THE SUPREME COURT OF APPEAL OF SOUTH AFRICA

JUDGMENT

Case No: 139/2012

In the matter between:

CIPLA MEDPRO (PTY) LIMITED **Appellant**

and

AVENTIS PHARMA SA **Respondent**

and

TREATMENT ACTION CAMPAIGN **Amicus Curiae**

Case No: 138/2012

In the matter between:

AVENTIS PHARMA SA **1st Appellant**
SANOFI AVENTIS SOUTH AFRICA (PTY) LTD **2nd Appellant**
WINTHROP PHARMACEUTICALS (PTY) LTD **3rd Appellant**

and

CIPLA LIFE SCIENCES (PTY) LTD **1st Respondent**
CIPLA MEDPRO (PTY) LTD **2nd Respondent**
MEDPRO PHARMACEUTICA (PTY) LTD **3rd Respondent**

and

TREATMENT ACTION CAMPAIGN **Amicus Curiae**

Neutral citation: *Cipla Medpro v Aventis Pharma* (139/12) *Aventis Pharma SA v Cipla Life Sciences* (138/12) [2012] ZASCA 108 (26 July 2012)

Coram: NUGENT, HEHER, SNYDERS, TSHIQI JJA and McLAREN AJA

Heard: **15 MAY 2012**

Delivered: **26 JULY 2012**

Summary: **Patent – validity – whether claim vague or otherwise revocable – contributory infringement –**

interim interdict – relevance of public interest.

ORDER

On appeal from: Commissioner of Patents (Southwood J sitting as court of first instance):

1. The appeal in the s 51(1) proceedings (Case No 139/2012) is dismissed with costs that include the costs of two counsel.

2. The appeal in the infringement proceedings (Case No. 138/2012) is upheld with costs that include the costs of two counsel, to be paid by the respondents jointly and severally. The order of the Commissioner in those proceedings is set aside and the following order is substituted:

'(a) Pending the outcome of the action for final relief the respondents are interdicted from procuring or inducing, aiding and abetting, advising, inciting or instigating or assisting any other person to infringe claim 1 of South African Patent no 93/8936 in the Republic, and from disposing of or offering to dispose of CIPLA DOCETAXEL and CIPLA DOCETAXEL solvent.

(b) The respondents, jointly and severally, are to pay the costs of the application, including the costs of two counsel, and the costs of the expert witness Prof Davies.'

JUDGMENT

NUGENT JA (HEHER, SNYDERS, TSHIQI JJA and McLAREN AJA CONCURRING)

[1] There are two appeals before us. The protagonists in each appeal are one or more companies within the Aventis group, on the one side, and one or more companies within the Cipla group on the other. There is no need to name each of the companies and for convenience I will refer to the companies in each group interchangeably as Aventis and Cipla respectively.

[2] Both appeals concern South African Patent 93/8936, which is registered in the name of Aventis.[1] The patent is due to expire on 30 November 2013. Claim 1 of the patent specification was amended on two occasions. The first amendment is not relevant to this appeal. The second amendment was made in 2007. For convenience I will refer to the claim before its amendment in 2007 as the 'original claim' and to the claim after that amendment as the 'amended claim'.

[3] Aventis sells in South Africa a pharmaceutical product known as Taxotere, which has been registered for sale under the Medicines and Related Substances Act 101 of 1965. The active ingredient is docetaxel – a chemical compound in the taxoid family, also referred to as a taxane derivative. Docetaxel was synthesized in 1986 and was the subject of a patent that expired in 2007. It is used in the treatment of various cancers,

1Aventis Pharma SA, a French corporation, to be precise.

diluted in a perfusion solution, typically a solution of saline,[2] and administered by way of a drip. The components of Taxotere are presented for sale separated in two vials. The contents of the two vials are mixed together immediately before use so as to produce a composite solution that is injected into the bag of saline solution. Aventis says that Taxotere falls within the terms of its patent.

[4] Early in 2011 Aventis became aware that Cipla had applied for registration of, and intended importing and selling, a generic equivalent of Taxotere that it calls Cipla Docetaxel. In all material respects the components of Cipla Docetaxel correspond with those of Taxotere. Its components are also presented for sale separated into two vials – one containing what it calls Cipla Docetaxel and the other containing Cipla Docetaxel solvent – to be mixed together and administered in the same way as Taxotere.

[5] On 9 May 2011 the attorneys for Aventis wrote to Cipla's attorneys alleging that 'the exploitation of Cipla Docetaxel and Cipla Docetaxel solvent' would infringe its patent, and calling for an undertaking that Cipla would not 'make, use, exercise, dispose or offer to dispose of or import the Cipla Docetaxel or Cipla Docetaxel solvent products' until expiry of the patent.

[6] Cipla declined to give the undertaking and two applications were brought before the Commissioner of Patents. The first was an application by Cipla for an order setting aside the 2007 amendment of claim 1.[3] That was followed shortly by an application by Aventis for an interim interdict

2The perfusion solution need not necessarily be a saline solution but for convenience I refer to it as such.
3 SCA Case No 139/2012.

against infringement pending the outcome of an action for a final order to that effect.[4]

[7] The two applications were heard together by Southwood J sitting as the Commissioner of Patents. Both applications were dismissed and the respective parties now appeal with his leave.

[8] Before turning to the specific issues that arise in each appeal it is convenient to set out some background that is common to both.

[9] Taxane derivatives are not easily soluble in water. To hold a taxane derivative in solution when it is introduced into the saline solution, according to the patent specification, it had been found necessary first to prepare a stock solution of the taxane derivative, dissolved in a mixture of solvents comprising a surface-active agent (a wetting agent) and ethanol. For reasons that are not material the ethanol is then withdrawn leaving the taxane derivative dissolved in the stock solution. It was found, however, that when the stock solution was introduced into the saline solution, it formed a gel that inhibited its dissolution. Various techniques existed to prevent the formation of gel or to break down the gel when it formed and the patent relates to one such technique.

[10] The invention of the patent consists in an intermediate solution containing the taxane derivative dissolved in a surface active agent, mixed with an additive (ethanol) that breaks the gel or prevents its formation when the intermediate solution is introduced into the saline solution. The invention – titled 'New Taxoid-Based Compositions' – was claimed as follows in the original claim 1:

4SCA Case No 138/2012.

'An injectable composition comprising a taxane derivative in a surface-active agent and an additive which prevents the formation of, or breaks, a gelled phase during the mixing of the solution with an aqueous medium.'

[11] In 2007 Aventis sought and was granted an amendment to claim 1 under s 51 of the Patents Act 57 of 1978. After amendment the invention was claimed as follows:

'An injectable composition comprising (a) a taxane derivative in a polysorbate and (b) an additive, (a) and (b) being provided in ampoules, bottles or a double compartment device, the injectable composition being produced by mixing (a) and (b) to form an intermediate solution, wherein the additive prevents the formation of, or breaks, a gelled phase during mixing of the intermediate solution with an aqueous medium'.

[12] The 'polysorbate' referred to in the amended claim is a 'surface-active agent' of the kind referred to in the original claim and is not significant. The material amendment lies in the words 'provided in ampoules, bottles or a double compartment device, the injectable composition being produced by mixing (a) and (b) to form an intermediate solution'.

The First Appeal: The Amendment of Claim 1 (SCA Case No. 139/2012)

[13] Section 51(1) of the Act allows a patentee at any time to apply to the registrar for the amendment of a patent specification. Under s 51(1) an amendment that has been made in conflict with the provisions of the Act may be set aside on application to the Commissioner. An amendment will be in conflict with s 51(7) of the Act

'if the specification as amended would include any claim not wholly within the scope of a claim included in the specification before amendment.'

That section is aimed at preventing the patentee from broadening the monopoly that was originally claimed. Whether the amendment indeed

does so is a matter for construction and comparison of the claim before and after amendment.[5]

[14] *Gentiruco A.G. v Firestone SA (Pty) Ltd*[6] remains the leading case on the construction of patent specifications, in which it was said that

'the rule of interpretation is to ascertain, not what the inventor or patentee may have had in mind, but what the language used in the specification means, i.e., what his intention was as conveyed by the specification, properly construed, … since he is presumed to have intended what his language means. To ascertain that meaning the words used must be read grammatically and in their ordinary sense.'[7]

[15] The affidavits in both applications need to be read together for the purpose of each appeal. They contain considerable evidence by experts on each side concerning the proper construction of the claims. I return presently to the role of experts in construing a specification. For the moment I need only say that it is common cause, and the Commissioner approached the matter on those lines, that the claim before and after amendment must be given its ordinary meaning. The evidence of the experts does no more than to advance the meaning that each attributed to the claim on the ordinary meaning of language. That evidence is neither helpful nor admissible and I say no more about it at this stage.

[16] Counsel on both sides approached the matter on the basis that the amendment altered the original claim so as to claim what was called at times a 'two vial composition' – whatever that might mean – or what counsel for Cipla called a 'kit' from which the composition was to be made. That was said by Cipla to have broadened the original claim and by

5*Kimberly-Clark of South Africa (Pty) Ltd v Proctor & Gamble SA (Pty) Ltd* 1998 (4) SA 1 (SCA) 12H-I.
6*Gentiruco A.G. v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A).
7At 614B-C.

Aventis to have narrowed it. The Commissioner approached the matter in the same way. He summarised the case put forward by Cipla as follows:

'The applicant … contends in the founding affidavit that the amended claim 1 is intended to cover an unmixed collection of the specified ingredient substances which Mr Puckrin SC on behalf of the applicant referred to as a 'kit' to distinguish it from the composition.'

but said that

'amended claim 1 cannot be properly interpreted in that way. It still refers to an injectable composition, i.e. something which is obtained by mixing the ingredients referred to, and the method of mixing is expressly provided for.'

and he concluded that

'by amending the claim as it has done the patentee has restricted its monopoly and not extended it'.

[17] The ordinary meaning of a 'composition' in the present context is 'a substance formed by combination of various ingredients'.[8] It goes without saying that before they were combined the two ingredients described in the original claim existed separately. And if they were solutions then they must necessarily each have been held in impervious containers – whether bottles or ampoules or any other kind of impervious container. All of that is silently stated by mere description of the invention as a 'composition' of the stated constituents.

[18] The words added by amendment do not purport to claim a different invention. The invention of the amended claim remains a 'composition' with the same constituents and effect as stated in the original claim. The added words do no more than describe the prior state of those constituents before they were brought together to form the composition. In so doing they merely express what was silent in the original claim and neither

8Meaning III 1. In The Shorter Oxford English Dictionary.

broaden nor narrow it. It matters not that the Commissioner found that the claim was narrowed – it is sufficient if it was not broadened, which it was not, and on that basis the application was rightly dismissed.

The Second Appeal: Infringement (SCA Case No. 138/2012)

[19] Section 65(4) of the Act allows any ground upon which a patent may be revoked under s 61 to be raised as a defence to an infringement claim. Four grounds for revocation of claim 1 were raised by Cipla. First, that the claim was not clear.[9] Secondly, that the invention claimed was not a new invention.[10] Thirdly, that the invention claimed did not involve an inventive step.[11] And fourthly, that the prescribed declaration lodged when the patent was applied for contained a false statement or representation.[12]

[20] The Commissioner found that claim 1 was not clear and thus invalid and for that reason he found it unnecessary to deal with the other grounds for revocation, though he expressed the view that none placed the validity of the claim in serious doubt. On the view that I take it becomes necessary to deal with each of the grounds of alleged invalidity, other than one. The statement in the declaration that was alleged to have been false was a statement that the invention was new. If the invention was not new then the patent is invalid on that ground. The statement to the contrary in the declaration thus takes the matter no further and I need say no more about that ground.

[21] It is curious that the Commissioner, having found sufficient meaning in the claim to enable him to find that the original claim had

9Section 61(1)(f)(i).
10Section 61(1)(c) read with s 25(1).
11Section 61(1)(c) read with s 25(1).
12Section 61(1)(g).

been narrowed, then proceeded to find that its meaning was uncertain. The explanation lies in the approach that he took to the admissibility of expert evidence. The approach adopted by the Commissioner when construing the claims for purposes of the s 51 was that expert evidence was not admissible and it fell to be construed according to its ordinary language. However, he said that expert evidence was admissible to determine whether the claim was 'clear' for purposes of s 61(1)(f)(i). In that respect he preferred the evidence that had been given by the expert on behalf of Cipla – who expressed the view that the amended claim was ambiguous – and held that the patent was invalid on that ground. In my respectful view that approach was erroneous. It seems to me to confuse the clarity of the claim with the sufficiency of the specification.

[22] Patent protection provides an inducement for new knowledge to be brought into the public domain. In return for the monopoly that is conferred upon the patentee for a fixed period the patentee must describe the invention sufficiently to enable it to be performed once the monopoly expires. For that reason a patent may be revoked under s 61(1)(e) if

'the complete specification concerned does not sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be carried out by a person skilled in the art of such invention'.

[23] As pointed out in *Burrell's South African Design and Patent Law,*[13] 'an inquiry as to this ground of revocation involves a question of fact, namely, whether to a person skilled in the art the specification contains proper instructions for enabling the invention to be put into use'. For that purpose expert evidence is admissible, but only for that limited purpose. As Nicholas J expressed it in *De Beers Industrial Diamond Division*

13Timothy Donald Burrell *Burrell's South African Design and Patent Law* 3 ed (1999) para 4.22.

(Pty) Ltd v Ishizuka[14]

'[i]nsufficiency is a matter on which the opinion of expert witnesses is admissible. It is one of those cases where the court is, by reason of a lack of special knowledge and skill, not sufficiently informed to enable it without the assistance of an expert to come to any useful conclusion …. An expert witness is therefore "entitled to say whether in his opinion that which is described in the specification *on a given hypothesis as to its meaning* is capable of being carried into effect by a skilled worker"' (my emphasis).

[24] It is a different question whether a claim is clear. Holmes JA pointed out in *Letraset Ltd v Helios Ltd*[15] that the function of the claim (in contradistinction to the body of the specification) is to 'inform prospective rivals of the limits of the field denied to them while the patent lasts' and for that purpose 'the monopoly must clearly and succinctly define the limits of the field closed to others so that he who runs may read.'[16] In determining whether the limit of the monopoly is sufficiently defined 'technical term[s] [are] to be interpreted in the light of evidence given by witnesses learned or skilled in the relevant art' but

'[w]ords which have no special technical meaning are to be interpreted, not by witnesses, but by the Court, and are to be given their natural and ordinary meaning'.[17]

[25] I have already found, when dealing with the s 51 application, that the invention of the amended claim remains a composition with the same constituents and effect as stated in the original claim, and that the added words merely describe what was previously silent. What is claimed is clearly and unambiguously stated and does not offend s 61(1)(f)(i).

14*De Beers Industrial Diamond Division (Pty) Ltd v Ishizuka* 1980 (2) SA 191 (T) 198H.
15*Letraset Ltd v Helios Ltd* 1972 (3) SA 245 (A).
16At 249F-G.
17At 250C-E. As to the limits of expert evidence generally see *Gentiruco*, above, at 617G-618A, quoting with approval from *British Celanese Ltd v Courtaulds Ltd* (1935) 52 RPC 171 at 195.

[26] For a patent to be granted the invention must be new. *Burrell* points out that 'the best workable method to test for novelty is to take the integers of a given claim seriatim and to look for their counterparts in the alleged anticipation'.[18] Leaving aside the superfluous words that I referred to earlier, the integers of the claim are (a) an injectable composition comprising (b) a taxane derivative (c) in a polysorbate and (d) an additive (e) wherein the additive prevents the formation of, or breaks, a gelled phase during the mixing of the intermediate solution with an aqueous medium. I do not think it is necessary to refer to any of the documents that are said to anticipate the claim. Suffice it to say that none describes integer (e).

[27] An invention must not only be new in order to qualify for a patent but must also involve an inventive step – as it is usually expressed, it must not be obvious. Reading ss 25(1), (6) and (10) together – described in *Ensign-Bickford (South Africa) (Pty) Ltd v AECI Explosives and Chemicals Ltd*[19] as constituting a 'statutory code' on the subject – the enquiry involves the following steps:[20]

'(1) What is the inventive step said to be involved in the patent in suit?

(2) What was, at the priority date, the state of the art (as statutorily defined) relevant to that step?

(3) In what respect does the step go beyond, or differ from, that state of the art?

(4) Having regard to such development or difference, would the taking of the step be obvious to the skilled man?'

[28] The inventive step claimed for the invention is the addition of an additive (ethanol) to the intermediate solution, having the effect of preventing or breaking a gelled phase during the mixing of the solution

18Para 4.71.2.

19*Ensign-Bickford (South Africa) (Pty) Ltd v AECI Explosives and Chemicals Ltd* 1999 (1) SA 70 (SCA) at 80F.

20At 80H-J. See, too, *Roman Roller CC v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405 (A).

with an aqueous medium. The expert opinion of Dr Parolis – who deposed to an affidavit on behalf of Cipla – was that if that step did indeed go beyond or differ from the state of the art at the priority date, then it would have been obvious to the skilled addressee to take that step. His evidence on that issue was countered by Dr Davies, who deposed to an affidavit on behalf of Aventis. Counsel for Aventis readily accepted that it was not open to us to resolve that dispute on the affidavits, and that it falls to be resolved in the action that has been commenced for final relief. Nonetheless, the evidence on affidavit, and particularly the description in the specification of the methods that had previously been used to overcome the difficulty, is sufficient to establish prima facie – and in my view strongly so – that the taking of that step was far from obvious, and that the patent is not susceptible to revocation on that ground. That being so Aventus has established at least prima facie an entitlement to enforce its patent.

[29] But here Aventis encounters a complication that precludes its main claim – that is, its claim for an interdict against infringement. The Act confines infringement to 'making, using, exercising, disposing or offering to dispose of, or importing the invention'.[21] I have already found that the invention claimed in claim 1 is a composition made up of the components, and having the effect, stated in the claim. The product being imported and offered for disposal by Cipla is not that composition but only its components. A health worker who mixes the contents of the two vials 'makes' the composition that is the subject of the claim, thereby infringing the patent, but the infringement is by the health worker who made the composition, and not by Cipla who supplied the means for infringing.

21Section 45(1).

[30] Nonetheless, it is clear that Cipla imports and supplies its product with the direct and sole intention that that act of infringement should occur. Indeed, the insert that accompanies the product directs health workers to use the product in that way. It is on that basis that Aventis claims, as an alternative to its main claim, pending the outcome of its action for final relief, an order interdicting Cipla

'from procuring or inducing, aiding and abetting, advising, inciting or instigating or assisting any other person to infringe claim 1 of [the patent] by [Cipla], in the Republic, disposing of or offering to dispose of CIPLA DOCETAXEL or CIPLA DOCETAXEL solvent'.

[31] The unlawfulness of what has come to be known as 'contributory infringement' has widespread acceptance internationally. In England, under s 60(2) of the Patents Act 1977, a person infringes a patent if, without the consent of the proprietor, he

'supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom'.

[32] In *Grimme Maschinenfabrik GmbH & Co KG v Derek Scott (t/a Scotts Potato Machinery)*[22] the Court of Appeal explained that the section has its origins in Art. 26 of the Community Patent Convention – which requires that as far as possible the same legal rules should apply across all the countries where the provisions of the Convention have been implemented. That Article is in substantially the same terms as s 60(2) of

22*Grimme Maschinenfabrik GmbH & Co KG v Derek Scott (t/a Scotts Potato Machinery)* [2010] EWCA Civ 1110.

the English Act. It also observed that that form of infringement has been recognised in the United States for more than 100 years and said that

'[t]he specific origin of the term [contributory infringement] appears to have been s.271 of the US Patent Act 1952, in which it is specifically mentioned. Section 271(c) has marked similarities to Art. 26.1, and is as follows:

"Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practising a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, shall be liable as a contributory infringer."

Section 271(b) also makes anyone who "actively induces infringement liable as an infringer".'

[33] There are no comparable provisions in our Patents Act but our law would be most deficient if it had no remedy against intentionally aiding and abetting infringement of a patent and in my view there is indeed no such deficiency.

[34] Almost a century ago, in *McKenzie v Van der Merwe,*[23] it was accepted by this court that a person is delictually liable if he aids and abets another to commit a delict. Although the court was divided on the outcome that principle was endorsed by both the minority and the majority. Solomon JA, with whom De Villiers AJA and Juta AJA concurred,[24] expressed the law on the point as follows:

'Under the *Lex Aquilia* not only the persons who actually took part in the commission of a delict were held liable for the damage caused, but also those who assisted them in any way, as well as those by whose command or instigation or advice the delict was committed. To a similar effect is the passage which was quoted from *Grotius* (3, 32,

23*McKenzie v Van der Merwe* 1917 AD 41.

24Innes CJ decided the matter on a different basis and did not touch directly on the point.

12, 13) that everyone is liable for a delict "even though he has not done the deed himself, who has by act or omission in some way or other caused the deed or its consequence: by act, that is by command, consent, harbouring, abetting, advising or instigating".'

(On the facts, the majority held the defendant not to be liable.) In a dissenting judgment C.G. Maasdorp JA said on that point of law:

'According to the *Digest* (47, 2, 54, 4), "he who knowingly furnished instruments for stealing is liable, although he did not counsel the theft." This law we find laid down also by *Van der Linden* (2, 1, 8), and *Matthaeus,* in his work on Crimes (1, 11). Here the writers speak of crimes from which a civil liability for damages arises. In *Voet* (47, 2, 7) special mention is made of the liability of a person who lends a thief a ladder, well knowing what it was to be used for.'

[35] The principle is not confined to inducing or aiding and abetting the commission of a delict. In *Atlas Organic Fertilizers (Pty) Ltd v Pikkewyn Ghwano (Pty) Ltd*[25] it was held to be a delict for a person to induce another to breach a contract. Van Dikhorst J expressed it as follows:

'A delictual remedy is available to a party to a contract who complains that a third party has intentionally and without lawful justification induced another party to the contract to commit a breach thereof. *Solomon v Du Preez* 1920 CPD 401 at 404; *Jansen v Pienaar* (1881) 1 SC 276; *Isaacman v Miller* 1922 TPD 56; *Dun & Bradstreet (Pty) Ltd v SA Merchants Combined Credit Bureau (Cape) (Pty) Ltd* 1968 (1) SA 209 (C) at 215.'

[36] In *Esquire Electronics Ltd v Executive Video*[26] a submission that for there to be an infringement of a trade mark there must be use by the alleged infringer personally or through his servant or agent was disposed of by this court as follows:

'I do not think that this argument has any merit. The modern law of trade mark infringement is statutory, but its origins are to be found in the common law rule that it

25*Atlas Organic Fertilizers (Pty) Ltd v Pikkewyn Ghwano (Pty) Ltd* 1981 (2) SA 173 (T).
26*Esquire Electronics Ltd v Executive Video* 1986 (2) SA 576 (A).

is an actionable wrong, ie, a delict, to filch the trade of another by imitating the name, mark or device by which that person has acquired a reputation for his goods (see *Policansky Bros Ltd v L & H Policansky* 1935 AD 89 at 97). A delict is committed not only by the actual perpetrator, but by those who instigate or aid or advise its perpetration. See *McKenzie v Van der Merwe* 1917 AD 41 .... In the present case Executive Video produced the video cassettes and disposed of them, knowing and intending that they would be put to use for the purpose for which they were purchased or hired and that such use would necessarily involve the visual representation of the trade mark. In the circumstances it is idle to contend that Executive Video is innocent of infringement.'

[37] In *Bayerische Motoren Werke AG v Auto Body Spares SA (Pty) Ltd*[27] it was not disputed that the decision in *Esquire Electronics* applied equally to aiding and abetting infringement of a design registered under the Designs Act 195 of 1993.

[38] The principle was asserted in relation to patent infringement in *Viskase Corporation v Columbit (Pty) Limited and Harold Henry Zeh.*[28] In that case the managing director of a company that was alleged to have infringed a patent was sought to be held liable, on the grounds that he had 'caused and/or procured the First Defendant to infringe the said patents and in the premises [had] aided and abetted the First Defendant in the ... infringement.'[29] Harms J appears to have accepted it as self-evident that one who intentionally aids and abets infringement of a patent commits a delict. Although not necessary for the decision in that case (the company was found not to have infringed) he made the following observations:

'As indicated, it is not alleged that second defendant committed an act of infringement but that he aided and abetted the first defendant. The whole case against second

27*Bayerische Motoren Werke AG v Auto Body Spares SA* (Pty) Ltd 1999 BP 51 (T).
28*Viskase Corporation v Columbit (Pty) Limited and Harold Henry Zeh* 1986 BP 432 (CP). See, too, *Grande Paroisse SA v SASOL Ltd* 2003 BIP 11 (CP).
29At 434D.

defendant was that he, as Managing Director of first defendant, controlled its affairs and was instrumental in the purchase and sale of the infringing casings by the first defendant. That fact may establish that the second defendant did aid the first defendant but it does not establish any abetting by him. I fail to see how a person can abet unless he knows or has reason to believe that the act in question is a tortuous act. The concept of aiding and abetting applies only to delicts committed with intent (or *dolus). In casu* there is no evidence that second defendant had a "weder-regtelikheidsbewussyn". I do not believe that the statement of the English law in *Morton-Norwich Products Inc & Others v Intercen Ltd* 1978 RPC 501 (Ch. D) is in accordance with our law where it was stated at 515 that:

"I hold that if there is a concerted design by two persons to sell goods which in fact infringe an English patent, then the parties who have such design and do so sell are in fact joining tortfeasors and both infringe the patent whether they knew that such a sale would be an infringement or not. Once tortfeasance is proved the knowledge as to whether the act in question is or is not a tort does not affect liability."

On the other hand I do believe that *Rainham Chemical Works Ltd (In Liq) v Belvedere Fish Guano Co Ltd* (1921) 2 AC 465 (HL) is in accordance with our law and I quote at page 476:

"If the company was really trading independently on its own account, the fact that it was directed by Messrs. Feldman and Partridge would not render them responsible for its tortuous act unless, indeed, they were acts expressly directed by them. If a company is formed for the express purpose of doing a wrongful act or if, when formed, those in control expressly direct that a wrongful thing should be done, the individuals as well as the company are responsible for the consequences."'

[39] I think it is plain from *McKenzie*, and the authorities relied upon in that case, that, upon ordinary delictual principles, it is unlawful to incite or aid and abet the commission of a civil wrong, and I do not think it matters whether it is a wrong at common law or whether it is a wrong created by statute. Indeed, the decision of this court in *Esquire Electronics* seems to me to be directly in point. That it concerned a trade mark, and this case concerns a patent, does not seem to me to be a

material distinction. It is clear that Cipla's product is to be imported and disposed of with the specific and sole intention that it will be used in a manner that will infringe the patent, and its conduct in doing so will be unlawful.

[40] I have already held that, but for the question of obviousness, no grounds have been shown for revocation of the patent. The question of obviousness will be determined in the pending action but the material before us establishes, at least prima facie, that the patent is valid, and that Cipla is intent upon inciting, aiding and abetting its infringement. Where the existence or otherwise of a right asserted by an applicant cannot be decided finally on affidavit, but is nonetheless 'prima facie established though open to some doubt', it is trite that a court has a discretion to grant an interdict pending the outcome of proceedings for its final determination. The classic formulation of how that discretion is to be exercised is that of Holmes J in *Olympic Passenger Service (Pty) Ltd v Ramlagan*:[30]

'In such cases, upon proof of a well grounded apprehension of irreparable harm, and there being no adequate ordinary remedy the Court may grant an interdict – it has a discretion, to be exercised judicially upon a consideration of all the facts. Usually this will resolve itself into a nice consideration of the prospects of success and the balance of convenience – the stronger the prospects of success, the less need for such balance to favour the applicant: the weaker the prospects of success, the greater the need for the balance of convenience to favour him.'

[41] Cipla contends that damages will be an adequate remedy if it is found in due course that the patent is valid but I do not think that can seriously be considered. The very nature of the market is such that it will be almost impossible to determine what sales would have been made but

30*Olympic Passenger Service (Pty) Ltd v Ramlagan* 1957 (2) SA 382 (D) at 383E-F.

for the presence of Cipla's product. Nor is it an answer to its claim for an interdict that Aventis might be awarded a reasonable royalty as an alternative to damages.[31] That is a remedy available at the option of a patentee and it cannot be compelled in effect to license the use of its patent. The case resolves itself, then, into balancing against one another its prospects of success in the action it has commenced and the balance of convenience if an interdict were to be granted or withheld, as the case may be.

[42] There is some mention in Cipla's affidavits of prejudice to cancer sufferers if an interdict were to be granted but it is perfectly plain that in reality Cipla's resistance to an interdict is founded upon its commercial interests. It explains, quite frankly, the advantage to be had from being the first in the market for the supply of cheaper generic products once a patent expires. It says that a generic can be expected to expand the market for the medicine and that the first generic on the market can be expected permanently to capture about 70% of the expanded market within about eighteen months, leaving the remaining 30% to be shared amongst the original product and other generics that come onto the market. At the time its answering affidavit was filed Cipla was due to receive stock of Cipla Docetaxel, had already taken orders, and was in a position to immediately enter the market to secure that commercial advantage.

[43] The Treatment Action Campaign (TAC) was admitted to the appeal as amicus curiae, with the consent of both parties. Although purporting to act as an amicus curiae in truth it aligns itself with Cipla's opposition to the grant of an interdict. Its objections to an interdict were more widely framed.

31Section 65(6).

[44] The TAC founded its objections upon s 27(1) of the Constitution, which guarantees to everyone the right to have access to health care services, which, it has been said, includes a right to have access to affordable medicines.[32] In its heads of argument the TAC submitted that the Patents Act must be construed 'through the prism of the Constitution' and in a way that appropriately balances the rights of a patentee against the constitutional rights of others, and that it 'must be interpreted and applied to ensure the public interest in patent protection is in fact served and ensuring other rights are not unreasonably limited thereby'.

[45] What we are to make of viewing the legislation through the prism of the Constitution was not developed by the TAC. Section 39(2) indeed calls upon a court to 'promote the spirit, purport and objects of the Bill of Rights' when interpreting legislation, as pointed out by the TAC, but that does not open the door to changing the clear meaning of a statute. If the clear meaning conflicts with the Bill of Rights then the remedy is to strike it down, but there has been no challenge to the constitutional validity of any of the provisions of the Act that are now material. There is also no suggestion that the meaning of those provisions is not clear. The disputes centre instead on the application of those provisions to the facts of this case. On the assumption that the patent is not revocable for want of an inventive step I cannot see how s 39(2) or the prism of the Constitution comes into play so as to deny Aventis its right to enforce its patent.

[46] The TAC is on stronger ground when it advances factors to be taken account of when weighing the balance of convenience. In that respect it submitted that the broader public interest, and not only the

32*Minister of Health v New Clicks SA (Pty) Ltd* 2006 (2) SA 311 (CC) per Ngcobo J para 514 and Moseneke J para 706.

interests of the litigating parties, must be placed in the scales when weighing where the balance of convenience lies. Apart from decisions to that effect in this country,[33] we were referred to cases in other jurisdictions, particularly the United States, where injunctions against infringement have been refused on that ground.

[47] In *EBay Inc. v Mercexchange, L.L.C.*[34] the United States Supreme Court affirmed that the ordinary requirements in that country for the grant of a permanent injunction[35] – which include demonstrating that 'the public interest would not be disserved' by an injunction – applied as much to injunctions against patent infringement. We were referred by counsel for the TAC to four decisions in that country in which that requirement played a material role in the refusal of an injunction.

[48] In *Innogenetics, N.V. v Abbott Laboratories*[36] the court took account of the fact that 'enjoining [the defendant] from selling its product could pose a serious risk to the public health if plaintiff [the patentee] cannot fill the diagnostic market need.' Whether that would occur was not decided but was referred for the hearing of evidence, at which the

'plaintiff will bear the burden of proving by the preponderance of the evidence that the needs of the Hepatitis C diagnostic market could continue to be met if an injunction issued against the defendant.'

33*See Bamford v Minister of Community Development and State Auxiliary Services* 1981 (3) SA 1054 (C) at 1061D-E; *Marinpine Transport (Pty) Ltd v Local Road Transportation Board, Pietermaritzburg* 1984 (1) SA 230 (N) at 234D-F; *Corium (Pty) Ltd v Myburgh Park Langebaan* (Pty) Ltd 1993 (1) SA 853 (C) at 858E-G; *Verstappen v Port Edward Town Board* 1994 (3) SA 569 (D) at 576H-I.

34*EBay Inc v Mercexchange*, L.L.C. 547 US 388 (2006) at 392.

35A plaintiff who seeks a permanent injunction must demonstrate: '(1) that it has suffered irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and the defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction' - *EBay Inc* at 391.

36*Innogenetics, N.V. v Abbott Laboratories* 578 F. Supp 2d 1079 (W.D.Wis 2007) at 1105.

[49] In *Bard Peripheral Vascular, Inc v W.L.Gore & Associates, Inc*,[37] the fact that the infringer's product had superior medical features weighed against the grant of an injunction.

[50] *Johnson & Johnson Vision Care, Inc v Ciba Vision Corporation*[38] concerned the sale of contact lenses in infringement of a patent. At the time the injunction was sought the infringing lenses had been on the market for five years, they were the largest single-selling lenses in the United States, they were being worn by approximately 5.5 million patients, and they were the preferred choice for first fits amongst eye care practitioners. In refusing an injunction the court said that the evidence

'convinces the Court that millions of innocent contact lens wearers will suffer real adverse consequences if sale of [the infringing lenses] is enjoined … There will also be significant disruption, confusion and cost (estimated to be in the hundreds of millions of dollars) caused by [infringing lens] patients being abruptly told that the contact lens for which they have been fitted and with which they are satisfied, is no longer available. Choosing a new lens will at minimum require refitting and the new lens may not prove as efficacious as the [infringing lens]. Moreover, patients may have to be refitted more than once until an appropriate lens is found. An unidentified number will not be able to be refitted appropriately at all.'

[51] In *Edwards Lifesciences AG and Edwards Lifesciences LLC v Corevale Valve, Inc and Medtronic Corevalve, LLC*[39] an injunction was sought against the manufacturing of a prosthetic cardiac valve that could be implanted without surgery. The infringing valve was being manufactured in the United State but was being sold abroad. The evidence established that the infringer was capable of moving its

37*Bard Peripheral Vascular, Inc v W.L.Gore & Associates, Inc* 2009 WL 920300 (D.Ariz.).
38*Johnson & Johnson Vision Care, Inc v Ciba Vision Corporation* 712 F.Supp.2d 1285 (M.D.Fla. 2010).
39*Edwards Lifesciences AG and Edwards Lifesciences LLC v Corevale Valve, Inc and Medtronic Corevalve, LLC* 2011 WL 446203 (D. Del).

manufacturing operation to Mexico immediately if an injunction was granted. In refusing an injunction the court said that

'[t]he public interest would not be substantially advanced or harmed by the issuance of an injunction, since [the infringer] would be able to continue manufacturing accused product abroad without seriously affecting the supply of the product available to the public.'

[52] The requirements for an interim interdict in this country are more flexible than those for a permanent injunction in the United States. Counsel for Aventis accepted, nonetheless, that the 'public-interest' factors identified in those cases can and ought to be taken into account in the exercise of our discretion, but amply demonstrated that none of those concerns arise on the facts of this case.

[53] Bearing in mind the commercial advantage of first-entry to the generics market, it is common for a patentee of a pharmaceutical product to enter the market shortly before its patent expires with an alternative product that will compete with anticipated generics. No doubt it was with that in mind that Aventis obtained Medicines Control Council registration in 2006 of a product that it calls Docetere. Docetere is the same product as Taxotere, but re-branded and priced to compete with generics that can be expected to enter the market when the patent expires. At the time the affidavits in this matter were filed Docetere had not yet been placed on the market.

[54] Both parties filed supplementary affidavits placing new evidence before us and in each case the evidence was admitted unopposed. It emerges from the affidavit filed by Cipla that after the interdict had been refused it launched its product onto the market and that by the end of

March 2012 it was being used in the treatment of some 65-70 patients. On the other hand, Aventis has also now placed Docetere on the market.

[55] There is no suggestion that Aventis is not able to meet demand for Taxotere or Docetere, which was the disputed issue in *Innogenetics, N.V. v Abbott Laboratories.* Nor can it be said that Cipla's product offers superior medicinal benefits, which was the case in *Bard Peripheral Vascular, Inc v W.L.Gore & Associates, Inc.* It is also clear that there will be no material disruption to patients if an interdict were to be granted, as there would have been in *Johnson & Johnson Vision Care, Inc v Ciba Vision Corporation*. When the application was heard there were no users of Cipla Docetaxel. By March 2012 there were some 65-70 users, and I assume that by now there are probably more, but switching to Taxotere or Docetere for future treatment involves no medicinal disruption. This is also not a case like *Edwards Lifesciences,* in which an interdict will have no practical effect.

[56] The TAC's opposition to the grant of an interdict really comes down to no more than opposition to the monopoly that the law confers upon a patentee. It submits that those who cannot afford Taxotere, but are able to afford the price of Cipla Docetaxel, will be prejudiced if distribution of the latter were to be prohibited. Where the public is denied access to a generic during the lifetime of a patent that is the ordinary consequence of patent protection and it applies as much in all cases. To refuse an interdict only so as to frustrate the patentee's lawful monopoly seems to me to be an abuse of the discretionary powers of a court. But in any event there will be no material prejudice of that kind on the facts of this case.

[57] Taxotere, Docetere and Cipla Docetaxel are each sold in dosages of 20 mg and 80 mg. The maximum price at which a medicine may be sold to the public is what is called its 'single exit price'. The single exit price of Taxotere is R2 048 for 20 mg and R7 532 for 80 mg.[40] The price at which it is sold to the state by Aventis is R680 for 20 mg and R2 327 for 80 mg. The single exit price of Docetere is R1 100 for 20 mg and R3 850 for 80 mg. The single exit price of Cipla Docetaxel is R1 000 and R3 500 for 20 mg and 80 mg respectively.

[58] It will be apparent, then, that Taxotere is considerably more accessible than Cipla Docetaxel to patients who are dependent upon public health care, and there will be no prejudice at all to those patients, or to the state, if an interdict were to be granted. Patients who are dependent upon private health care will continue to have access to Taxotere (albeit at a considerably higher cost) and will have access to Docetere at only a marginally higher cost than Cipla Docetaxel (R100 more for a 20 mg dosage and R350 more for a dosage of 80 mg). Many of those patients will have access to medical insurance that will meet the additional cost, and for those who do not, the additional cost of Docetere is marginal.

[59] Thus the only implication for health care of granting an interdict is that patients who receive private health care, and who are not able to recover the cost of treatment from a private medical fund, will be obliged to pay 10% more for treatment than they might have done had Cipla's product remained on the market. Neither Cipla nor the TAC has identified any other prejudice that might be suffered by the public.

40The prices have all been rounded to the nearest Rand.

[60] As to the commercial prejudice to Cipla if an interdict were to be granted – the loss of the advantage of having the first generic on the market – Aventis has as much interest as Cipla in establishing the first foothold in the generic market and the prejudice to it if an interdict is refused will be precisely the same.

[61] But as appears from *Olympic Passenger Service* the balance of convenience is not evaluated in isolation: the stronger the prospects of success in the main proceedings, the less need for the balance to favour the applicant, and vice versa. If Aventis eventually establishes the validity of its patent, and has meanwhile been denied an interdict, it will have lost the advantage given to it by its monopoly of establishing itself unimpeded in the generic market before the patent expires. In the interim it will also have lost sales of Taxotere or Docetere. On the other hand, if Aventis does not establish the validity of its patent, and an interdict has meanwhile been granted, Cipla will have been denied that same opportunity to establish a foothold in the market, and will have lost sales of its product. In either event the public interest will not have been materially affected. The most that can be said is that patients who receive private health-care, and who are not able to recover the cost of treatment from a private medical fund, will have been required to pay 10% more for treatment than they might otherwise have done. In those circumstances the balance of convenience does not seem to me to fall substantially on one side or another and the prospects of success or failure in the action become prominent. In that respect I have already said that such doubt as there might be as to the validity of the patent seems to me to be slight and that becomes decisive. In those circumstances I can see no proper ground for denying Aventis the relief that it claims.

[62] For those reasons

1. The appeal in the s 51(1) proceedings (Case No. 139/2012) is dismissed with costs that include the costs of two counsel.

2. The appeal in the infringement proceedings (Case No. 138/2012) is upheld with costs that include the costs of two counsel, to be paid by the respondents jointly and severally. The order of the Commissioner in those proceedings is set aside and the following order is substituted:

'(a) Pending the outcome of the action for final relief the respondents are interdicted from procuring or inducing, aiding and abetting, advising, inciting or instigating or assisting any other person to infringe claim 1 of South African Patent no. 93/8936 in the Republic, and from disposing of or offering to dispose of CIPLA DOCETAXEL and CIPLA DOCETAXEL solvent.

(b) The respondents, jointly and severally, are to pay the costs of the application, including the costs of two counsel, and the costs of the expert witness Prof Davies.'

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R W NUGENT
JUDGE OF APPEAL

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Case 139/2012

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