REPUBLIC OF SOUTH AFRICA

IN THE HIGH COURT OF SOUTH AFRICA

GAUTENG DIVISION, PRETORIA

CASE NO.: 2024-008772

(1) REPORTABLE: NO
(2) OF INTEREST TO OTHER JUDGES: NO
(3) REVISED: NO

Date: 6 August 2024 E van der Schyff

In the matter between:

V-TECH (PTY) LTD APPLICANT

and

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY RESPONDENT

JUDGMENT

Van der Schyff J

Introduction

[1] The applicant, V-Tech, seeks interdictory relief against the respondent, the South African Health Products Regulatory Authority (SAHPRA), pending the outcome of two internal appeals lodged in terms of section 24A of the Medicines and Related

Substances Act 101 of 1965 (the Medicines Act) against various decisions of SAHPRA.

[2] SAHPRA is an organ of state established in terms of section 2 of the Medicines Act. It is the regulatory authority responsible for the monitoring, evaluation, regulation, investigation, inspection, registration, and control of medicines, scheduled substances, clinical trials, and related matters in the public interest.

[3] V-Tech (Pty) Ltd is the owner of two community pharmacies, one of which is V-Tech Prescriptions Pharmacy. V-Tech Prescriptions Pharmacy is a compounding pharmacy. For approximately the past 15 to 20 years,[1] V-Tech Prescription Pharmacy and its predecessor have been importing internationally sourced active pharmaceutical ingredients (APIs), which are scheduled substances, for purposes of compounding veterinary medicines. Few APIs are manufactured locally for use in veterinary medicines, and the veterinary medicines industry cannot function without accessing the international market for both active and inactive ingredients.

[4] Neither SAHPRA nor its predecessor, the Medicines Control Council, required V-Tech or its community pharmacy, V-Tech Prescriptions Pharmacy, to have an import licence in terms of section 22C(1)(b) of the Medicines Act. It was only recently, during the last 12 to 15 months, that SAHPRA raised the issue that V-Tech Prescription Pharmacy, or V-Tech (Pty) Ltd, requires an import licence in terms of the Medicines Act to import APIs. SAHPRA detained consignments of APIs at the port of entry on 30 May 2023, 11 June 2023, 12 June 2023, and 19 June 2023. During June 2023, V-Tech noted an appeal in terms of section 24A of the Medicines Act against SAHPRA's decision to detain and place an embargo on several consignments of AIPs.

[5] Despite raising the licence issue, SAHPRA continued to release the APIs imported by V-Tech on a without prejudice basis when V-Tech provided documentary proof

[1] The founding affidavit and annexures thereto refer respectively to 'more than 10 years', 'between 15 and 20 years' and 'approximately 20 years.' In the answer to the supplementary affidavit filed by SAHPRA, V-Tech refers to a period of 'more than 18 years'.

that it previously imported the relevant APIs without a licence. During December 2023, SAHPRA apparently changed tack and communicated the following to V-Tech:

> 'I wish to draw your attention to the provisions of section 22C(1)(b) of the Medicines and Related Substances Act, as amended which stipulates that the importer of a scheduled substance must be the holder of a licence issued in terms of Section 22C(1)(b).
> Please be advised that, without any admission of wrongdoing and for the purposes of resolving this matter, V-Tech will be allowed to import Methocarbamol on Bill of Entry 023-488366664.
> Please be advised that from the 28th of February 2024, all medicine and scheduled substances imports must comply with the requirements, failing which release for import will not be authorised from the port of entry. Further be advised that SAHPRA has licenced companies to import scheduled substances, and such information is publicly available and accessible on SAHPRA's website,'

[6] V-Tech approached the urgent court for an urgent interim interdictory relief to suspend SAHPRA's decision not to release for import any APIs from 28 February 2024 unless V-Tech holds an import licence as envisaged by section 22C(1)(b) of the Medicines Act until the statutory appeal committee which has already been appointed by the Minister of Health, has made a ruling regarding the question whether a licenced community pharmacy such as V-Tech Prescriptions Pharmacy, requires an import licence to import APIs or not. The application was struck from the roll. V-Tech subsequently enrolled the application on the opposed motion roll. The applicant effective seeks an order that the *status quo ante* as it prevailed before 1 March 2024 when SAHPRA commenced enforcing their interpretation of section 22C(1)(b) of the Medicines Act be preserved pending the exhaustion of the internal remedies provided for in the Medicines Act.

Applicable legal principles

[7] Before the parties' respective contentions are analysed, it is necessary to reflect on the legal principles that apply in interim applications for interim relief and the purpose affidavits serve in motion proceedings.

[8] To be successful, an applicant seeking interim relief must establish four factors. The factors are summarised in *Reckitt & Colman SA (Pty) Ltd v SC Johnson & Son (SA) (Pty) Ltd.*[2] The applicant must establish- (i) that it has a clear right or, if not clear a *prima facie* right, (ii) that there is a well-grounded apprehension of irreparable harm if the interim relief is not granted and the ultimate relief is eventually granted, (iii) that the balance of convenience favours the grant of an interim interdict; and (iv) that the applicant has no other satisfactory remedy.

[9] The court in *Reckitt* explained that in determining whether the applicant's right is *prima facie* established, though open to some doubt, a court should consider the facts set out by the applicant together with any facts set out by the respondent which the applicant cannot dispute, and consider whether having regard to the inherent probabilities, the applicant could obtain final relief at the trial of the main action. The facts set out by the respondent should then be considered, and if serious doubt is thrown upon the case of the applicant, it cannot succeed.[3]

[10] It is trite law that the affidavits in motion proceedings serve to define the issues between the parties and place the essential evidence before the court.[4] The facts set out in the founding affidavit must be set out simply, clearly, and in a chronological manner. Primary facts constitute the evidence before the court. It is well-established that the drawing of inferences from primary facts is the function of the court. In the absence of primary facts, the inferences drawn by a deponent are nothing more than

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[2] 1995 (1) SA 725 (T) 729I-730G.

[3] See also *Webster v Mitchell* 1948 (1) SA 1186 (W) 1189-1190.

[4] *Swissborough Diamond Mines v Government of the RSA* 1999 (2) SA 279 (TPD) 323-324.

that deponent's conclusions, and it does not constitute evidential material capable of supporting a cause of action.[5]

The parties' respective contentions

The applicant's case

[11] V-Tech Prescriptions Pharmacy is registered as a community pharmacy and authorised to compound medicines or scheduled substances for veterinary use.[6] The pharmacy does not sell its product wholesale.

[12] V-Tech Prescriptions Pharmacy and its predecessor have been using internationally sourced pharmaceutical ingredients for a period of approximately 20 years. Few APIs are manufactured locally, and the industry relies on imported ingredients. SAHPRA and its predecessor allowed V-Tech to import APIs without requiring a licence, until the recent change of stance.

[13] V-Tech contends that it has a *prima facie* right to import scheduled substances without having to obtain a licence from SAHPRA. It submits that under proper construction and interpretation of the relevant statutory provisions, a community pharmacy is entitled to import APIs for compounding purposes without having to acquire a licence in terms of section 22C(1)(b) of the Medicines Act. There is no statutory provision in either the Medicines Act or the Pharmacy Act requiring a community pharmacy to acquire an import licence to import any scheduled substance. In fact, V-Tech contends, 'a community pharmacy, licensed with the SAPC, is specifically not included in the list of entities to whom a licence to import a medicine or scheduled substance may be granted by the respondent in terms of Section 22C(1)(b).' The right of a community pharmacy to import scheduled

[5] *Die Dros (Pty) Ltd v Telefon Beverages (Pty) Ltd* 2003 (4) SA 207 (C) at para [28].

[6] Regulation 18(2) of the Regulations Relating to the Practice of Pharmacy made in terms of section 35A of the Pharmacy Act 53 of 1974; section 14(4) of the Medicines Act, the Rules Relating to Good Pharmacy Practice, regulations 1 and 3 of the General regulations promulgated in terms of the Medicines Act.

substances is only limited in terms of section 22A(11)(a) relating to specified schedule 5, schedule 6, and schedule 7 substances.

[14] V-Tech is registered with and falls under the auspices of the South African Pharmacy Council (SAPC). The SAPC has inspected V-Tech regularly to ensure compliance with the Pharmacy Act and its regulations. SAHPRA serves a different purpose than SAPC, with the latter controlling the conduct of pharmacists.

[15] V-Tech contends that SAHPRA's decision threatens V-Tech's very existence as the compounding of veterinary medicines on prescriptions of veterinary professionals constitutes the core business of its two pharmacies.

[16] The inability to import APIs 'will undoubtedly lead to the termination of the applicant's business and the closure of its two community pharmacies.' This will result in the loss of millions of Rands in turnover, equipment, and investment, and fifty employees will be left destitute. The ensuing consequences will have a devastating effect on veterinarians, their animal patients, and animal owners all over South Africa, an absence of compounded veterinary medicine could lead to scores of livestock getting sick with resultant food shortages. The large wildlife industry in South Africa relies on the applicant's compounded medicines because there are no registered medicines available. If the applicant is prevented from rendering its service of providing compounded medicines on prescription, it will have a severe negative impact on animal health and food security in the country. V-Tech was officially approved by the SAPC as a training facility in 2019. The cessation of V-Tech Prescriptions Pharmacy's community pharmacy activities will bring an end to all training services.

[17] V-Tech contends that it has a reasonable apprehension-

> 'that if [SAHPRA] were to place an embargo on all scheduled substances and APIs imported by the [it] from 28 February 2024, unless [it's] V-Tech Prescriptions Pharmacy has an import licence, it will cause irreparable harm to [V-Tech].'

[18] The termination of its business would, among others, cause V-Tech not to be able to pursue the internal appeals before the appeal committee appointed in terms of section 24A.

[19] V-Tech contends that the balance of convenience clearly favours it if regard is had to the prejudice that V-Tech will suffer if the interim interdict is not granted, SAHPRA will not suffer any prejudice. There have not been any adverse consequences as a result of V-Tech importing APIs through the years. V-Tech complies stringently with the norms and standards required of a community pharmacy as set out in the regulations to the Pharmacy Act and the SAPC's Rules. To ensure that the APIs used by V-Tech Prescriptions Pharmacy comply with the highest pharmaceutical standards, V-Tech, among others, sources APIs only from reputable foreign and local suppliers that are ISO-GMP or GDP certified, test all injectable compounds for sterility by an independent SANAS or SAHPRA accredited laboratory, test batches of compounded medicines by accredited laboratories, keeps retention samples of each batch of compounded medicine, use the draft SAHPRA GMCP Guidelines to standardise the compounding process. Due to the services V-Tech provides, the 'wider public interest' favours it.

[20] V-Tech contends that there is no other remedy available to it. An embargo on all scheduled substances imported by it would lead to the termination of its business, and an action for damages cannot be pursued by an entity that has ceased to exist.

The respondent's answer

[21] SAHPRA acknowledges that V-Tech imported APIs for a substantial period of time, possibly spanning 20 years, without having been required to acquire a licence to import. SAHPRA explains that until recently it had no presence at South Africa's ports of entry. And had to rely on Port Health officials who neither reported nor were accountable to SAHPRA. This has now changed and enables SAHPRA to identify long-standing practices in direct contravention of the Medicines Act regulatory framework. SAHPRA emphasises that it advised V-Tech already in June 2023 that

it is unlawful to import scheduled substances without a licence issued in terms of section 22C(1)(b) of the Medicines Act.

[22] SAHPRA states that the primary difficulty with V-Tech's case is that the detained goods were released to V-Tech subsequent to the lodging of the section 24A appeals. In SAHPRA's view, the matters giving rise to the appeals have been resolved, essentially ousting the appeals committee's jurisdiction to entertain the merits of the appeals. In addition, SAHPRA contends it is the detainment of consignments that is the subject matter of the appeals lodged and not SAHPRA's decision of 7 December 2023. Until that decision has been reviewed and set aside, it must be given full legal effect. SAHPRA submits that the appeal committee does not have the power to declare an administrative decision *ultra vires*; only a High Court can make that determination.

[23] SAHPRA states that V-Tech mischaracterises the decision conveyed to it in the letter of December 2023 referred to above. SAHPRA does not insist that V-Tech Prescription Pharmacy acquire a licence to import APIs but that V-Tech (Pty) Ltd, as the company that owns the community pharmacy, must either obtain a licence itself to import or use the services of an entity that is licensed to import.

[24] SAHPRA submits that if V-Tech succeeds in obtaining the relief it seeks, it will effectively be given free reign, without any regulatory oversight, to continue importing APIs of untested quality and continue using those APIs without any oversight by SAHPRA.

[25] SAHPRA denies that V-Tech established a *prima facie* right and contends that V-Tech's interpretation of the applicable legal framework is fatally flawed. V-Tech Prescriptions Pharmacy's entitlement to compound in accordance with section 14(4) of the Medicines Act is neither here nor there. The action SAHPRA is regulating through requiring a section 22C(1)(b) licence is the actual importing of APIs. SAHPRA submits that the only reasonable way to understand section 22C(1)(b) it its broader regulatory context is by understanding that this provision authorises SAHPRA to issue licences to <u>only</u> the persons and entities listed in the section, and absent a licence to import, an entity may not import scheduled substances.

[26] SAHPRA takes issue with the fact that V-Tech seeks interim interdictory relief without informing the court- (i) when it expects a new consignment of APIs to arrive in South Africa, (ii) by when it expects to run out of its current stock. Without this information, and (iii) whether and to what extent suitable alternative products are locally available, SAHPRA contends, it is impossible to determine when and how SAHPRA's decision to enforce the licence requirement will impact on V-Tech. SAHPRA submits that V-Tech allegation that the decision to require V-Tech to obtain a licence for importing APIs will cause it irreparable harm is V-Tech's opinion and not substantiated by primary facts. There is no evidence even to suggest that in the absence of granting an interim interdict SAHPRA's decision could 'result in the termination of its entire business …' To be irreparable or irreversible, the alleged harm would have to be such that by the time the appeal committee has made its ruling, V-Tech's community pharmacies will no longer be trading.

[27] As far as the balance of convenience is concerned, SAHPRA submits that while it is unlikely to suffer prejudice or harm if the interdictory relief is granted, the public interest requires SAHPRA to exercise regulatory control over the importation of APIs of unproven quality and safety which is used to supply compounded medicines.

[28] SAHPRA contends that V-Tech has not even considered the option of contracting with a licenced entity to source APIs as an interim mitigating measure, or explained why V-Tech (Pty) Ltd does or did not attempt to secure its own importing licence.

The applicant's reply

[29] I note only the most pertinent aspects replied to by V-Tech, although I have considered the totality of the replying affidavit.

i. V-Tech states that the appeals lodged under section 24A of the Medicines Act deal not only with the detained consignments of APIs but also with SAHPRA's reasons for the detention;

ii. V-Tech denies that SAHPRA made it clear during the preceding 12 months that V-Tech (Pty) Ltd, the juristic entity, must obtain a licence to import or use the services of an entity that is licenced to import;

iii. V-Tech, ironically, takes issue with SAHPRA releasing the consignments it detained since June 2023 without V-Tech having acquired an import licence and for failing to explain why the *status quo* should not be extended for a further 2 to 3 months until the appeal committee has considered the matter, or even a further 6 months thereafter if there is a review by the High court;

iv. V-Tech reiterated that the APIs are used to treat severe animal diseases in respect of which, in some cases, no alternative medicines are available. If the compounded medicine cannot be provided, such animals will suffer severely or die;

v. V-Tech denies that it needed to inform SAHPRA of when it expected consignments of APIs to arrive in South Africa, and by when it expects to have run out of stock. It is sufficient that SAHPRA is aware of V-Tech's core business and that it uses imported APIs because these substances cannot be sourced locally;

vi. V-Tech contends that 'it is a matter of simple logic that if a compounding pharmacy's entire compounding business is reliant on the APIs which are imported from abroad, that such business cannot continue to function in accordance with ordinary business principles if its importation of APIs is suddenly stopped.'

vii. V-Tech explains that while it may theoretically be able to register a wholesale pharmacy which would be able to apply for an import licence, its business model is not designed for conducting the business of a wholesale pharmacy;

viii. V-Tech claims that the current licensed wholesale pharmacies do not have the technical expertise to source the very specialized APIs required to compound veterinary medicines, nor the infrastructure to confirm the quality thereof. In addition, it would have a serious negative effect on V-Tech's entire cost structure, resulting in substantially higher prices of the compounding medicines, which would have a severely prejudicial effect on its business in a competitive market.

Papers filed subsequent to the matter being struck from the roll

[30] V-tech did not supplement its papers before enrolling the application on the opposed motion court roll. SAHPRA filed an application to file a supplementary affidavit, to which V-Tech filed an answer. SAHPRA's application was granted since V-Tech did not object and had the opportunity to answer to the supplementary affidavit.

[31] SAHPRA again addressed the issue of V-Tech's claim that it will suffer irreparable harm if the interim interdict is not granted. SAHPRA pointed out that V-Tech has not been importing any APIs now for four months and appears to have used the services of a licenced entity such as a licenced wholesaler or a distributor. According to correspondence presented by a licenced entity, Multichem, it is evident that V-Tech made use of MultiChem's services to obtain three of the four substances that are the subject of the section 24A appeal.

[32] V-Tech reiterated in its answer to the supplementary affidavit that a business such as V-Tech 'cannot disclose what APIs scheduled substances it currently has in stock, and what (and by when) any replacement stocks are expected to arrive in South Africa. This is privileged information which, if disclosed in a public document such as this, V-Tech's competitors will use to their advantage, which would be detrimental to V-Tech's business.'

[33] V-Tech confirmed that MultiChem has been one of V-Tech's local suppliers for more than seven and a half years. It also, sometimes. Procured scheduled substances abroad on V-tech's behalf. Circumstances now necessitated V-Tech to expand its purchases of certain APIs from MultiChem. V-Tech claims, however, that as foreseen the increased procurement of scheduled substances APIs from MultiChem proved not to be feasible and cannot be continued by V-Tech in the long term. While V-Tech has the expertise to source suitable APIs and to perform the necessary quality control on the API, MultiChem does not have the technical expertise to source the very specialized APIs required to compound veterinary medicines, nor the infrastructure to confirm the quality thereof. In addition, there is a substantial extra cost added to the APIs when sourcing it via the licenced importers and distributors.

Discussion

[34] Despite SAHPRA's explanation that it did not have a presence at the country's ports of entrance, it was difficult to understand why the reality of V-Tech importing APIs only became an issue recently and why it was able to import scheduled substances for almost twenty years ostensibly under the radar of the authority claiming to be the regulatory authority. Although neither of the parties referred thereto, I found it of significance to note that section 22C(1)(b) of the Medicines Act was amended in 2015, and the amendment only commenced on 1 June 2017. Section 22C(1)(b) did not, before this amendment, contain the words 'import' or 'export'.[7]

[35] The question of whether V-Tech has established *prima facie* that it is entitled to import API-scheduled substances, lies at the interface of the regulatory authority of the South African Pharmacy Council and SAHPRA. It is wholly dependent on the interpretation of the legal framework constituted by the Pharmacy Act and the Medicines Act. As I indicated to counsel, I am of the view that the SAPC has an interest in the outcome of this matter. V-Tech essentially contends that it is authorised to import the APIs because of its status as a licenced community pharmacy and that the SAPC is the regulatory authority overseeing its activities.

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[1] [7] Prior to its amendment section 22C(1)(b) provided as follows:

> 'the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a product, medical device or IVD a licence to manufacture, act as a wholesaler of or distribute, as the case may be, such product, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.'

In its recent formulation, section 22C(1)(b) provides as follows:

> 'the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, Scheduled substance, medical device or IVD a licence to manufacture, **import, export,** act as a wholesaler of or distribute, as the case may be, such medicine, Scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.'

SAHPRA essentially contends that the scope of a communit y pharmacy, as provided for in regulation 18 of the Regulation pertaining to the Practice of Pharmacy,[8] is subject to the Medicines Act. A determination of the legal question that underpins the existence of V-Tech's alleged *prima facie* right will potentially affect every compounding pharmacy in the country, and as the regulatory authority of pharmacists, the SAPC, and perhaps even the Association of Compounding Pharmacies, have an interest in the outcome of the litigation and should be provided with an opportunity to present their submissions before a final determination is made. However, even if I accept that V-Tech made out a case that it has a *prima facie* right to import APIs, V-Tech faces an insurmountable hurdle.

[36] This court must decide on the basis of the primary facts presented to it, whether V-Tech will suffer irreparable harm if the interim relief is not granted and V-Tech ultimately succeeds in its appeal against SAHPRA's decision that it requires a licence before it is allowed to import APIs.[9]

[37] V-Tech's submission is that it is a matter of simple logic that it will suffer irreparable harm. The facts indicate that V-Tech is seriously inconvenienced by SAHPRA's decision. However, no case is made out that it will suffer irreparable harm. In a matter involving business or financial concerns, the applicant must, in its founding affidavit, set out in detail the nature of its business **and** the loss of revenue that the applicant is likely to suffer.

[38] Contrary to what V-Tech submitted, the court should have been presented with detailed facts relating to the prejudice and harm V-Tech suffers and will suffer in future as a result of SAHPRA's decision to enable the court to draw inferences from the primary facts presented. SAHPRA's decision does not prevent V-Tech from compounding medicine, or prevent V-Tech from sourcing the required APIs from licenced wholesalers. V-Tech does not indicate what percentage of the required APIs cannot be sourced from licenced wholesalers, or how it will impact on the prices of its products if the APIs are to be sourced from licenced wholesalers.

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[8] GNR 1158 of 20 November 2000.

[9] *Ex Parte Lipshitz* 1913 CPD 737.

[39] Irreparable harm is generally not a matter of ‘simple logic’. This becomes clear when regard is had to some of the broad-stroked averments made by V-Tech – e.g. it was already indicated above that V-Tech submitted in its founding affidavit that SAPHRA’s decision affects animal owners all over South Africa, that an absence of compounded veterinary medicine could lead to scores of livestock getting sick with resultant food shortages, that the large wildlife industry in South Africa relies on the applicant’s compounded medicines because there are no registered medicines available, that the applicant is prevented from rendering its service of providing compounded medicines on prescription, it will have a severe negative impact on animal health and food security in the country. In the replying affidavit and the answer to the supplementary affidavit filed by SAHPRA, V-Tech, however, contends that its business rivals will benefit unduly if it must mark up prices because it is forced to buy APIS from licenced wholesalers at higher prices, or reveal in public documents what APIs it requires or have in storage. The whole veterinary community is thus not solely dependent on the medicine compounding by V-Tech, as there are other rival pharmacies compounding medicine for the veterinary community.

[40] As for the impact of the decision on V-Tech’s revenue, no facts were presented that allow the court to draw the inference that any prejudice suffered by V-Tech is, or would be irreparable. In the urgent court, V-Tech contended that if the matter was not heard as a matter of urgency, it would have devastating consequences for V-Tech’s future. Five months down the line, V-Tech is still in business. By not confiding the costs of staying in business to the court, but holding the view that it needs not to inform SAHPRA of the measures it took to remain in business, V-Tech deprived the court of the factual basis to conclude that it will suffer irreparable harm if the interim relief is not granted. As a result, the application stands to be dismissed with costs, and I need not deal with the remaining requirements for obtaining interim relief.

[41] The general principle is that costs follow success. Both parties used the services of two counsel. Considering the complexity of the issues at hand, it is just that the respondent’s counsel’s costs are determined on Scale B.

ORDER

In the result, the following order is granted:

1. **The application is dismissed with costs, which costs include the costs of two counsel on Scale B.**

E van der Schyff
Judge of the High Court

Delivered: This judgment is handed down electronically by uploading it to the electronic file of this matter on CaseLines.

For the applicant:	Adv. J. H. Ströh SC
With:	Adv. O Ben-zeev
Instructed by:	Ciliers & Reynders Inc.
For the respondent:	Adv. J.M. Berger
With:	Adv. E.C. Chabalala
Instructed by:	Maluks Attorneys
Date of the hearing:	31 July 2024
Date of judgment:	6 August 2024