARM, ALTERNATIVE REMEDY AND BALANCE OF CONVENIENCE

Irreparable harm and absence of alternative remedy

85. It is trite that these two requirements are very closely related in most cases, the present being no exception. Bayer says that it has and will continue to suffer irreparable harm by the continued sale of Rivaroxared. The launch of Rivaroxared will have an immediate and detrimental effect on the sales of Xarelto and iXarola (the clone sold under a distribution agreement with Bayer). Further, that because of the notorious difficulty in proving damages in patent infringement cases, damages are not an effective alternative remedy.
86. Bayer sets out detailed evidence in support of its case. The evidence includes comparisons with the effect on its market share and sales with the introduction of Rezalto, the Austell product that was subsequently interdicted. In the case of Rezalto, its sales volumes increased significantly from its launch in December 2020 to May 2021, when the interdict took effect. By May 2021 it had 16.4% of the market share. At the same time, Xarelto's market share declined steeply from 68.7% to 35.9% in May 2021. In *Austell*, based on similar evidence, Fourie J accepted that Bayer had established that it had suffered irreparable harm as a result of Rezalto's entry into the market.
87. There is no reason offered as to why the same trend should not be followed on the back of Rivaxored's launch by Dr Reddy. In fact, early sales figures obtained by Bayer demonstrate that Rivaxored's sales increased by about 650% between the March/April 2021 figures to May 2021. Bayer says that in light of the Austell interdict, it is likely that patients will switch to the other available generic, Rivaxored. The latter is marketed at 40% cheaper than Xarola and 31% cheaper than the clone, iXarola, in the private sector. Rivaxored's price was reduced in the

price war with Austell's Rezalto, before the latter was halted under the interdict. This bears out Bayer's case that generic pharmaceutical companies can afford to drop their prices to a greater extent than drug originators because the latter have to recoup the costs of research and development, costs that are not borne by generic companies. Bayer says that this is why it is not simply a matter of drug originators being able to compete by dropping their prices, as suggested by Dr Reddy's.

88. Bayer also points out in its evidence that it will inevitably lose market share, and hence profits, because it simply cannot compete pricewise with generic companies like Dr Reddy's. The latter contends that the anticoagulant market in South Africa is vibrant and growing, particularly in light of the increase for demand brought on by the Covid pandemic. It suggests, without any supporting evidence to substantiate the suggestion, that the competition it provides will in fact grow the anticoagulant market. The clear implication of this submission is that Bayer will be able to maintain its sales figures as the market will continue to grow because of increased demand. However, Bayer, correctly in my view, submits that based on what occurred after the launch of Rezalto this is an unlikely scenario and that, even in the unlikely event that it were to eventuate, Bayer would still lose out on sales that it otherwise would have cornered without Rivoxared entering the market.
89. Dr Reddy's does not dispute that its selling price is substantially cheaper than that of either of the rivaroxaban products. It also does not dispute, in fact it concedes, that under our legal regime, pharmacies are obliged to offer a patient the cheaper generic product. It seems to me to be obvious that, in these circumstances, many patients will switch to the cheaper generic. Also, medical aids will likely insist on the generic rather than the original drug. The likely impact that this will have on Bayer's market share is substantial and long-lasting.

90. In the circumstances, I am persuaded, on a *prima facie* basis, that Bayer has established irreparable harm. That there is no effective alternative remedy is also, in my view, established. As Fourie J noted in *Austell*, it is well established in our law that in patent infringement cases proof of damages is notoriously difficult. This is because it will be very difficult to prove what part of reduced turnover was caused by a respondent's entry into the market.³¹ Dr Reddy's does not dispute this. It suggests that its undertaking of paying 5% of its sales to Bayer as a reasonable royalty in the event of Bayer ultimately being successful in its action in lieu of an interdict will provide a satisfactory alternative. A royalty *in lieu* of damages lies at the option of a plaintiff, not at the option of a defendant. Bayer is not prepared to accept this undertaking as an alternative remedy, and I can see no reason why it should be directed to do so.
91. For these reasons, I am satisfied that Bayer has established that it has no effective alternative remedy available to it.

Balance of convenience

92. It is trite that this requirement requires the court to weigh the prejudice to the applicant if the interlocutory interdict is refused against the prejudice to the respondent if it is granted.³² The stronger the prospects of the applicant's success in the main action, the less need for the balance to favour it, and *vice versa*.
93. The fact that Bayer is likely to suffer irreparable harm weighs in its favour in balancing the respective prejudice to the parties. In addition, Bayer avers, based on the evidence of Ms Steenkamp, who has two decades experience in the marketing of anticoagulants, that the cost of developing a new pharmaceutical

31 At para 74, citing *Pfizer v Cipla Medpro* 2005 BIP 1 (CP) 11-12

32 More recently confirmed by the Constitutional Court in *Tshwane City v Afriforum* 2016 (6) SA 279 (CC) at 302

product is extremely high, averaging more than US\$1million per drug. Bayer alone invests more than five billion Euros annually in the research and development of new products. Its business model, which is common in the industry, is built on the expectation that sales generated from successful products will fund the cost of the company's research and development into, among others, that product, potential new products and new uses for or improvements to existing products. Achieving this expectation is reliant on the exclusivity conferred by its patents so that the investment may be recouped. Bayer also had to create the market for rivaroxaban in South Africa. This involved a substantial investment of more than R150 million.

94. Bayer contrasts its situation in this regard with that of Dr Reddy's. As a generic drug company, it did not have to bear the significant research and development costs borne by Bayer. It could also piggyback, so to speak, on the market created by Bayer.
95. Based on these averments, Bayer submits that Dr Reddy's entry into the market at this late stage means that the competition between the two companies will not be on an equal footing. It submits further while while the sale of generic products in South Africa is supported by policy and legislation, it can never be in the public interest to permit or encourage the infringement of *prima facie* valid patent rights through premature and unlawful entry. Bayer also points out that to the extent that Dr Reddy's is prejudiced by the imposition of an interdict, it opened itself up to the risk of this occurring by launching its product in the face of the patent-in-suit that was in force.
96. Dr Reddy's places great store on what it says is Bayer's enjoyment of its patents associated with rivaroxaban for more than 20 years. It says that the patent-in-suit

is a clear attempt at “evergreening”, or an unlawful attempt to extend a patent beyond its original lifetime by securing new patents for the same product towards the end of the life of a patent. This, it says, can never be in the public interest. It lays particular emphasis on what it says are constitutional considerations, involving the need to improve access to life saving medication by fostering generic entry in the market rather than permitting the extension of patent monopolisation. It says that these constitutional considerations are even more important now in the Covid era, when anticoagulants are in high demand.

97. There is no specific evidence to back up Dr Reddy’s averments in this regard. It does not provide proof, for example, that Bayer is unable to meet the need for rivaroxaban in the public sector. Bayer avers that it is able to do so through its distribution agreement involving iXarola. In fact, Bayer shows that the price of iXarola in the public sector, as opposed to the private sector, is 8% to 10% less than the price of Rivarexored. Bayer also points out that Dr Reddy’s has not yet provided Rivaroxared to the public sector. At best, it says that it intends to do so. It has a licence to market its generic, Rivaroxared, but that is as far as its evidence goes in this regard, save to say that it has not yet had time to supply Rivoroxared on a “buyout basis” to the public sector.

98. It can’t be denied that the protection of a patent serves the public interest. The monopoly given to the originator of a drug ensures that the public interest is served by ongoing research and development. This principle underpins the protection of patents in our law. In this case, Bayer has established a *prima facie* right in its patent, an infringement of its right by Dr Reddy’s, irreparable harm and an absence of an alternative remedy. In my view, in these circumstances, Dr Reddy’s would need to provide persuasive evidence that competing public interest considerations should sway the balance of convenience in its favour. Generalised

averments are not sufficient. I am not satisfied that it has made out a proper case on this score.

99. Finally, I accept that Dr Reddy's is in a somewhat different position to that of Bayer insofar as an alternative claim in damages is concerned. Bayer has tendered damages in the event that it ultimately loses its action. Unlike Bayer, Dr Reddy's is a new entrant in the market. It has a number of months' sales under its belt to provide it with a basis on which to predict what its further sales would have been absent the interdict. It will also be able to track future sales if it succeeds in its revocation application. It thus has evidence at its disposal which will provide it with a good basis on which to estimate its damages. For obvious reasons, the process of calculating damages would be far more complex, if possible at all, for Bayer.

100. I am satisfied, therefore, that the balance of convenience favours Bayer.

CONCLUSION AND ORDER

101. I conclude, for all the above reasons, that Bayer 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 applicants' expert witnesses.

This judgement 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 09 November 2021.

KEIGHTLEY J
JUDGE OF THE HIGH COURT
GAUTENG LOCAL DIVISION

Date Heard (Microsoft Teams): 20 August 2021

Date of Judgment: 09 November 2021

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