REPUBLIC OF SOUTH AFRICA

IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, JOHANNESBURG

(1) REPORTABLE: No
(2) OF INTEREST TO OTHER JUDGES: No

1/8/2022
DATE SIGNATURE

CASE NO: 2022/004040

In the matter between:

HOMEMED (PTY) LIMITED	Applicant
and	
PETRUS JACOBUS CLAASEN	First Respondent
EXPERT LABORATORY SERVICES (PTY) LIMITED	Second Respondent
THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY	Third Respondent

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JUDGMENT

This judgment is deemed to be handed down upon uploading by the Registrar to the electronic court file.

Gilbert AJ:

1. The applicant seeks on an urgent basis various interdictory relief pending the finalisation of an action restraining the first and second respondents from trading in competition with the applicant in Drugs of Abuse ("DOA") rapid screening tests.

2. In essence, the applicant contends that:

   2.1. the first respondent ("Claasen") is in breach of restraint of trade and confidentiality undertakings given by him in 2009, and further in breach of renewed confidentiality undertakings given by him in 2019, in favour of the applicant as his then employer by taking up employment with the second respondent ("ELS"), which has recently become a direct competitor of the applicant, and is pursuing the applicant's customers in the DOA rapid screening test market;

   2.2. Claasen and ELS are utilising the applicant's customer connections and confidential information which Claasen built up on the applicant's behalf during his lengthy employment with the applicant to compete unlawfully with the applicant in the DOA rapid screening test market;

   2.3. ELS is, in any event, competing unlawfully in the DOA rapid screening test market in that it does not have a medical establishment licence as required in terms of the regulatory regime imposed by the third respondent ("SAHPRA") under the Medicines and Related Substances

Act, 101 of 1965 ("the Medicines Act") and its accompanying Regulations and directives.

3. The applicant contends that it seeks interim relief in both form and substance, which is pending the finalisation of an action to be instituted within 30 days of the order in which the applicant presumably will seek final relief to similar effect.[1]

4. Unsurprisingly in matters of this nature, Claasen and ELS who oppose the relief (and who will be referred to as 'the respondents"), contend that the relief is final in effect in that by the time the trial action is finalised the period of restraint would have run out. Therefore, they argue, in looking at substance rather than form, the relief sought was final relief and therefore the applicant had to satisfy the requirements for final interdictory relief, relying upon the well-known *BHT Water Treatment (Pty) Limited v Leslie and another* 1993 (1) SA 47 (W). The applicant argued that the relief nonetheless remained interim relief and so that it need only satisfy the requirements for an interim interdict. Although not referenced by the parties, the applicant's position is supported by *Radio Islam v Chairperson, Council of the Independent Broadcasting Authority and another* 1999 (3) SA 897 (W), which differs from *BHT*.

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[1] Although prayer 3 of the notice of motion seeking interdictory relief arising from what the applicant contends is the unlawful competition by ELS as it is unlicenced is not framed as being sought pending the action, this was an editing error in the notice of motion as this relief too is sought on an interim basis, as appear from the affidavits and as confirmed by the applicant's senior counsel in argument. The respondents raised no objection.

5. I will return to this aspect later in the judgment.

6. The papers are voluminous. The affidavits in the application alone exceed 670 pages. In addition, the parties delivered various confidential affidavits, which themselves numbered some 211 pages, some of which were only made available to the court at the commencement of the hearing. While these two bundles of affidavits do contain many annexes, as would be expected, including of a very detailed nature, they also contain hundreds of pages of affidavits.

7. It is a challenge for a busy urgent court to be able to digest such volumes, particularly in what is not garden-variety restraint and unlawful competition litigation. I enquired of the parties now that the matter was ripe for hearing (as they have managed to achieve an exchange of all the affidavits that they wished and also comprehensive heads of argument - for which I am indebted to counsel) whether they were amenable to approaching the ordinary opposed motion court which would have more time to consider and determine the matter, the indications being that the matter could be heard by that court in October 2022. The applicant's counsel submitted that would be too late in relation to what the applicant contends is the on-going prejudice that it suffers by the continued daily trading by ELS in the products.

8. And so, as the parties understandably appreciated, that should the urgent court hear the matter (as the respondents argued that the matter was not urgent and so should not be heard at a;; by the urgent court as it lacked urgency), it came with the limitations inherent in an urgent court hearing a voluminous matter of particular complexity.

9. I am satisfied that a sufficient case for urgency has been made out, particularly given the nature of the relief sought in what is a complex commercial matter. There is an inherent urgency to restraint litigation, and in my view the applicant has not unreasonably delayed in launching these proceedings. The applicant's stipulated timetable for the exchange of affidavits as provided for in its notice of motion ultimately proved effective given that the matter as between the parties was ripe for hearing by the urgent court, notwithstanding the numerous affidavits that have been exchanged.

10. The applicant is an established supplier of medical devices and diagnostic tests. It was established some sixteen years ago in 2006. It supplies a wide range of rapid diagnostic test and medical devices, including Glucose, HbAlc, Cholesterol, Cardiac Markers, HIV, Malaria, PSA, Pregnancy, Urinalysis and Drugs of Abuse ("DOA") products. The applicant's range of Drugs of Abuse products is extensive. These include the DoA rapid testing products that ELS markets in competition.

11. In contrast, ELS is a relatively new business, having commenced business in March 2021 as a forensic toxicology laboratory. ELS was founded by Dr Johannes Laurens ("Dr Laurens") and Ms Maraliese Jordaan ("Ms Jordaan"), who are its protagonists, who have filed affidavits supporting Claasen's answering affidavit.

12. Between Dr Laurens and Ms Jordaan, they have over 40 years' experience in the field of workplace drug testing. Dr Laurens is a medical biochemist and forensic toxicologist. He holds an honour's degree in chemistry, a master's

degree in physical chemistry, a doctor's degree in analytical chemistry and a master's degree in applied toxicology. Ms Jordaan is a medical scientist. She holds a bachelor's degree in human Physiology and Psychology, a bachelor's degree in Chemical Pathology and a master's degree in Chemical Philology.

13. Dr Laurens and Ms Jordaan's working relationship started at the Lancet Toxicology Centre in 2004. In 2009, Dr Laurens and Ms Jordaan established the forensic toxicology lab at the University of Pretoria ("the UP Lab").

14. During their time at the UP Lab, which spanned over a decade, Dr Laurens and Ms Jordaan: (i) performed and/or oversaw more than 50 000 drug confirmation tests; (ii) presented more than 150 invited seminars on the issue of workplace drug testing; (iii) advised multiple industries on drug and alcohol testing policy matters and testing strategies; (iv) provided expert witness testimony in court cases and disciplinary hearings; (v) provided scientific and general advice to DOA screening test suppliers, including to the applicant, regarding minimum product specifications, quality, minimum operational criteria and the cross-reactivity of certain substances with drug tests..

15. It is undisputed on the facts that ELS is seeking to expand from a forensic toxicology laboratory which performs inter alia 'confirmation testing' (and in which Dr Laurens and Ms Jordaan have participated for years) into distributing the DOA rapid screening tests themselves (in which the applicant is an established player). Should ELS be restrained from doing so, it would not affect its primary business of a forensic toxicology laboratory. On the other hand, as the respondents argue, the DOA rapid testing business of the

applicant only constitutes a portion of its overall business, albeit that it has been conducting that part of its business for many years. Either way, it does not appear from the papers that the grant or refusal of the interdictory relief, as the case may be, will result in the demise of either the applicant or ELS as corporate trading entities.

16. The position of Claasen is that should the interdictory relief be granted restraining him from being employed by ELS in the DOA rapid testing market, he would then be restrained from being employed in the field where he has particular experience. The prejudice suffered by Claasen is therefore not quite of the same nature as that which may be suffered by the applicant and ELS as the trading entities. During argument, applicant's counsel pointed out and as appears from paragraphs 220 and 221 of the founding affidavit, the applicant's concern with Claasen as their erstwhile employee being employed by ELS is not that he is per se employed by ELS, but rather that his employment by ELS was specifically for competing in the DOA rapid screening testing market.

17. The applicant's interdictory relief as appears from the notice of motion and the founding affidavit is founded primarily on three pillars.

18. The first pillar is directed at Claasen as the applicant's erstwhile employee who undertook various contractual restraints and confidentiality undertakings in favour of the applicant. The applicant contends that Claasen's taking up of employment with ELS following his resignation from the applicant in January 2022 and in using what the applicant says is its customer connections and confidential information results in breaches of those contractual undertakings.

19. Claasen commenced employment with the applicant in 2006 as a sales representative. On 7 December 2009 Claasen signed an employment agreement as the a regional sales manager, which contained both a three-year restraint and confidentiality undertaking.[2]

20. On 14 December 2011 Claasen was called upon to again sign a employment agreement, which he did as a key account manager,[3] but which did not include his signature of a 12-month restraint of trade undertaking that was attached as annexure "C"[4] to that agreement. While during argument there appear to be some debate as to whether Claasen may had agreed to this restraint of trade given the manner in which he had signed and initialled the documents, the applicant accepted that the case that it sought to make out against Claasen in the affidavits based upon the restraint undertakings, in contrast to the confidentiality undertakings, was based upon the 2009 restraint of trade undertaking, and not the 2011 agreement or any later agreement.

21. The applicant underwent various restructuring and required its employees to reapply for new positions. Claasen did so and was appointed as the corporate health and sales manager in May 2019. He again signed an employment agreement, containing the presently relevant confidentiality undertakings.[5] Claasen, on the common cause facts, refused to sign the attached restraint of

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[2] Annexe "FA2" at 02-98. The restraint is clause 5 at 02-107.

[3] Annexe "RA0" at 002-541.

[4] At 02-554.

[5] Annexe "FA13" at 02-137.

trade undertaking. That unsigned restraint of trade agreement reflects an express manuscript annotation made by the applicant's relevant representative at the time that Claasen "*'[d]oesn't want to sign*".[6]

22. Of some significance, it is Claasen that attaches the unsigned 2019 restraint undertaking to his answering affidavit, to demonstrate what he contends is his deliberate decision not to commit to a restraint undertaking, as distinct from the confidentiality undertakings.

23. The applicant, as stated, does not rely on any restraint of trade other than that signed by Claasen in 2009, which is for three years after he ceased his employment. The applicant also relies upon Claasen's confidentiality undertakings (as distinct from the restraint of trade undertakings) in Claasen's most recent employment contract of May 2019.

24. It is common cause that Claasen resigned in January 2022 and took up employment with ELS as the sales and marketing director (as well as a directorship and shareholding) where he is presently engaged in competing with the applicant in the DOA rapid screening testing market.

25. Amongst the grounds of opposition raised by Claasen to the enforcement of the restraint is that the restraint undertakings given by him in 2009 were either novated by the subsequent employment agreements where he did not, deliberately, undertake any restraint undertakings, alternatively that the

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[6] Annexe "AA7" at p 02-416.

applicant in failing to insist that he sign the subsequent restraints in 2011 and 2019 had waived its entitlement to rely on the 2009 restraint and/or that such conduct by the applicant constituted an representation by omission that the applicant did not regard Claasen as bound by a restraint of trade and so that the applicant is now estopped from relying upon the historical 2009 restraint.

26. The second pillar of the relief sought by the applicant is that Claasen in any event as well as ELS as the second respondent are restrained under common law from competing unlawfully with the applicant on the basis that the respondents are making use of the applicant's customer connections and confidential information as a springboard to compete with it. The applicant relies upon the two usual forms of proprietary interests, namely customer connections and confidential information (trade secrets). The confidential information, the applicant alleges, consists of information relating to the applicant's suppliers, customers and their requirements, the formulation of product and customer strategies, pricing and costing strategies including the formulation and negotiation of discounts and rebates, profit margins for all products, overall sales figures of the applicant, including its performance and sales trends.[7]

27. The respondents' opposition to this category of relief is wide-ranging and includes challenging the proprietary interests asserted by the applicant.

28. Much of the affidavits are directed at these disputes as to whether the applicant has proprietary interests deserving of protection. For example, the respondents

[7] FA para 101 at 02-35.

deny that the customer connections are those of the applicant, at least exclusively, asserting that the protagonists behind ELS, namely Dr Laurens and Ms Jordaan have over the years established their own relationships with many of the customers that the applicant contends are theirs, and so the applicant cannot contend for those customers moving with Claasen 'in his pocket' to ELS.[8]

29. The respondents also challenge the confidential nature of the confidential information asserted by the applicant as well as the usefulness of that information to ELS.

30. What also features prominently in the affidavits and in the argument before me is what is to be made of the conduct of Claasen commencing in March 2021, which was some time before he resigned from applicant's employee in January 2022. There is no dispute that an exchange of emails took place at the instance of Claasen commencing March 2021 while he was still employed with the applicant with *inter alia* Dr Laurens and Ms Jordaan after they had established ELS.[9] Mr Botha SC for the applicant argued with vigour that on the applicant's interpretation of the facts this demonstrates that from as early as March 2021 Claasen while still an employee of the applicant had in concert with ELS began to take steps towards setting up ELS in competition with the applicant in the DOA rapid testing screening market. The email exchanges include Claasen

[8] *Rawlins v Caravantruck* 1993 (1) SA 537 (A) at 451 G-I.

[9] See, for example, "CA19" to the confidential affidavit at pages 65 to 67, dated March and April 2021, and "CA20" at page 68 dated 17 May 2021.

sending a customer list to *inter alia* Dr Laurens and Ms Jordaan at ELS. Mr Michau SC for the respondents on the other hand argued with equal vigour that there is no merit in this and advance their own, innocent, explanation for the exchange of these emails.

31. As each parties' senior counsel argued why their submitted interpretation of the facts was so clear that the other parties' version must be rejected as far-fetched and fanciful, what did become clear is that a motion court, and more so an urgent court, would not be able to make any final finding on this aspect. As will appear for reasons that follow later, it is undesirable for me as an urgent court to express any views on this dominant dispute between the parties given that such dispute would probably feature prominently in further litigation between the parties.

32. The third pillar of the relief sought by the applicant is to rely upon a second and distinct species of unlawful competition, namely that ELS was competing unlawfully with the applicant in that it was not licenced to participate in the DOA rapid screening testing market. It is now to that relief that I turn as a determination in relation thereto provides a basis to decide what to do in relation to the applicant's remaining pillars of relief.

33. The applicant contends that DOA rapid screening tests are "*medical devices*" as defined in the Medicines Act, and more particularly Class B medical devices. The applicant's argument continues that in terms of section 22C(1)(b) as read with section 22C(6) of the Medicines Act, a distributor of a medical device must have a medical establishment licence.

34. As it is common cause that ELS, a distributor, does not have such a licence, the applicant argues that ELS by trading contrary to a statutory prohibition requiring it to be licenced constitutes a form of unlawful competition entitling the applicant to interdictory relief.

35. The main basis of opposition by ELS is to dispute that the DOA rapid screening tests are 'medical devices' as defined, but if they are medical devices, then they are not Class B devices but rather non-measuring, non-sterile Class A medical devices, for which no medical establishment licence is necessary in terms of a exclusion in a directive issued in 2017 by the regulatory authority ["the 2017 Directive"].[10]

36. The respondents do not dispute, justifiably, that should ELS be required to have a medical establishment licence, their distribution of the products where such a licence is required, would constitute an actionable form of unlawful competition entitling the applicant to relief. For example, in the *locus classicus* of *Patz v Greene & Co* 1907 TS 427 the competing respondent carried on business as a general dealer, butcher and eating-house in close proximity to the applicant in circumstances where the respondent was not licenced to do so. The Full Bench of this Division found that such illegal trading can sustain an interdict at the instance of the licenced party, and granted relief.

37. A more recent decision, closer to the present facts, is *Ingelheim Pharmaceuticals (Pty) Limited v Novartis SA (Pty) Limited and another* [2005]

[10] Annexe "AA10" at 02-428.

4 All SA 453 (W) where the court granted an interdict restraining a competitor selling its own unregistered tonic in competition with the applicant's registered tonic where that tonic was required to be registered as a medicine under the Medicines Act. The respondent was interdicted from dealing in its tonic while that product remained unregistered.[11]

38. ELS do not seriously dispute that if the products are 'medical devices', and, if so, if those medical devices did not fall within the exclusion, that it would be precluded from trading in those product. Section 22C(6) of the Medicines Act expressly provides that "*[n]o medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection 1(b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any medicine, scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection*". Section 22C(1)(b) provides for SAHPRA upon for application in the prescribed manner and on payment of the prescribed fee to issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of *inter alia* a medical device, a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medical device upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as SAHPRA may determine.

[11] In the present instance it is not a matter of the DOA rapid screening tests not being registered – they presently have not been called up for registration in terms of section 14(2) of the Medicines Act – but rather that ELS does not have a medical establishment licence as required in terms of section 22C(1)(b).

39. The two central issues for the court to consider at this stage based upon ELS' grounds of opposition are (i) whether the DoA rapid screening tests are 'medical devices' as envisaged in the Medicines Act, and (ii) if so, whether they fall within the exclusion provided for in the 2017 Directive.

40. First it is necessary determine the threshold that the applicant needs to satisfy in these proceedings in relation to these two issues. This requires a consideration of whether the relief that the applicant seeks under this pillar is interim relief or final relief.

41. The applicant seeks that pending the finalisation of an action to be instituted within 30 days of this order ELS as the second respondent be interdicted and restrained from distributing the products until ELS has been licenced to do so by SAHPRA in terms of the Medicines Act. This relief is cast in the form of interim relief,[12] but the respondents contend nonetheless that it is final in effect.

42. Keightley J, also sitting as an urgent court, in *Andalusite Resources (Pty) Limited v Investec Bank Limited and another* 2021 (1) SA 140 (GJ) had to wrestle with this issue. When presented with the divergence of the authorities in this Division presented by *BHT* and by *Radio Islam*, which ultimately Keightley J found that she need not resolve because of the nature of the

[12] See again footnote 1 above.

interdict being sought before her (which was not a restraint of trade of a limited duration), had the following to say[13]:

> "*[19] To date there has been no finality as to which of these decisions is correct. The most recent authority to give consideration to the issue was the Supreme Court of Appeal in Cipla. Neither the minority nor the majority judgment made a determination on whether the BHT or the Radio Islam line of authority was correct. The minority judgment assumed, without deciding, that BHT was correct. However, the majority considered that —*
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> > *'it (was not) necessary or advisable to express an opinion on the correctness or otherwise of the approach taken by the court of first instance in BHT. That issue may arise for consideration in another matter. It does not arise here. This appeal raises four square the time-honoured criteria as to what is meant by "final in effect" in distinguishing between interlocutory and final interdicts. It does not implicate the correctness or otherwise of BHT.'*
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> *[20] As Rogers AJA pointed out in the minority judgment in Cipla:*
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> > *'An interim interdict pending the determination of an action is not final in effect, which is why matters decided for purposes of granting an interim interdict do not become res judicata.'*
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> *This is because the interim order does not finally dispose of the rights between the parties: the lis between them remains to be disposed of in the pending main proceedings. In my view this explains why the*

[13] After considering some of the more well-known decisions, including *Cipla Agrimed (Pty) Limited v Merck Sharp Dohme Corporation and others* 2018 (6) SA 440 (SCA) and *Cronshaw and another v Coin Security Group (Pty) Limited* 1996 (1) SA 686 (A)

court in BHT found that the effect of the interdict in that case was final. For all practical purposes, in that case the lis between the parties would not be finally resolved before the restraint period ended and the interdict fell away. So, the interim interdict gave full (and final) effect to the applicant's right to restrain the respondent from taking up other employment for the entire restraint period, notwithstanding that the applicant's right to do so was in dispute. It is for this reason that the BHT approach has been applied, in some cases, in circumstances where the rights underpinning the interdict are time-bound as in, for example, restraint of trade cases.

[21] However, it is important in this regard to distinguish between the effect of the interdict on the disputed right itself, on the one hand, and its effect on the object of that right, on the other. In the present case the grant of the interdict will not have any final effect on the underlying, but disputed, right of Investec to enforce its cession over the bank account. This is a matter that will be determined in due course by the court in the money judgment application. What the interdict would have a final effect on is the current object of that right, viz the moneys in respect of which it would otherwise be permitted to enforce its right of cession. If the interdict were to be granted, and Investec were later to be vindicated in its money judgment, its right of cession would be fully effective once again. The difference then would be that it would be exercised over a different object, viz the moneys then standing to the credit of the account. Thus, although it would never be able to exercise its right again over moneys paid out while the interdict was in place, it nonetheless could exercise its right over new moneys coming in. The important point, in my view, is that the interdict will not have any final effect on Investec's right of cession, but only on the object of Investec's right.

[22] It is not necessary for me to make any finding as to whether the court in BHT was correct. Even if I were to follow BHT, as Investec

> *suggests, the present case does not fall into the same category. The interdict, if granted, will not have final effect on Investec's rights. The rights of the parties in respect of the bank account will be finally determined by the court in the money judgment. What will be affected is Investec's access to, and preservation of, the moneys currently standing to the credit of the bank account. In this respect, undoubtedly there will be prejudice to Investec. It will never be able again to assert its rights over the funds disbursed from the account. However, it is not every kind of prejudice that is relevant to determining whether an interdict will have final or only interim effect. As the majority in Cipla noted:*
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> > *'(I)t has been consistently held that "final in effect" means that an issue in the suit has been affected by the order such that the issue cannot be revisited either by the court of first instance or that hearing the action."*[14]

43. In my view, the right underpinning the interdict under this pillar is not necessarily time-bound[15] as it may endure indefinitely as ELS may never be licensed. This can be contrasted to an interdict under the first two pillars, where the underlying rights would be time-bound, whether by the period of the contractual restraint or the shelf-life of the usefulness of the confidential information and customer connections. I therefore too[16] need not find which of the *BHT* or *Radio Islam* lines of authority is to prevail when dealing with relief that is time-bound.

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[14] My emphasis.

[15] Para 20 above, in *Andalusite*.

[16] As Keightley J too did not need to decide: para 22.

44. Applying Keightley J's analysis to the present pillar of interdictory relief, should I make an interim order it would not finally dispose of the rights between the parties in that the trial court would itself have to revisit the disputed issues and decide those issues for itself. My finding whether the products constitute medical devices that fall outside the exclusion would not be *res judicata*.[17] It will be for the trial court to finally decide whether the products are medical devices, and if so, excluded devices. I therefore find that the applicant needs to establish the requirements for interim interdictory relief rather than final interdictory relief.

45. This entails the applicant establishing *inter alia* that it has a *prima facie* right, although open to some doubt.

46. Whereas the applicant's case is that the DOA rapid screening tests are non-exempted Class B medical devices under the Medicines Act, ELS contends that the products tests are not 'medical devices' but if they are, then they are exempted Class A medical devices under the 2017 Directive as they are non-measuring non-sterile devices.

47. To the extent that this involves a dispute of fact, the test to be applied at this stage in these interim proceedings is that stated in *Simon NO v Air Operations of Europe AB and others* 1991 (1) SA 217 (SCA) at 228 G-H, where the relevant test in *Webster v Mitchell* 1948 (1) SA 1186 (W) at 1189, as modified in *Gool v*

[17] Rogers AJA in the minority judgment in *Cipla*, cited in para 20 of *Andalusite*.

Minister of Justice and another 1995 (2) SA 682 (C) at 688 B-F, was summarised:

> *"The accepted test for a prima facie right in the context of an interim interdict is to take the facts averred by the applicants, together with such facts as set out by the respondent that are not or cannot be disputed and to consider whether, having regard to their inherent probabilities, the applicants should on those facts obtain final relief at the trial. The facts set up in contradiction by the respondent should then be considered and, if serious doubt is thrown upon the case of the applicant, he cannot succeed".*[18]

48. The definition of 'medical device' in the Medicines Act is wide:

> "***"medical device"*** *means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) -*
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> *(a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:*
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> *(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;*
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> *(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;*

[18] As cited is *Annex Distribution (Pty) Limited and others v Bank of Baroda* 2018 (1) SA 562 (GP) at para 19.

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means."

49. The applicant argues that the DOA rapid screening tests diagnose, monitor, treat or alleviate a disease as contemplated in section 1(a)(i) of the definition, particularly as drug abuse is classified as a disease according to the Diagnostic and Statistical Manual of Medical Disorders, 5th Edition (known as the "DSM5"). The applicant further argues that DOA rapid screening tests provide information for medical or diagnostic purposes by means of *in vitro* (i.e. outside the human body) examination of specimens derived from the human body, as contemplated in section 1(a)(vii) of the definition.

50. Given the wide wording of the definition, at least *prima facie* for present purposes, that there is much to be said for the argument that DOA rapid screening tests fall within the plain meaning of the definition.

51. To counter this, ELS contends in its answering affidavit that DOA screening tests do not fall within the definition of 'medical device' for the reasons set out in paragraphs 141 to 141.7 of the answering affidavit.

52. Relying upon what ELS asserts is the expert evidence of Dr Laurens,[19] it argues that DOA screening tests are not used for diagnostic purposes but rather for compliance testing and therefore cannot be medical devices.[20]

53. Relying on the expertise of Dr Laurens, ELS contends that if the DOA screening tests are medical devices, they ought to be classified as non-measuring, non-sterile Class A medical devices, for which it is common cause no medical establishment licence is required.[21]

54. Dr Laurens testifies that there is no risk to a patient or public health in using a DOA screening test and that urinating into a cup attracts no risk to any person performing that task. Therefore, he testifies, DOA screening tests should be classified under Class A of the SAHPRA guidelines (as they are low risk[22]) if they are indeed medical devices at all.[23]

55. Dr Laurens further testifies that DOA screening tests do not have a measuring function because they merely indicate the possible presence of a specific drug

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[19] See paragraphs 39 to 46 of Dr Lauren's confirmatory affidavit at 02-449 to 02-452.

[20] Paragraph 42 at 02-451.

[21] Paragraph 43 at 02-451.

[22] See paragraph 176 of the respondents' heads of argument, at 05-179.

[23] Paragraph 44 at 02-451.

and they do not confirm the presence or quantities of a potential drug. Confirmation testing still needs to be done in the laboratory. As the product is merely a screening test, and which requires a laboratory confirmation where accurate measuring then takes place, the test itself, Dr Lauren opines, cannot constitute a measuring device,[24] and so the non-measuring requirement of the exclusion applies.

56. Dr Laurens testifies that that sterility means that the medical device must be pathogen-free. As this is not a requirement for screening tests in that screening tests must merely be free from drug contamination, the non-sterile requirement of the exclusion applies.[25]

57. And so the conclusion reached by Dr Laurens, and advanced by ELS, is that DoA rapid screening tests, if they are medical devices, are Class A medical devices that are do not perform a measuring function or which are required to be sterile, and so fall within the exclusion in the 2017 Directive.

58. In reply, the applicant persists that the products are Class B medical devices. The applicant is supported in this by the view of the third respondent as the statutory authority, who confirmed in an email to the applicant dated 11 July 2022 that the products are Class B medical devices.[26] More particularly the Authority's medical device technical officer recorded in the email that:

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[24] Paragraph 45 at 02-451.

[25] Paragraph 46 at 02-451, 2.

[26] Annexe "RA6" at 02-579.

"Yes they are in vitro diagnostics tests similar to pregnancy test kits i.e. reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of multiple drugs of abuse in a clinical specimen".

59. The applicant's position is further supported by that of the US Food and Drug Administration ("FDA"), which classifies the applicant's supplier's DOA screening tests as Class II, which it says is similar to South Africa's Class B. The FDA has classified ELS' supplier's (AllTest) DOA screening tests as Class II, as is evident from the extract of the FDA's 510(k) Substantial Equivalence Determination Decision Summary attached to the replying affidavit.[27]

60. The European Union's ("EU") Medical Device Coordination Group ("MDCG") also classifies the DOA screening tests as Class B in accordance with their relevant Guidance on Classification Rules for *in vitro* Diagnostic Medical Devices for Regulation EU 2017/746.[28]

61. In addition, the applicant relies upon an extract from correspondence from the FDA addressed to one of its suppliers of the DOA test.

62. This documentation emanating from these various regulatory authorities, including our own, support the applicant's position that the products are class B products.

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[27] Annexe "RA7" at 02-582 to 585.

[28] Annexe "RA8" at 02-586.

63. Although ELS challenges this evidence as inadmissible hearsay evidence, given the nature of these proceedings, which are urgent motion proceedings for interim relief, and considering the various factors in section 3(1)(c) of the Law of Evidence Amendment Act, 1998 (unfortunately the urgent nature of these proceedings precludes a close written consideration of these factors) I find the evidence to be admissible for present purposes.

64. In any event, it appears to me in determining whether the applicant has a *prima facie* right although open to some doubt that the definition of medical device is sufficiently wide so that even without this supporting material from the regulatory authorities, the DOA rapid screening tests are medical devices. It also appears to me in determining whether the applicant has a *prima facie* right although open to some doubt that the DOA rapid screening tests although they produce either a negative or non-negative result, rather than a true positive result, are nonetheless measuring devices, and therefore cannot fall within the exclusion. For purposes of founding a *prima facie* right in the present context, I (as does SAHPRA) do not see a significant difference between a DOA screening test and a pregnancy test, particularly adopting a purposive approach towards interpreting the relevant provisions of the Medicines Act.

65. I too, as the court did in *Ingelheim*,[29] refer to the graphic description by Kriegler AJA in *Administrator, Cape v Raats Rontgen and Vermeulen (Pty) Limited* 1992 (1) SA 245 (A):[30]

> *"It would be advisable to pause for reflection lest the wood become obscured by the trees. Manifestly the Act was put on the statute book to protect the citizenry at large. Substances for the treatment of human ailments are as old as mankind itself; so are poisons and quacks. The technological explosion of the twentieth century brought in its wake a flood of pharmaceuticals unknown before and incomprehensible to most. The man in the street – and indeed many medical practitioners – could not cope with the cornucopian outpourings of the world-wide network of inventors and manufacturers of medicines.*
>
> *Moreover, the marvels of advertising, marketing and distribution brought such fruits within the grasp of the general public. Hence an Act designed, as the long title emphasises, to register and control medicines. The enactment created a tightly meshed screening mechanism whereby the public was to be safeguarded: in general any medicine supplied to any person is, first, subject to stringent certification by experts; then it has to be clearly, correctly and comprehensively packaged and labelled and may only be sold by certain classes of persons and with proper explanatory information; to round it out detailed mechanisms for enforcement are created and ancillary measures are authorised."*

66. The respondents argued that there was no danger to the public in performing a DOA screening test and therefore adopting a purposive approach towards the

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[29] In para 6.

[30] At 254B-E.

Medicines Act, which was passed in the interests of the public and particularly from a health and safety perspective, that DOA rapid screening tests cannot be medical devices. Mr Botha SC for the applicant countered this by saying that there was a very real danger should defective DOA screening tests be used. If the screening tests failed to record a non-negative result (and erroneously recorded a negative result) and so failed to detect persons who might (albeit not definitely) be under the influence of drugs of abuse, and so results in those undetected persons operating heavy equipment and machinery, that would pose a real danger to the public. In my view, this is a persuasive argument as to why those that distribute DOA rapid screening tests should fall within the scope of those who are required to be licenced under the Medicines Act.

67. Mr Michau SC for ELS argued that it should not be for the court to determine whether the DOA rapid screening tests were medical devices or fell within the exclusion as that should be within the purview of the regulatory authority. Mr Michau pointed out that the SAHPRA had not called up the products for registration.

68. The courts have decided issues of this nature. The decision of MM Jansen J in *Allergan Pharmaceuticals (Pty) Limited v Medicines Control Council and others* [2015] 3 All SA 173 (GP) is an example. In that matter the court decided on a semi-urgent basis whether a range of solutions acting as dry eye lubricants constituted medical devices as defined in the Medicines Act. In *Treatment*

Action Campaign and another v Rath and others [2008] 4 All SA 360 (C)[31] the court found that it was for it, and not the regulatory authority, to decide whether a particular substance was a medicine.

69. That SAHPRA has not called up the DOA screening tests for registration as it is empowered to do under section 14(2)(a) of the Medicines Act is not of decisive significance. The Medicines Act does not require a medical device to be called up for registration or to be registered before a distributor of that device must hold the required medical establishment licence in terms of section 22C(1)(b).

70. Mr Michau SC argues that the expert evidence under oath of its expert witness, Dr Laurens, should prevail over what is the inadmissible hearsay evidence of the applicant. Mr Botha SC for the applicant countered that whatever Dr Lauren's experience, that did not extend to experience in whether a particular product constituted a medical device, and if so, what kind of medical device.

71. Apart from having already found the material emanating from the regulating authorities is admissible for present purposes, in my view, as already stated, even if that material is excluded, it appears to me, bearing in mind that approach to be taken in assessing expert evidence,[32] that at least on a *prima facie* basis

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[31] At para 62, particularly, *"[the term "medicine" is defined in the Medicines Act and if there is a dispute about the nature of a substance it is for the courts to make a determination whether or not a particular substance is a medicine as defined in the Medicines Act."*

[32] *Michael and another v Linksfield Park Clinic (Pty) Ltd and another* 2001 (3) SA 1188 (SCA), para 26 and 36.

the DOA rapid screening tests are medical devices that fall outside the exclusion.

72. Bearing in mind that the applicant need only at this stage establish a *prima facie* right although open to some doubt, I find that the DOA rapid screening tests are medical devices and are not non-measuring, non-sterile Class A medical devices falling within the exclusion in the 2017 Directive, and so find that ELS requires a medical establishment licence in terms of section 22(1)(b) of the Medicines Act.

73. In the circumstances, I find that the applicant has established its *prima facie* right to found a restraint preventing ELS from competing with it in distributing DOA rapid screening tests while ELS remains unlicenced.

74. Insofar as the requirements that there must be a well-grounded apprehension of irreparable harm if interim relief is not granted and the ultimate relief is granted and the absence of an alternate remedy adequate in the circumstances, these do not present any particular difficulty. ELS is trading in the products without the required medical establishment licence and intends continuing to do so. The applicant who is licenced will for the usual reasons find it difficult to quantify such losses as it suffers by ELS trading unlawfully in the products and having distributed products that the applicant might (but not necessarily would have) otherwise have distributed. The difficulties in the applicant establishing the requirements of causation and damages in a subsequent delictual action does not make such an action an adequate alternative remedy in the circumstances.

75. In relation to the remaining requirement for an interim interdict, namely weighing the prejudice to the applicant if the interim relief is refused against the prejudice that ELS will suffer if the interim relief is granted, I find that the balance of convenience favour granting the interim interdict. As already described, it is ELS who as a fledgling company is seeking to expand into a new market separate from its primary business of a forensic toxicology laboratory. In doing so, ELS can be expected to have ensured that it had abided with the relevant regulatory framework and, in seeking to participate in this market, should it find itself on the wrong side of an interim finding that it needs to comply with the regulatory framework by obtaining an medical establishment licence, especially where the regulatory authority is of the view that it needs to do so, its prejudice is outweighed by that of applicant who has gone to the effort and expense of complying with the prescribed regulatory requirements.[33]

76. Also relevant in this regard is that the applicant has placed on record that should ELS establish in due course that it has suffered damages because it was prevented by way of an interim interdict from distributing DOA rapid screening tests and a court ultimately finds that it was not required to be so licenced, that the fact that an interim order was in place will not be relied upon by the applicant as a defendant in any subsequent delictual action by ELS as a basis for arguing that its conduct was not unlawful as it was under the protection of an interim order.

[33] See *Ingelheim* para 30.

77. In the circumstances, I find that the applicant is entitled to interim relief restraining ELS from distributing DOA rapid screening tests until it has been licenced to do so by SAHPRA in terms of the Medicines Act, and I intend granting such relief.

78. What does this then mean for the applicant's remaining pillars of interdictory relief?

79. Assuming (but not deciding) in favour of the applicant that the remaining relief is interim in nature and so only the requirements for interim relief need be satisfied, I intend, rather than entering the treacherous terrain bristling with factual disputes whether the applicant has established even a *prima facie* right, although open to some doubt, considering the relief from the perspective of the remaining requirements for interim relief.

80. Bearing in mind that the various requirements for an interim interdict are not to be considered separately or in isolation but in conjunction with each other in order to determine whether the court should exercise its discretion in favour of granting the interim relief sought,[34] the applicant having already succeeded in obtaining interdictory relief that restrains ELS from distributing the products, has secured adequate protection, albeit in a different form and under a different cause of action. ELS cannot distribute the products until it is licenced and therefore as matters stand the relief sought against the respondents based

[34] See the authorities cited in Erasmus *Superior Court Practice* RS17, 2021, at D6-16D, in footnote 160.

upon the alleged unlawful competition arising from the alleged use by ELS of the applicant's trade connections and confidential information is unnecessary.

81. Similarly, I find that the interdictory relief against Claasen as the first respondent based on his contractual undertakings is also unnecessary because the applicant's concern is not that Claasen is employed by ELS per se but rather that he is employed by ELS in competing with it in the DOA rapid screening testing market. Once ELS cannot so compete because of the relief to be granted against it, there is no pressing need to restrain Claasen.

82. What also weighs on me in exercising my discretion against granting any further relief to the applicant is that apart from the applicant having now obtained a satisfactory remedy in the form of the interim relief that will be granted, I have doubt that such proprietary interests as the applicant seeks to protect are still sufficiently extant and worthy of protection to outweigh the prejudice that the respondents may suffer if interim relief is granted. I say this because it is now six months since Claasen left the employ of the applicant in January 2022. Assuming in favour of the applicant that Claasen immediately upon joining ELS commenced wilfully exploiting the applicant's confidential information and trade connections for the benefit of ELS, and ELS deriving the benefit thereof from that date, six months will have now passed. The respondents' version is that six months would be a sufficient sterilisation period to have enabled the applicant to maintain the customer connections and so therefore remove any springboard that ELS may have had in engaging Claasen in February 2022 and/or in making use of the alleged confidential information.

83. Bearing in mind the applicant's posited case that Claasen had already from March to May 2021, over a year ago, started passing on this information to ELS for purposes of trading illegally with the applicant in the forthcoming year, i.e. from the beginning of 2022 (without obviously deciding that this in fact occurred), the usefulness of any such trade connections and confidential information would have been significantly diluted.

84. The restraint signed by Claasen in 2009 was three years commencing upon the termination of his employment. The applicant pared that three-year period to 18 months in these proceedings.[35] The applicant then further as an alternative pared the restraint period to twelve months because this was the restraint period that it sought that the applicant agree to in the most recent restraint undertaking that Claasen refused to sign, in 2019. Bearing in mind that Claasen's position and influence within the applicant had significantly increased from his initial engagement in 2016 as a sales representative to his appointment as the corporate health and sales manager in May 2019, that the applicant itself found a restraint period of 12 months to be sufficient in May 2019 does demonstrate that that would be a more appropriate period than 18 months.

85. If that 12-month period is applied from February 2022, half of that restraint period would already be up, assuming in favour of the applicant that it would be entitled to a restraint for that period and that it satisfied the other requirements for interim relief. I do not find favour with the applicant's argument that this period must only start in June 2022 when Claasen's erstwhile position in the

[35] See, for example, *Den Braven SA (Pty) Ltd v Pillay and another* [2008] 3 All SA 518 (D).

applicant was formally filled. As the respondents explain in their affidavits, which is not disputed, there were already personnel in place within the applicant that could immediately attend to maintain its customer connections and dilute any customer connections that the applicant alleges that Claasen could take with him in his pocket. The person appointed as Claasen's replacement emanated from within the applicant, being a sales representative, having served under and with Claasen for some time before Claasen departed to ELS in February 2022. The point is that the applicant did not have to start from scratch in maintaining its customer connections.

86. Depending how long-lived the interim relief may be that I intend granting in that it would remain in place until ELS is licenced, assuming that that takes place before the applicant's contemplated action is finalised, it may be that 12 months would have passed since January 2022. While it may also be that the licencing may occur within the 12 months, upon a consideration of all the factors, in the exercise of my discretion,[36] I find that the relief that I intend granting under the third pilar of relief is sufficient and that the applicant does not require further relief.

87. Although the applicant has succeeded in obtaining interdictory relief against ELS as the second respondent, I intend granting the usual form order that such

[36] As the wide nature of the discretion, see *Knox d'Arcy Ltd and others v Jamieson and others* 1996 (4) SA 348 (A) at 360D – 361E.

costs as were incurred between the applicant and ELS are reserved for determination by the trial court in the applicant's intended action against ELS.

88. Insofar as the costs of Claasen are concerned, I do not intend making any order for costs. Although the applicant has not obtained relief against Claasen, this is largely because the relief granted against ELS suffices to protect the applicant's interests and where the predominant factor that weighed against the granting of relief against Claasen separately as the first respondent was that effective relief would be granted in any event as against ELS as the second respondent.

89. I considered whether the costs of the application insofar as Claasen was concerned should also stand over for a trial court to determine. Upon reflection, an order of no costs would be more appropriate. It may transpire that following upon this judgment that the applicant wishes only to institute action proceedings against ELS and should the applicant be required also to institute action proceedings against Claasen only to prevent it otherwise becoming liable for the costs of these proceedings because it did not institute action against Claasen, an order that that the costs vis-à-vis Claasen stand over for trial may precipitate an action against a defendant that would not otherwise have taken place.

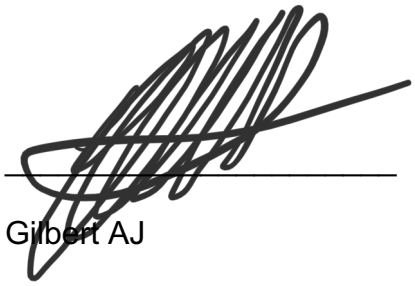
90. The following order is made:

90.1. Pending finalisation of an action to be instituted by the applicant against the second respondent within 30 court days of this order, the second respondent is interdicted and restrained from distributing drugs of abuse

rapid screen testing products until it has been licenced to do so by the third respondent in terms of the Medicines and Related Substances Control Act, 1965.

90.2. The costs of the application as between the applicant and the second respondent are reserved for determination by the trial court in the action to be launched by the applicant, save that if the applicant does not launch the action within the stipulated period, then the applicant will pay the second respondent's costs of this application.

90.3. No order of costs is made in relation to the application as between the applicant and the first respondent.



Gilbert AJ

Date of hearing:	27 July 2022
Date of judgment:	1 August 2022
Counsel for the applicant:	A Botha SC with K Turner
Instructed by:	Bouwer and Olivier Inc

Counsel for the first and second respondents:	R Michau SC with C W Pretorius
Instructed by:	Barnard Inc
Counsel for the third respondent:	No appearance