THE SUPREME COURT OF APPEAL OF SOUTH AFRICA

JUDGMENT

Reportable

Case no: 294/2025

In the matter between:

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA	**FIRST APPELLANT**
ASTELLAS PHARMA EUROPE LTD	**SECOND APPELLANT**
ASTELLAS PHARMA INC	**THIRD APPELLANT**
ASTELLAS PHARMA (PTY) LTD	**FOURTH APPELLANT**
and	
EUROLAB (PTY) LTD	**FIRST RESPONDENT**
DIS-CHEM ONCOLOGY (PTY) LTD	**SECOND RESPONDENT**
DIS-CHEM ONCOLOGY DISTRIBUTION (PTY) LTD	**THIRD RESPONDENT**
DIS-CHEM PHARMACIES (PTY) LTD	**FOURTH RESPONDENT**

Neutral citation: *The Regents of the University of California & Others v Eurolab (Pty) Ltd & Others* (294/2025) [2026] ZASCA 30 (17 March 2026)

Coram: MOLEMELA P, SMITH and BAARTMAN JJA

Judgments: Smith JA: [majority] [1] to [124]

Molemela P: [concurrence] [125] to [145]

Baartman JA: [minority] [146] to [179]

Heard: 8 September 2025

Delivered: 17 March 2026

Summary: Patent Law – application for revocation in terms of s 61 of the Patents Act 57 of 1978 (the Act) – whether entitlement to apply for a patent must exist at time of filing a patent application or when revocation application is brought – application under s 70 of the Act for interdict to prevent groundless threats of patent infringement litigation – whether the invention is obvious – interim interdict prohibiting infringement of the patent – relevance of public interest considerations.

ORDER

On appeal from: Court of the Commissioner of Patents, Pretoria (Le Grange AJ sitting as the Commissioner of Patents):

1 The appeal is upheld with costs, including the costs occasioned by the employment of two counsel.

2 The order of the Court of the Commissioner of Patents is set aside and replaced with the following:

'(a) The application by the first respondent, Eurolab (Pty) Ltd, brought under the provisions of s 70 of the Patents Act 57 of 1978, is dismissed with costs on Scale C, including the costs occasioned by the employment of two counsel where so employed, and the qualifying fees for the expert witnesses representing the applicants (the Regents of the University of California; Astellas Pharma Europe Ltd; Astellas Pharma Inc and Astellas Pharma (Pty) Ltd, respectively).

(b) The counter-application for revocation of patent no 2007/10870 instituted by the second to fourth respondents (Dis-Chem Oncology (Pty) Ltd; Dis-Chem Oncology Distribution (Pty) Ltd; and Dis-Chem Pharmacies (Pty) Ltd, respectively) is dismissed with costs on Scale C, including the costs of two counsel where so employed, and the qualifying fees of the applicants' expert witnesses.

(c) The application for interim relief instituted by the applicants is dismissed. Each party shall pay its own costs.'

JUDGMENT

Smith JA (Molemela P concurring)

Introduction

[1] This is an appeal against the decision of the Court of the Commissioner of Patents (the Commissioner) revoking patent 2007/10870 (the patent) on the ground that the first appellant, the Regents of the University of California (UC), was not a person entitled to

apply for the patent in terms of s 61(1)*(a)*,[1] read with s 27(1)[2] of the Patents Act 57 of 1978 (the Act). The patent claims a novel hormone treatment therapy, Xtandi, used for treating prostate cancer. The appeal is with the leave of the Commissioner.

[2] UC is the registered owner of the patent, and the second to fourth appellants, Astellas Pharma Europe Ltd, Astellas Pharma Inc., and Astellas Pharma (Pty) Ltd (Astellas), are licensees. For convenience and where the context so requires, I also refer to the appellants collectively as UC.

[3] The first respondent, Eurolab (Pty) Ltd (Eurolab), is a generic oncology company and holds a generic registration with the South African Health Products Regulatory Authority for a product named Enzutrix. This product was introduced in South Africa and is distributed by the second, third, and fourth respondents: Dis-Chem Oncology (Pty) Ltd, Dis-Chem Oncology Distribution (Pty) Ltd, and Dis-Chem Pharmacies (Pty) Ltd, respectively. Where appropriate, these parties are referred to collectively as 'the respondents', and the Dis-Chem companies as 'Dis-Chem'.

[4] The following three related applications served before the Commissioner:

(a) Eurolab's application for an interdict to prevent UC from making groundless threats of patent infringement litigation;

(b) UC's application for an interim order to prohibit Eurolab and Dis-Chem from making, importing, or selling Enzutrix, a generic of Xtandi; and

(c) A counterapplication filed by Dis-Chem to revoke the patent under s 61 of the Act.

[5] The Commissioner determined that, under s 27(1) of the Act, an applicant for a patent must acquire rights to the invention from the inventor before submitting the

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[1] Section 61(1)*(a)* reads as follows:

'Grounds for application for revocation of patent

(1) Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely-

(a) that the patentee is not a person entitled under section 27 to apply for the patent.'

[2] Section 27(1) reads as follows:

'Who may apply for a patent

(1) An application for a patent in respect of an invention may be made by the inventor or by any other person acquiring from him the right to apply or by both such inventor and such other person.'

application. Crucially, in accordance with that finding, the relevant time for assessing whether an applicant is entitled to apply for a patent is the date on which the patent application is filed, not the date of any later revocation proceedings. The Commissioner found that UC had not secured assignments from all inventors prior to the filing of the patent application. Consequently, UC was deemed not to have met the entitlement requirement at the critical time. Therefore, the Commissioner dismissed UC's request for interim relief and granted the applications brought by Eurolab and Dis-Chem.

[6] The Commissioner's decision was limited to the interpretation of s 61(1)*(a)* of the Act, without consideration of other matters raised during the proceedings. Before this Court, Eurolab submitted that the Court should confine its adjudication to issues previously determined by the Commissioner, leaving all other questions for future consideration. Conversely, UC proposed that all outstanding issues be resolved in the present hearing, emphasising the importance of avoiding extended litigation and unnecessary delays. Given the imminent expiration of the patent, this Court determined that a comprehensive and timely resolution of all issues was required in the interests of justice.

The facts

[7] The material facts can be briefly summarised as follows. Xtandi, the pharmaceutical compound central to the patent, utilises enzalutamide as its active pharmaceutical ingredient (API). The invention resulted from a collaboration between UC and the Howard Hughes Medical Institute (HHMI). Of the eight inventors, five were employed by UC (the UC inventors) and three by HHMI (the HHMI inventors). The patent application was filed on 29 March 2006 and will expire on 29 March 2026.

[8] Upon commencing employment with UC, each of the five inventors employed by it executed patent acknowledgments. Through these acknowledgments, the inventors agreed to assign to UC all rights in any inventions they created during their employment. UC subsequently secured formal assignments from these inventors at two key intervals. First, in July and August 2005, the inventors assigned their rights pertaining to the USA priority patent application to UC. Second, in May and June 2006, assignments were

obtained in respect of priority applications P2 and P3, as well as the Patent Cooperation Treaty (PCT) application corresponding to the patent.[3]

[9] HHMI and UC concluded a Collaboration Agreement in 1986 (the 1986 Collaboration Agreement) in terms whereof HHMI, inter alia, granted UC the right to take assignment of any inventions made by its employees pursuant to a program of research funded wholly or partially by UC. It is common cause that the patent was such an invention. The three remaining inventors, namely Mr Charles Sawyers (Mr Sawyers), Mr Chris Tran (Mr Tran), and Mr John Wongvipat (Mr Wongvipat), were employed by HHMI at the time of the invention. In 2003, they assigned all their rights in inventions created during their employment with HHMI to the latter under Intellectual Property Statements of Agreement.

[10] HHMI purportedly assigned its rights in accordance with the 1986 Collaboration Agreement to UC in 2009 (2009 assignment). In that transaction, HHMI was represented by Mr Sawyers, who ostensibly acted as its agent. The respondents assert that UC failed to establish Mr Sawyers's authority.

[11] The respondents concede that Enzutrix constitutes an infringement of the patent; however, they oppose UC's application for an interim interdict on the following grounds:
(a) Eurolab argues that the patent is invalid under s 61(1)*(a)* and *(g)* of the Act due to UC's alleged lack of entitlement and material misrepresentations in the application (P3), also citing an 'obviousness' challenge in terms of ss 61(1)*(c)* and 25.
(b) The Dis-chem respondents withdrew their s 61(1)*(c)* and *(g)* revocation arguments but maintained opposition against the interdict, asserting invalidity for lack of inventiveness in terms of s 61(1)*(g).*

[12] The following issues must consequently be addressed:

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[3] The Patent Cooperation Treaty is an international agreement that allows inventors and companies to seek patent protection for their inventions in multiple countries simultaneously by filing a single application. Instead of submitting separate applications to each country, applicants file one PCT application, which is then processed and examined centrally. After this initial phase, the applicant can pursue national patent protection in participating countries. The treaty is administered by the World Intellectual Property Organisation.

(a) Was UC entitled to apply for the patent under s 27 of the Act, and should this entitlement exist at the initial filing or at the time of the revocation application? A negative answer resolves all three applications; if positive, the following questions are relevant:

(b) Did UC make material misrepresentations in the Form 3 declaration?

(c) Was the invention unpatentable due to lack of an inventive step, i.e., was it obvious to a skilled person?

(d) Has UC met all the requirements for interim relief?

Is UC a person entitled to apply for the patent in terms of s 27 of the Act?

The respondents' submissions

[13] The respondents assert that the phrase 'entitled to apply' in s 61(1)*(a)* of the Act pertains to the point in time when the patent application is submitted, rather than any subsequent period. They emphasise that this section addresses the process of applying for patents and determines eligibility. According to the respondents, UC's entitlement to apply for the patent must be assessed with specific reference to the date on which the application was filed.

[14] The respondents further argue that s 27 of the Act does not provide that simply having the right to an assignment is sufficient to establish entitlement to apply for a patent. In their submission, a proper interpretation of the section confirms that only the actual owner of the right may submit a patent application. This means that a person seeking to apply as a secondary applicant must first acquire the right to apply from the true owner before applying. Furthermore, the respondents maintain that the language in s 27 – specifically the phrase "any other person acquiring from him the right to apply" – implies that there must have been an actual transfer of the right to apply for the patent. Accordingly, they contend that a mere expectation of assignment or a contractual right to receive an assignment does not meet the requirement; actual transfer is necessary for entitlement.

[15] According to the respondents, the 2009 assignment cannot assist UC since it seeks *ex post facto* to validate UC's entitlement to apply for the patent. That right should have existed at the time of the patent application. Also, Mr Sawyers did not have the authority to assign anything other than the invention (RD162) to UC because he only had

the authority to assign the first priority application (P1), which did not include the claimed invention (RD162'). I explain the chemical properties of these compounds below.

[16] The respondents further assert that UC's argument – that it is eligible to apply in terms of the 1986 Collaboration Agreement in conjunction with the Intellectual Statements of Agreement – is untenable. The latter agreement did not confer any rights upon UC, and the 2009 assignment could not validate UC's rights, as it was not in existence at the time of the patent application. The 1986 Collaboration Agreement stipulates, among other provisions, that HHMI will assign all rights in HHMI inventions to UC. Consequently, the respondents contend, this agreement merely establishes a general framework for collaboration and includes an undertaking by HHMI to assign inventions to UC in the future; it does not transfer ownership of the patent to UC.

[17] Furthermore, they submit, s 73(3) of the Act is fatal to UC's reliance on the Collaboration Agreement. That section provides:

'Except for the purposes of section 52, a document or instrument in respect of which no entry has been made in the register in terms of section 10, shall not be admitted in evidence in any proceedings in proof of the title to a patent or application for a patent or to any interest therein unless the commissioner or a court, on good cause shown, otherwise directs.'

[18] The respondents further submit that the 1986 Collaboration Agreement was not filed or recorded in the patents register and is consequently not admissible to prove UC's title. UC did not show good cause for its failure to file the 1986 Collaboration Agreement, and it is consequently not entitled to rely on that document.

[19] Moreover, they argue, s 60(1) provides that an applicant for a patent or a patentee may assign his or her rights in an application or patent to any other person. Unless the assignment is duly recorded in terms of that section, 'it shall not be valid, except as between the parties thereto'.

[20] The respondents consequently submit that as of 29 March 2006, UC had not obtained rights from the HHMI inventors for the following reasons: (a) the inventors assigned their rights to HHMI in 2003. HHMI assigned those rights to UC in 2009, after

the PCT application; (b) the 2009 assignment was ineffective because Mr Sawyers's authority pertained only to P1, which did not encompass the invention RD162'; and (c) UC is not able to rely on the 1986 Collaboration Agreement for the reasons previously outlined.

UC and Astellas' submissions

[21] UC criticises the Commissioner for having ignored the plain language of s 61(1)(*a*), in particular, the phrase 'the patentee is not a person entitled under s 27 to apply for the patent'. The term 'patentee' is defined in the Act as the person whose name is for the time being entered into the record as the grantee or proprietor of the patent. The Act further distinguishes between a 'patentee' as the proprietor and 'patentee' being the person who applies or is applying for the patent.

[22] UC argues that since this section is drafted in the present tense, s 61(1)(*a*) does not require an investigation into the patentee's right to apply at the time of the application but instead focuses on whether, at the time of revocation proceedings, the patentee would have been entitled to apply at the time of the application.

[23] They argue that the cross-reference in s 61(1)(*a*) to s 27 serves to identify what rights the patentee must possess at the time of the revocation application to avoid revocation. The operative words being, 'the patentee is…'. Section 27 makes it clear that the patentee must have acquired the right to apply for the patent from the inventor. The right to apply vests in the owner or the person who has a claim or contractual rights to compel the inventor to assign or transfer rights to the invention. According to UC, this interpretation gives effect to the purpose of s 27 because otherwise a firm that owns the rights in an invention may be precluded from applying because it was unable to secure the assignment timeously.

[24] UC maintains that, as of the date of the revocation application, it had fulfilled the requirements to be regarded as a person entitled to apply for the patent under s 27. UC asserts its entitlement based on a series of assignments that collectively establish its right to apply. As stated, UC initially secured assignments directly from its own inventors in 2005 and again in 2006. Beyond these internal assignments, UC also acquired rights

from the HHMI inventors, which occurred through a succession of agreements. This included the Intellectual Property Statements of Agreement as well as a subsequent assignment executed in 2009. The 2009 assignment was significant as it implemented the terms of the longstanding 1986 Collaboration Agreement between UC and HHMI, thereby confirming the transfer and formalisation of the relevant patent rights to UC.

[25] Furthermore, UC maintains that even if s 61(1)(*a*) were interpreted in the manner contended by the respondents – meaning it would consequently be precluded from relying on the 2009 assignment – UC would still meet the eligibility criteria to apply for the patent. This is so because at the time of filing the patent application, UC had secured all requisite assignments and authorisations from both UC and HHMI inventors. In sum, UC contends that its entitlement is firmly grounded in the assignments and authority originating from both groups of inventors and formalised through the relevant collaborative and intellectual property agreements.

[26] With respect to the question of Mr Sawyers's authority, UC contends that Dis-Chem has not established a *prima facie* case demonstrating that Mr Sawyers lacked the requisite authority to assign HHMI's rights. Dis-chem instead relied solely on its attorney's interpretation of the 2009 assignment. Even if this interpretation is accepted, Dis-Chem has not provided evidence indicating that Mr Sawyers was not authorised to assign rights in all patentable inventions. In his affidavit, Mr Sawyers expressly affirms that he was empowered to assign the PCT patent application to HHMI, and any assertion to the contrary is purely speculative. The 2009 assignment explicitly indicates that Mr Sawyers acted as a representative of HHMI. Consequently, Dis-Chem, as a non-party to the agreement, is precluded from challenging its validity where the parties themselves are in agreement regarding its enforceability.

[27] UC also relies on the abstract theory of ownership. It asserts that even though there may have been shortcomings in the underlying assignment agreements, once the right had been transferred, ownership vested in it.

Analysis and discussion

[28] The foundational legal principles governing the interpretation of statutory provisions and contracts are firmly established. According to these principles, statutory language and contractual terms must be given practical meaning and effect by considering the language employed in light of standard rules of grammar and syntax. The starting point is the language of the provision itself, which must be read in its proper context and with regard to the purpose behind the provision, as well as the background circumstances surrounding the creation and drafting of the document.[4]

[29] In *Capitec Bank Holdings Limited and Another v Coral Lagoon Investments 194 (Pty) Ltd and Others,*[5] this Court cautioned that 'the triad of text, context and purpose should not be used in a mechanical fashion. It is the relationship between the words used, the concepts expressed by those words and the place of the contested provision within the scheme of the agreement (or instrument) as a whole that constitutes the enterprise by recourse to which a coherent and salient interpretation is determined'. The interpretation of s 61(1)(*a*), must align with these legal principles.

[30] The first question that must be addressed in the light of the abovementioned legal principles is whether the entitlement to apply in terms of s 27 is assessed at the time of the filing of the application or when the revocation application is filed. The answer to this question determines whether UC can rely on the 2009 assignment.

[31] The Commissioner interpreted 'any other person acquiring from him [the inventor] the right to apply' in s 27 of the Act as requiring a non-inventor to have obtained this right – by assignment, agreement, or other legal means – before filing for a patent. I agree with this interpretation for the reasons outlined below.

[32] In my view, revocation proceedings pursuant to s 61(1)(*a*) involve a retrospective assessment of whether the patentee, as defined by statute, was eligible to apply for the

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[4] *Natal Joint Municipal Pension Fund v Endumeni Municipality* [2012] ZASCA 13; [2012] 2 All SA 262 (SCA); 2012 (4) SA 593 (SCA) para 18; *Airports Company South Africa v Big Five Duty Free (Pty) Ltd and Others* [2018] ZACC 33; 2019 (2) BCLR 165 (CC); 2019 (5) SA 1 (CC) para 29.

[5] *Capitec Bank Holdings Ltd and Another v Coral Lagoon Investments 194 (Pty) Ltd and Others* [2021] ZASCA 99; [2021] 3 All SA 647 (SCA); 2022 (1) SA 100 (SCA) para 25; *University of Johannesburg v Auckland Park Theological Seminary and Another* [2021] ZACC 13; 2021 (6) SA 1 para 65.

patent at that point in time. Any alternative interpretation would compromise the legislative purpose of the section.

[33] In proceedings under s 61(1)(*a*), the applicant must prove that the patentee is not a person entitled to apply under s 27 – either because they were not the inventor or did not validly acquire the right to apply from the inventor. UC argued that the use of the present tense in the section compels the inference that the patentee's entitlement to apply must be assessed at the time of the revocation application. I do not agree with that argument. The purpose of s 27 is to delineate the criteria applicants must satisfy when applying for a patent. The section therefore applies at the time when the patent application is filed, thus making the assessment contingent upon the patentee's rights as of the application date.

[34] UC further argued that the respondents' interpretation would lead to absurd results, citing a scenario in which a patentee assigns their patent years after its registration. UC claimed this would shift focus to whether the assignee – and not the original patentee – could apply for the patent under s 27 of the Act at the time of revocation. However, this example instead supports the opposite view, namely that the key issue is whether the assignment is valid and whether the original patentee had the right to file the initial application.

[35] Section 61(1)(*a*) thus establishes a clear requirement that the right to apply for a patent under s 27 must exist at the time the application is submitted. This means that the applicant must either be the inventor themselves or must have lawfully acquired the right to apply for the patent before filing the application. If this criterion is not satisfied, any patent issued as a result is invalid. The process of revocation treats such a patent as if it was never granted, effectively nullifying its legal standing. Importantly, transferring rights after the application has been filed does not remedy the original deficiency. If the applicant lacked entitlement at the time of filing, the patent cannot be retrospectively validated, and its revocation confirms its invalidity from the outset.

[36] This interpretation finds support in the legal systems of other international jurisdictions. The United Kingdom Patents Act 1977, in s 7(2),[6] outlines the basis on which applications can be made in that country. In *Thaler v Comptroller,*[7] which concerned an Artificial Intelligence generated invention, the UK Supreme Court confirmed that the applicant's entitlement is assessed at the time of filing. That court affirmed that the applicant must identify a human inventor from whom the right to the patent was derived. It held that the applicant's failure to do so at the time of the application led to the application being deemed withdrawn.

[37] Similarly, in *Edwards Lifesciences v Cook Biotech Inc*,[8] the English Patents Court emphasised that an assignment of rights must have been legally executed before the filing date of the application to be valid for priority claims. In that case, the plaintiff sought revocation of the defendant's patent, inter alia, on the ground that priority was improperly granted to a US provisional application. The defendant only acquired assignment of two of the inventors' rights after the patent application was filed. The plaintiff argued that because the patent was not entitled to an earlier priority date, relevant prior art would have become available which had the potential to validate the claims. Citing, inter alia, ss 5[9] and 7 of the UK Patents Act 1977, the Court states at para 95 of the judgment:

'…A person who files a patent application for an invention is afforded the privilege of claiming priority to himself only if he himself filed the earlier application from which priority is claimed or if he is the successor in title to the person who filed that earlier application. If he is neither the person who filed the earlier application nor his successor in title then he is denied the privilege. Moreover, his position is not improved if he subsequently acquires title to the invention. It remains the case

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[6] That section reads as follows: 'A patent for an invention may be granted –
(a) primarily to the inventor or joint inventors;
(b) in preference to the foregoing, to any person or persons who, by virtue of any enactment or rule of law, or any foreign law or treaty or international convention, or by virtue of an enforceable term of any agreement entered into with the inventor before the making of the invention, was or were at the time of the making of the invention entitled to the whole of the property in (other than equitable interests) in the United Kingdom;
(c) in any event, to the successor or successors in title of any person or persons mentioned in paragraph *(a*) or paragraph *(b)* above or any person so mentioned and the successor or successors in title of another person so mentioned; and to no other person.'

[7] *Thaler v Comptroller* [2023] UKSC 49, on appeal from: [2021] EWCA Civ 1374.

[8] *Edwards Lifesciences v Cook Biotech Inc.* [2009] EWHC 1304 (Pat).

[9] Section 5(1) of the UK Patents Act 1977 reads as follows: 'For the purposes of this Act the priority date of an invention to which an application for a patent relates and also of any matter (whether or not the same as the invention) contained in any such application is except, as provided by the following provisions of the Act, the date of the filing of the application.'

that he was not entitled to the privilege when he filed the later application and made his claim. Any other interpretation would introduce uncertainty and the risk of unfairness to third parties.'

[38] The European Patent Office, which governs patents for most of Europe, also requires the entitlement to be established at the time of filing. Article 61 of the European Patent Convention provides that where an application has been filed by a person who was not properly entitled to do so, the true inventor is allowed to take over the application or to file a new one. The inventor may also request that the patent application should be refused. However, the assessment of entitlement is based on the original application date.

[39] These authorities reinforce the core idea that entitlement to apply for a patent is a foundational requirement assessed at the very beginning of the patent process. Any subsequent actions, such as a later assignment cannot retroactively cure a defect that existed at the time of filing.

UC's entitlement to apply for the patent

[40] The question then arises as to whether UC is a person entitled to apply for the patent in terms of s 27. As mentioned, that question must be answered having regard to the rights UC had at the time of the original filing of the application.

[41] It is common cause that UC sought to rely on the following grounds to establish its entitlement to apply for the patent. First, the five UC inventors all signed patent acknowledgments, agreeing to assign their rights in any inventions made while in the employ of UC. They had in fact subsequently formally assigned those rights to UC in P1 and the priority applications P2 and P3 in 2005 and 2006, respectively. The remaining three inventors (which included Mr Sawyers) assigned their rights to HHMI in 2003 by virtue of the 'Intellectual Property Statements of Agreement'. This is common ground.

[42] Second, the assignments in terms of the Intellectual Property Statements of Agreement were made pursuant to the 1986 Collaboration Agreement**,** concluded between UC and HHMI. In terms of that agreement HHMI granted UC the right to take assignment of any patentable inventions made by its employees pursuant to research

financed wholly or partly by UC. The patent was such an invention. Exhibit H of that agreement (The Patent Agreement) provides in paragraph B:

'Except as provided for in paragraph F of this Article II, HHMI shall assign to the University all of its rights, title and interest in HHMI Patent Inventions, and HHMI further agrees that the University's policies and procedure, including the execution of the Patent Agreement pursuant to the University's Patent Policy, pertaining to the management and disposition of such Patentable Inventions shall apply thereto subject to the following conditions…'[10]

[43] Third, HHMI formally assigned its rights in the invention to UC in 2009. However, for the reasons stated above, UC is precluded from relying on the 2009 assignment to resist an attack on the validity of the patent based on s 61(1)(*a*) because the assignment did not exist at the time of the patent application. In light of this finding, it is not necessary to determine the question of Mr Sawyers's authority. However, of significance is that the employment of the three inventors with HHMI on the terms asserted by UC is confirmed in Sawyers's affidavit and stands undisputed. Furthermore, on 31 August 2005, under a document titled 'Appointment of Investigator as Agent' HHMI confirmed Mr Sawyers' appointment as its agent for the purpose of assigning certain rights in respect of the patent entitled 'Novel Androgen Receptor Inhibitors with Minimal Agonistic Activities' to UC.

[44] UC argues that even if the 2009 assignment is ignored, it was nevertheless a person entitled under s 27 to apply for the patent by virtue of the assignments by the UC inventors of their rights and the provisions of the 1986 Collaboration Agreement, read with the Intellectual Property Statements of Agreement concluded between the HHMI inventors and the HHMI. I agree.

[45] The respondents' reliance on ss 30(4); 59; and 60(1)(*a*) and regulations 22 and 58 for the submission that UC is not entitled to rely on the 1986 Collaboration Agreement because it has not been recorded in the Patents Register, is misplaced. This is so because: (a) s 30(4)[11] pertains to the submission of evidence demonstrating title or

[10] Paragraph F is not applicable because it refers to inventions involving third parties and the conditions pertain to the patents being made available to the public on a non-discrimination basis, HHMI has the right to non-exclusive license.

[11] Section 30(4) reads as follows:

authority to apply for a patent. The critical enquiry under s 61(1)(*a*) is whether the applicant held the necessary authority at the time of the application; the subsequent filing of supporting documents is not relevant for that determination; (b) ss 59 and 60 prescribe formalities for the assignment of patents or patent applications that have already been filed and therefore find no application under s 27 of the Act; (c) regulation 22 requires an applicant who has acquired a right to apply from the inventor, to file together with the patent application form, an assignment or other proof, to the satisfaction of the registrar, of the right apply. This requirement is, however, also not relevant to the enquiry whether UC had right to apply for the patent at the time of filing; and (d) regulation 58 provides for the recording of assignments of title to and interest in inventions, patent applications and patents. It requires the filing of proof of such assignments. These provisions are therefore irrelevant for the enquiry under s 61(1)(*a*), read with s 27 of the Act.

[46] The respondents' contention that the provisions of s 72(3)[12] of the Act preclude UC from relying on the 1986 Collaboration Agreement because it was not filed or recorded in the patents register as required in terms of the regulations is similarly untenable. That section provides that a document which has not been so entered shall not be admitted in evidence in any proceedings in proof of (a) the title to a patent; (b) an application for a patent; or (c) of any interest in the patent. UC does not rely on the 1986 Collaboration Agreement either to prove title to the patent or to prove a patent application. It relies on that agreement to establish that it had acquired the right to apply for the patent from HHMI before the filing of the application.

[47] The respondents further contend that the 1986 Collaboration Agreement did not vest any rights in the UC but was at best a general framework for cooperation. Accordingly, it did no more than record an *inter partes* obligation to execute future

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'Any person other than the inventor making or joining in an application for a patent shall in the prescribed manner shall furnish such proof of his title or authority to apply for a patent as may be prescribed.'

[12] That section provides:

'**72. Register to be evidence**

(3) Except for the purposes of section 52, a document or instrument in respect of which no entry has been made in the register in terms of section 10, shall not be admitted in evidence in any proceedings in proof of the title to a patent or application for a patent or to any interest therein unless the commissioner or a court, on good cause shown, otherwise directs.'

assignments. Exhibit H does not contemplate direct assignments and immediate vesting of the rights to the patent. This was what UC purported to correct by filing the 2009 assignment. But that assignment, they argue, is inconsequential for a revocation application since it did not exist at the time of the initial filing of the application.

[48] Relying on *E I Du Pont de Nemours and Company v SA Nylon Spinners (Proprietary) Limited*, (*Du Pont*)[13] UC argued that properly interpreted, the Collaboration Agreement vests in it the rights to all patentable inventions made by the HHMI inventors. UC, however, did not contend that the 1986 Collaboration Agreement constituted an immediate assignment of ownership – neither could it because that agreement clearly contemplated assignment at some time in the future.

[49] In my view, the facts in *Du Pont* are clearly distinguishable. The relevant clause of the employment agreement in that case provided as follows:

'Any and all improvements and inventions conceived or made by the employee during the period of his said employment, relating in any way to the activities or business of the employer, shall be disclosed promptly to the employer and shall be the sole and exclusive property of the employer or it nominee; and whenever requested so to do by the employer, the employee shall execute any and all applications, assignments and other documents which the employer shall deem necessary to apply for and obtain Letters of Patent…'

[50] In *Du Pont*, the agreement unequivocally and automatically vested ownership of any patentable invention in the employer. The 1986 Collaboration Agreement in this matter does not affect such automatic vesting of ownership in UC but rather envisages future action in terms of which 'HHMI shall assign to the University all of its rights, title and interest in HHMI Patent Inventions'.

[51] The conclusion in the preceding paragraph does not in any manner impact UC's right to apply for the patent because it was not constrained to prove ownership by way of assignment to establish entitlement to do so. Section 27 of the Act also permits an individual who has lawfully acquired the right to apply from the inventor – whether by

[13] *E I Du Pont de Nemours and Company v SA Nylon Spinners (Proprietary) Limited* 1987 BP 287 (CP) at 287F-G.

contract or other legal mechanisms – to submit a patent application. Notably, unlike its predecessor, s 8 of the repealed Patents Act 37 of 1952, s 27 of the current Act omits any reference to an ‘assignment agreement’ or ‘assignee’.

[52] It was therefore sufficient for UC to show that it had authority to apply for the patent by virtue of a contractual provision. In this regard it relied on the 1986 Collaboration Agreement. The question then arises whether that agreement authorises UC to apply for patents in respect of all patentable inventions made by the HHMI inventors. In my view, and for the reasons explained below, it clearly does.

[53] As stated earlier, the 1986 Collaboration Agreement expressly obligates HHMI to assign to UC all of its rights, title, and interest in HHMI Patent Inventions.' HHMI agreed to do so in return for a multimillion-dollar investment by UC. And contrary to Eurolab’s contentions, that obligation is unconditional. The clauses on which Eurolab relies for its assertion that the obligation is conditional are terms that relate to UC’s contractual obligations following the grant of a patent. They do, therefore, not constitute conditions precedent.

[54] Apart from HHMI’s irrevocable contractual obligation to assign to UC all its rights, title, and interest in ‘HHMI Patentable Inventions’, in terms of the 1986 Collaboration Agreement, UC assumed the obligation ‘to file for patent protection and prosecute diligently such application with respect to any such HHMI patentable Invention for which patent protection can be obtained… .’ It is only in the event of UC declining or failing to do so ‘after reasonable request and notice by HHMI’, that it must ‘assign back’ to HHMI all right, title, and interest in such patentable inventions. In effect, therefore, the parties agreed that UC bore the primary obligation to apply for patents in respect of all ‘HHMI Patentable Inventions’ for the duration of the 1986 Collaboration Agreement. The parties’ subsequent conduct supported this interpretation of the agreement. The evidence indicates that they shared a mutual understanding concerning UC’s authority to apply for the patent. They have been performing their respective obligations in terms of that agreement for almost 20 years, including sharing the royalties derived from the commercial exploitation of the patent.

[55] I therefore find that UC properly obtained the right from HHMI to apply for the patent under the terms of the 1986 Collaboration Agreement and was therefore ‘a person who is entitled to apply for the patent’ as contemplated by s 27 of the Act.

Did UC make any material misrepresentations?

[56] Section 61(1)(*g*) of the Act provides that any person may apply for the revocation of a patent on the ground that ‘the prescribed declaration lodged in respect of the application for the patent contains a false statement or representation which is material and which the patentee knew or ought reasonably to have known to be false at the time when the statement or representation was made’. Eurolab submitted that the declaration contained two material misrepresentations.

[57] The first argument was that UC's declaration, stating it had acquired ‘the right to apply by virtue of an assignment from the inventors,’ was false. The respondents contended that this statement materially misrepresented the timing of UC's acquisition of rights, implying that UC had already obtained such rights prior to the patent application being filed. It was undisputed that UC had not secured HHMI's patent rights in the form of an assignment of the type executed in 2009 before submitting the application. They argued that UC must have been aware of the absence of such rights at the relevant time, given that the assignment from HHMI was only filed in 2009. I find no merit in this argument.

[58] When the statement in P3 was made, HHMI had already received assignment through the 2003 agreement and was contractually required to assign invention rights to UC. There was no dispute that UC had obtained assignment form the UC inventors by the filing date. In addition, it was contractually entitled to the invention rights of the HHMI inventors by virtue of the 1986 Collaboration Agreement. Given the various legal instruments granting these rights to UC, it would be unreasonable to assert that UC’s agent should have known that there was a possibility that the statement could be incorrect, let alone false.

[59] Second, Eurolab posited that the prescribed declaration falsely claimed priority from the US patent application (P1) whereas the claims in the application filed, the PCT

application, were not fairly based on the priority document. In my view, there is also no merit in this contention.

[60] The global patent system allows a patentee to secure a priority date by filing a provisional or priority patent application in any country that is a party to the Paris Convention, provided that a complete application is filed within 12 months. When the application is filed, the patentee may claim priority in terms of s 31 of the Act for those aspects of the invention which are fairly based on the disclosure in the priority application. That section provides:

'An application accompanied by a complete specification may claim priority from–

(a) the date of the lodging of a prior application relating to the same subject-matter, accompanied by a provisional specification;

(b) the date of the lodging of a prior application relating to the same subject-matter, accompanied by a complete specification and claiming no priority; or

(c) the date of an application in a convention country relating to the same subject-matter.'

[61] In respect of any matter not sufficiently disclosed in the first priority application, the patentee may claim priority either from any later priority application filed in respect of that matter or, in the absence of any priority application, the filing date of the complete patent application. A patentee can therefore claim priority from more than one earlier priority.

[62] Where the patentee claims priority from more than one priority application or adds new matter not disclosed in any priority application, the priority date of the complete application shall be the earliest priority date claimed in an application in terms of s 33 of the Act. The onus is on the applicant for revocation to show that the patentee is not entitled to that priority date.

[63] Form P3 requires an applicant to identify the earliest priority claimed. The form states that 'the earliest application from which priority is claimed as set out above is the first application in a convention country in respect of the invention claimed in any of the claims.' The form does not state that the complete application is fairly based on the

earliest patent application as s 33 of the Act[14] allows for various aspects of the invention to be based on different priorities.

[64] The first priority application was P1, which was followed by priority applications P2 and P3. The identification of P1 as the earliest priority application was therefore correct and did not amount to a materially false statement or representation. The respondents consequently failed to establish any basis for the revocation of the patent under s 61(1)(*g*) of the Act.

Was the invention patentable under s 25 of the Act?

[65] Section 25 of the Act provides that a patent 'may be granted for any new invention which involves an inventive step, and which is capable of being used or applied in trade or industry or agriculture'. Notably, s 61(1)(*c*) provides a patent may be revoked on the ground that the invention is not patentable under s 25 of the Act.

[66] In terms of s 25(10), an invention 'shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which, immediately before the priority date of the invention, forms part of the state of the art by virtue only of subsection (6) (and disregarding subsections (7) and (8))'. Subsection 25(6) provides that the state of the art shall comprise 'all matter (whether a product, a process,

[14] Section 33 provides: **'Priority dates**
(1) For the purposes of this Act, the priority date of an invention to which an application for a patent relates, and also that of any matter contained in any such application, whether or not such matter is the same as the invention, shall, except as otherwise provided in this Act, be the date of the lodging of the application.
(2) Where priority is claimed in an application in terms of section 31(1) from one or more prior applications, or one or more prior applications in a convention country or countries, or both, and the invention claimed in the application is fairly based on matter disclosed in one or more of any such prior applications, the priority date of the invention shall be the date of lodging of the earliest of such prior applications in which that matter was disclosed in so far as it is fairly based on such earliest application.
(3) Any invention claimed in an application may have one or more priority dates.
(4) Until the contrary is proved, the priority date of an invention shall be the earliest priority date claimed in an application.
(5) In determining whether an invention claimed in an application is fairly based on the matter disclosed in a prior application or a prior application in a convention country, regard shall be had to the disclosures contained in all documents lodged at the same time as and in support of that prior application or prior application in a convention country.
(6) The priority date of new matter introduced by way of a supplementary disclosure in terms of section 51(8) shall be the date of lodging of the supplementary disclosure.'

information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way'.

[67] This Court in *Ausplow (Pty) Ltd v Northpark Trading 3 (Pty) Ltd and Others*[15] (*Ausplow*), set out the issues to be determined as part of the obviousness enquiry as follows: (a) who is the notional person skilled in the art? (b) what is the relevant common knowledge that person has of the state of the art? (c) what is the inventive concept of the claim? (d) the difference between the state of the art and the inventive concept; and (e) viewed without knowledge of the alleged invention, do the differences constitute steps that would have been obvious to the person skilled in the state of the art? While the ultimate question of the validity of a patent is a question of law, the preceding enquiries are factual in nature and must thus be considered on a case-by-case basis – drawing on the evidence adduced in each specific matter.

[68] The United States Supreme Court in *Graham v John Deere Co.,*[16] stated that, as part of the factual enquiry into obviousness, 'secondary considerations' such as, amongst others, commercial success, long felt but unresolved needs, and failure of others 'might be utilised to give light to the circumstances surrounding the origin of the subject matter sought to be patented'. In my view, and depending on the specific circumstances of the case, the abovementioned factual enquiries can encompass such secondary considerations.

[69] Eurolab advanced its obviousness attack based on the evidence of Prof Veale supplemented by the evidence of Prof Greeff, as a defence in the interim interdict. Dis-Chem's attack on inventive step was initially advanced as a ground in the revocation application. However, it has abandoned that stance and now also advances that point as a defence in the interim interdict proceedings.

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[15] *Ausplow (Pty) Ltd v Northpark Trading 3 (Pty) Ltd* 2011 BIP 12 (SCA); [2011] ZASCA 123; [2011] 4 All SA 221 (SCA); 2011 JDR 1058 (SCA) (*Ausplow*) paras 34 and 35.
[16] *Graham v John Deere Co.,* 383 U.S. 1 (1966) at 383.

[70] To address whether the patent in this matter involves an inventive step, it is important to outline the established causes of prostate cancer and the history of its treatment. The key facts are common cause.

[71] Androgens, such as testosterone and its metabolite 5a-dihydrotestosterone (DHT), are steroid hormones essential for prostate development and function. Testosterone is mainly produced in the testicular stroma. Both testosterone and DHT bind to the androgen receptor (AR), activating it. Upon activation, AR changes shape, forms a dimer (a molecule made of two similar subunits and joined by a chemical bond), moves to the nucleus, and triggers pathways that regulate cell growth and survival in normal and cancerous cells.

[72] When androgen receptors are activated, they affect certain genes, especially the gene responsible for producing prostate-specific antigen (PSA). Because people suffering from prostate cancer often have higher PSA levels, PSA is commonly used by doctors to determine how the disease is progressing. When PSA levels go down, it typically means that the activity of androgen receptors in the tissue has decreased.

[73] Treating advanced prostate cancer at first involved lowering male hormones, either by surgery to remove the testicles or by using estrogen therapy. However, estrogen therapy caused many side effects, so it was not used widely. These methods mainly helped ease symptoms but did not cure the disease. More definitive treatments included surgically removing the prostate, using external radiation, or placing radiation directly into the prostate.

[74] LHRH, a drug developed in the 1990s, helped to reduce circulating androgens to castrate levels after an initial stimulus. Androgen deprivation resulted in a reduction of the rate at which the cancer cells proliferated. More drugs were developed in the 1960’s and 1980s.

[75] Prior to the development of the patent, metastatic or recurrent cancer was commonly managed by reducing androgen or testosterone levels in patients. Alternative treatments included the administration of anti-androgens instead of castration therapy.

Hormonal therapies aimed at decreasing activity at the androgen receptor are collectively referred to as Androgen Deprivation Therapy (ADT).

[76] The invention described in the patent addresses a significant challenge in the treatment of prostate cancer, specifically the transition from Hormone Sensitive Prostate Cancer (HSPC) to Hormone Resistant Prostate Cancer (HRPC) following the application of ADT. Historically, available therapies failed to provide effective solutions once prostate cancer progressed to a hormone-resistant state. The inventive step, as claimed by UC, lies in the development of enzulatamide as a treatment for prostate cancer, with particular focus on its efficacy against HRPC. This advancement represents a critical improvement in therapeutic approaches, targeting the problem of resistance that undermined previous treatments.

The person or team skilled in the art

[77] UC argues that a team skilled in the art would be a biologist specializing in prostate cancer treatment and an advanced synthetic or medicinal chemist. It relies on the evidence of two experts: (a) Prof Neal, a renowned urological surgeon and prostate cancer researcher with several peer-reviewed publications; and (b) Prof Carreira, a chemistry professor at the Eidgenossische Technische Hochschule, Zurich, for 26 years, experienced in API design, drug development, and patent inventorship.

[78] Eurolab asserts that a team skilled in the art would include a medicinal chemist, biologist, pharmacologist, therapeutic specialist, and pharmaceutic chemist. Their experts are: (a) Prof Greeff, an experienced pharmacologist in drug development, including oncology drugs like nilutamide; (b) Prof Horak, a biochemist; (c) Dr Lourens, a urologist since 2017; and (e) Prof Veale, a medicinal chemist.

[79] UC contends that Eurolab’s experts do not possess the requisite expertise. It maintains that, as a pharmacologist, Prof Greeff does not engage in the design or synthesis of new APIs for biological diseases, which they assert is the domain of medicinal chemists.

[80] The respondents stated that the difference between RD162 and RD162' primarily concerns the evaluation of the safety and efficacy of the compound following a change to a less expensive substituent at C5 of the middle ring. This decision typically falls under the responsibility of a pharmacologist. Accordingly, even if Prof Greeff does not have the qualifications to provide an opinion on earlier stages of API development, the final phase of lead optimization – specifically the transition from RD162 to RD162' – is within the scope of pharmaceutical expertise.

[81] I find it unnecessary to decide if the respondents' experts are a skilled team for the obviousness enquiry. Instead, I shall instead evaluate all expert evidence according to the following dictum from this Court in *Schlumberger Logelco Inc v Coflexip SA*:[17]

'It is the technical evidence by expert witnesses in respect of the nature of the step claimed to have been inventive, the state of the art as at the priority date relevant to that step and the respect or respects in which the step goes beyond or differs from that state of the art, which constitutes the primary evidence.':

This Court further stated that expert evidence should be evaluated without considering experts' opinions on obviousness. While experts may express views regarding this issue, their conclusions about obviousness are not relevant.

The state of the art

[82] It is not disputed that the prior art is represented by slides prepared by one of the HHMI inventors (the slides), and a poster (the poster) used in a presentation at a conference in Scottsdale, Arizona, from 29 September to 1 October 2005. The slides describe a process to develop a drug that has stronger antagonism than classic agonists[18] and was not an agonist in the presence of high levels of AR, ie, in HRPC.

[83] The slides further describe the development of a component called RD162 from RU59063. The latter component had agonist properties in HRPC conditions. It is the only component whose structure is depicted with a substituted dimethyl in the middle thiohydantoin ring (the C5 position). Starting from RU59063, the slides depict RD37, which differs structurally from RU59063 in that (a) RD37 includes a phenyl group on the

[17] *Schlumberger Logelco Inc v Coflexip SA* 2002 BIP 35 (SCA); 2003(1) SA 16 (SCA) para 34.
[18] An agonist is a substance that initiates a physiological response when combined with a receptor. An antagonist is a substance that interferes with or inhibits the physiological action of another.

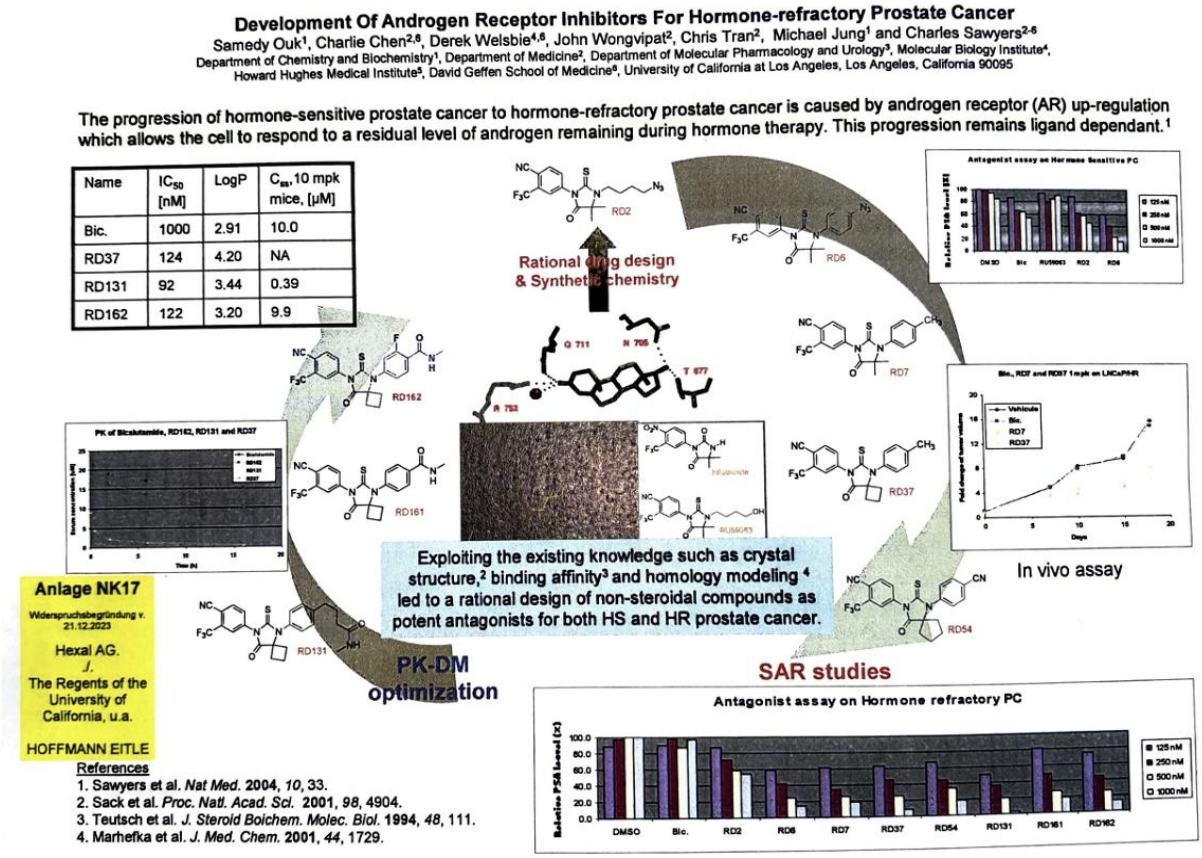
right-hand side of the structure, to which a methyl group is attached; and (b) the dimethyl at position C5 has been replaced with a cyclobutyl.

[84] The introduction of two specific structural modifications resulted in a marked enhancement of the molecule's biological activity. In particular, RD37 was demonstrated to function as a highly potent antagonist in *in vitro* studies – those performed outside a living organism – across HSPC and HRPC models. This advancement effectively addressed the previously observed issue wherein antagonists would convert into agonists under HRPC conditions, thereby losing their therapeutic effectiveness. Nevertheless, the efficacy of RD37 was found to be sustained only for a brief period, necessitating very frequent dosing to maintain therapeutic levels. Alternatively, the compound required formulation as a slow-release preparation to extend its duration of efficacy.

[85] The authors therefore developed further compounds to try and solve the problem. This resulted in the development of RD162. Improved properties were achieved by changing substituents on the phenyl group on the right-hand side. RD162 retained the activity achieved with RD37.

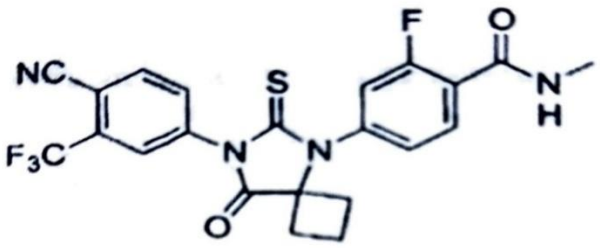
[86] The poster, which is reproduced below, shows that the authors tested dimethyl (RD2, 6 and 7), cyclobutyl (RD37), and cyclopentyl (RD54) substituents at C5, then positively selected the cyclobutyl to take forward in the later RD compounds, namely RD131, 161, and finally 162. The poster includes a graph on the right-hand side comparing RD7 (dimethyl) and RD37 (cyclobuthyl), respectively at C5 in an *in vivo* experiment, and shows that RD37 performed better than RD7. It also includes a histogram which shows that when tested at the highest concentration, RD37 was more potent than RD7.

[87] The poster indicates that modifying the substituent at C5 influences activity. Compounds with dimethyl and cyclobutyl groups at C5 show different levels of activity compared to those with only a cyclobutyl group. The inventors compared these variations and selected cyclobutyl due to its observed performance.

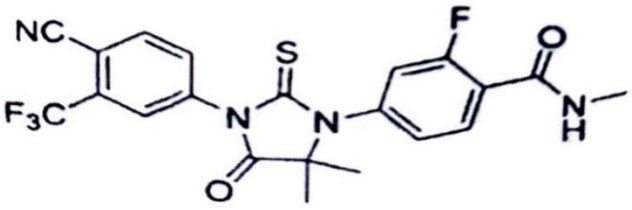


Difference between the state of the art and the inventive concept

[88] It is common cause that the difference between the prior art, namely RD162 and enzalutamide (RD162'), is the creation of a substituent through the substitution at position C5 of the thiohydantoin (central) ring of the compound, namely dimethyl in RD162' and cyclobutyl in RD162. The following diagrams better illustrate this.



RD162



RD162'

Was the inventive step obvious to a person skilled in the art?

[89] Eurolab contends that RD162 and RD162' are, in terms of efficacy, equivalent, ie, they do exactly the same thing. There is nothing in the specifications to suggest that one of the two analogues is better than the other. Thus, Eurolab submits, simply choosing one above the other cannot involve an inventive step and would be obvious to a person skilled in the art.

[90] Eurolab's experts explained the process involved in subjecting a lead compound to modifications, considering chemical stability, costs, clinical efficacy and the ability to formulate satisfactorily for administration with the objective to generate structural analogues of lead compounds. According to them, once the lead compound, namely RD162, is identified, it becomes a matter of routine experimentation to ascertain whether substitutions would produce a superior result. The skilled team would have been influenced by the dimethyl on RU59063. Having used that structure as the initial starting

point, the skilled team would have been led to test for activity by replacing cyclobuyl with dimethyl. The skilled team would then have been motivated to experiment with dimethyl as the substituent because of the substantial cost savings, the former being at least 1000 percent cheaper. Prof Greeff submitted that it was therefore obvious to try a dimethyl at position C5 instead of cyclobutyl because it would lower the cost of manufacturing and both RU59063 and nilutamide – which is also nonsteroidal antiandrogen – included a dimethyl at position C5.

[91] UC, on the other hand, argued that it would not have been obvious in 2006 to the skilled person that one could change the substituent at C5 of RD162 from a cyclobutyl to a dimethyl and have any confidence that it would be effective in the treatment of HRPC. This is so because, in taking that step, the skilled team would have to ignore the fact that the slides and poster show that the authors proposed to take RD162 into *in vivo* trials, ie, medical experiments involving living organisms, which is the next stage of the pharmaceutical development process. The slides did not suggest to the skilled team that any structural changes needed to be made to RD162. It is only with hindsight that one will focus on C5 and consider only dimethyl as a potential substituent in that position.

[92] Furthermore, even accepting that the skilled team would have focussed on C5, the step taken would have required them to reverse the developmental steps already taken in developing RD162 from RU59063. Such a step would have risked the biological potency achieved with RD37 and RD162. The developmental step from RD162 to RD 162', UC submits, would therefore not have been obvious to the skilled team.

[93] In my view, a person skilled in the art and having regard to the slides would have noticed that: (a) the cyclobutyl at position C5 was introduced for the first time on RD37; (b) RD37 was the first compound that exhibited the desired activity; (c) the authors did not thereafter change the cyclobutyl and appeared to have settled on it. The skilled person would, therefore, having read the slides, clearly be concerned that changing back to a dimethyl at C5 would reverse the progress achieved with the development of RD37 and RD162.

[94] Counsel for UC correctly argued that if one were to make structural changes to the compound, then there are many other possible changes on other parts of the molecule, other than C5, that one would consider. There would have been no reason to make changes to C5 only. Even if there were such an improbable focus on C5, there are literally thousands of other chemical substituents that could have been considered, and the slides and poster show that there were good reasons to choose cyclobutyl over dimethyl in that position.

[95] Furthermore, such a step would have been counterintuitive to the skilled person, dimethyl having been previously discarded in favour of cyclobutyl. Dimethyl had been used in less effective compounds, and the preference for cyclobutyl indicates that it was considered optimal for the desired activity. There would therefore have been no motivation for the skilled team to make any changes to RD162. It is only with hindsight that there would be a focus on C5 and a preference for dimethyl over cyclobutyl. Additionally, there would have been no motivation for the skilled team to use a substituent from RU59063 and nilutamide, a compound which was not effective in HRPC conditions.

[96] Prof Greeff's claim that cost savings motivated further development of RD162 is undermined by hindsight, as he had read a post-priority article by inventor, Mr Michael Jung, discussing manufacturing cost benefits. Similarly, Prof Veale and Dr Horak's evidence was also influenced, since they had seen Prof Greeff's affidavit and would have known about the Jung article.

[97] Curiously, both Prof Greeff and Dr Horak disavowed any knowledge of the Jung article in their replying affidavits. They did so to explain that their testimonies were based on their knowledge and experience of how the skilled team would have gone about developing an identified lead compound by March 2006. It appears that they both overlooked the fact that Prof Greeff had referred to the article in his initial affidavit. While I am satisfied that they did not intend to mislead the Commissioner, the inference is ineluctable that their evidence was fundamentally tainted by hindsight.

[98] There is therefore very little, if any, cogent evidence to challenge Prof Carreira's compelling testimony. He explained that the costs of manufacturing a drug are a small

fraction of the costs of developing a new drug and would therefore not have been a relevant or primary consideration for the skilled team at that stage of the invention.

[99] These findings are consistent with the approach adopted by the English, Dutch, and German courts, where the validity of the patent was challenged on the same grounds. In those cases, the courts were also called upon to determine whether enzalutamide, claimed in the European Patent, was invalid as obvious in light of prior art, namely the posters and slides.

[100] In *Accord Healthcare Ltd and Others v Regents of the University of California and Another,*[19] the claimants also argued that the poster and slides disclose that RD126 is structurally close to enzalutamide and that substituting the cyclobutyl with dimethyl at position X (C5) was a routine and obvious modification. They further argued that the skilled medicinal chemist would have been motivated to explore such substitutions as part of structure-activity relationship studies. The skilled team, they submitted, would therefore have experimented with substituents and inevitably arrived at enzalutamide.

[101] UC argued that the modification was not routine and that small changes in substituents could yield unpredictable and sometimes adverse pharmacological results. Furthermore, the poster and slides taught away from enzalutamide by highlighting cyclobutyl or cyclopentyl rather than dimethyl.

[102] On appeal, the court upheld the trial judge's finding that the intense focus by the experts on the change from cyclobutyl to dimethyl was tainted by hindsight, namely the knowledge that RD162' was the target. It held that obviousness must be assessed on a case-by-case basis. Just because institutions embark on research does not present a point against obviousness.

[103] The court emphasised that it is not necessary to establish a specific motivation to determine whether a claimed invention is obvious. While the presence of strong motivation can make it easier to prove obviousness, the absence of motivation does not

[19] *Accord Healthcare Ltd and Others v Regents of the University of California and Another* [2025] EWHC Civ 936.

preclude a finding of obviousness, particularly if the inventive step in question is not a trivial one. However, the court noted that lack of motivation may be a relevant consideration, especially in cases where the modification is not straightforward or routine. Ultimately, motivation is not a decisive factor, but rather one aspect among many to be weighed in the overall assessment. On this basis, the court dismissed the obviousness challenge. This approach was consistent with the conclusions reached in similar proceedings before the Dutch[20] and German[21] courts, where the validity of the patent was also upheld because obviousness had not been established.

[104] Finally, there is no merit in the argument that the invention of RD162' should be considered obvious merely because enzalutamide is allegedly functionally equivalent to RD162. This Court, in *Ausplow*, clarified the misconception that an inventive step necessarily requires an invention to be 'a step forward' in the sense of being superior to prior products. The Court explained that such a view is misleading and does not accurately reflect the requirements for inventiveness. The Court further illustrated this point by noting that a new analgesic does not need to surpass the efficacy of Aspirin, a century-old remedy, to qualify as inventive. Similarly, the seeding apparatus at issue in *Ausplow* might perform the same general function as existing seeding machines; however, if it achieves its purpose more effectively or in a sufficiently distinct manner, it may still be considered inventive, even if it is not categorically better in every respect.[22]

[105] As counsel for UC has correctly pointed out, there is no evidence that RD162 was tested in clinical trials to determine its efficacy in treating HRPC. Enzalutamide, on the contrary, has been proven to be effective and has been recognised as a ground-breaking drug and a huge advancement in the treatment of prostate cancer. This, in my view, is a secondary consideration which also weighs against a finding that the inventive step was obvious to the skilled person.

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[20] *Accord Healthcare Ltd and Another v The Regents of the University of California* C/09/654970/HAZA 23 -903; *Sandoz AG v The Regents of the University of California* C/09/654975.
[21] *Hexal AG v The Regents of the University of California* 3 Ni 20/23 (EP) BPatG (8 April 2025).
[22] *Ausplow* op cit fn 17 above, para 31.

[106] For all the above reasons, I find that the invention of RD162' would not have been obvious to a person skilled in the art, having regard to matters which formed part of the state of the art, immediately before the priority date of the invention.

Did UC establish all the requirements for an interim interdict?

[107] It is trite that an applicant for interim relief must establish: (a) a *prima facie* right, though open to some doubt; (b) that there is a well-grounded apprehension of irreparable harm if the interim relief is not granted; (d) the balance of convenience favours the granting of interim relief; and (e) it has no other satisfactory remedy.

[108] The *prima facie* right does not have to be established on a balance of probabilities. In *Webster v Mitchell* the legal position was explained as follows:[23]

'The proper manner of approach…is to take the facts as set out by the applicant, together with any facts set out by the respondent which the applicant cannot dispute, and to consider whether, having regard to the inherent probabilities, the applicant could on those facts obtain final relief…The facts set up in contradiction by the respondent should then be considered. If serious doubt is thrown on the case of the applicant, he could not succeed in obtaining temporary relief…But if there is mere contradiction, or unconvincing explanation, the matter should be left to trial and the right be protected in the meanwhile, subject of course to the respective prejudice in the grant or refusal of interim relief…the position of the respondent is protected because…the test whether or not temporary relief is to be granted is the harm which will be done…'

[109] An applicant must also establish that the *prima facie* right is being threatened by an impending or imminent irreparable harm. The Constitutional Court held in *National Treasury and Others v Opposition to Urban Tolling Alliance and Others*:[24]

'…[T]he prima facie right a claimant must establish is not merely the right to approach a court in order to review an administrative decision. It is a right to which, if not protected by an interdict, irreparable harm would ensue. An interdict is meant to prevent future conduct and not decisions already made. Quite apart from the right to review and to set aside impugned decisions, the applicants should have demonstrated a *prima facie* right that is threatened by an impending or imminent irreparable harm.' (Citations omitted.)

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[23] *Webster v Mitchell* 1948 (1) SA 1186 (W) at 1189-1190.
[24] *National Treasury and Others v Opposition to Urban Tolling Alliance and Others* 2012 (6) SA 223 (CC); [2012] ZACC 18; 2012 (11) BCLR 1148 (CC) para 50.

[110] However, even if all the foregoing requirements are met, the Court still has a discretion whether to grant the interim interdict.[25] Holmes J explained in in *Olympic Passenger Service (Pty) Ltd v Ramlagan*[26] how that discretion is to be exercised:

'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 the 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.'

[111] The decision on the revocation application indicates that UC has demonstrated a clear right and strong prospects of success in the enforcement proceedings. The respondents acknowledge that the ongoing production and sale of Enzutrix is causing harm to UC, though they argue that the harm is not irreparable. Eurolab began selling Enzutrix in April 2024 and has continued to increase its market share as the first producer of the generic drug. UC references the case of Zytiga, another prostate cancer treatment, which lost approximately 83 percent of its market share within a year of the generic product entering the market. UC asserts that this example demonstrates that an originator's market share typically declines rapidly and significantly after a generic is introduced. It is agreed that Enzutrix has secured a notable portion of the market share in its initial month.

[112] UC contends that damages cannot adequately compensate for its harm, as quantifying losses is challenging due to the complex prostate cancer drug market. Xtandi's market growth before Enzutrix's launch is hard to project, and competition involves multiple drugs, making it unlikely that each lost sale by Xtandi directly benefits Enzutrix. Additionally, Enzutrix's entry affects other drugs' sales, so losses suffered by UC and Astellas cannot be precisely measured.

[113] In addition, UC contends, Eurolab's conduct is likely to lead to job losses at Astellas SA. The sale of Xtandi is one of the major contributors to its revenues, and if losses

[25] *Setlogelo v Setlogelo* 1914 AD 221.
[26] *Olympic Passenger Service (Pty) Ltd v Ramlagan* 1957 (2) SA 382 (D) at 383E-F.

continue at the current rate, it stands to lose close to a third of its revenue. The harm that they will suffer if interim relief is not granted is both substantial and irreparable.

[114] UC further asserts that its clear entitlement and strong likelihood of prevailing in the patent enforcement action significantly diminishes the relevance of the balance of convenience. In any case, the balance of convenience strongly favours UC, as it will experience substantial harm if interim relief is not granted, while Eurolab's potential harm is minimal. UC has invested nearly USD 1.5 billion in developing Xtandi, whereas Eurolab bears no comparable development costs. Furthermore, as previously outlined, losses incurred by UC and Astellas would be difficult to quantify precisely, while those suffered by Eurolab are limited to loss of profits and are therefore more readily ascertainable. Additionally, Astellas SA has offered to compensate Eurolab and Dis-Chem for any damages they may demonstrate, should it be determined that the interim interdict was improperly issued.

[115] It is undisputed that the interim relief requested by UC may result in cancer patients without medical aid being unable to afford Enzulamide treatment. This potential outcome of the interim interdict should be acknowledged. The issue to consider is the degree of significance this factor holds when evaluating the balance of convenience.

[116] In *Cipla Medpro (Pty) Ltd v Aventis Pharma SA and Related Appeal*[27] (*Cipla*) the amicus, namely the Treatment Action Campaign (TAC), founded its opposition to the granting of an interdict on s 27(1) of the Constitution, which guarantees to everyone the right to have access to health care services, including the right to have access to affordable medicines. Although the Court found no merit in that argument, it considered the TAC to be 'on stronger ground when it advances factors to be taken account such as, the broader public interests, and not only the interests of the litigating parties, must be placed in the scales when weighing where the balance of convenience lies'[28].

[117] The Court reviewed relevant local and foreign cases, including those from the United States, where injunctions against patent infringements were denied due to public

[27] Ibid.
[28] Ibid.

interest reasons. It concluded that while interim interdict requirements here are more flexible than permanent injunctions in the U.S., public interest considerations should still influence the court's discretion. However, counsel for Aventis showed these concerns do not apply to that case. [29]

[118] The Court was not convinced that the evidence demonstrated serious negative outcomes for patients if the sale of the infringing product was prohibited. Concluding that an interdict would not cause significant disruption to patients, and that the TAC's opposition was primarily against the patent holder's monopoly rather than the interdict itself, the Court proceeded to grant the interdict.

[119] While UC correctly submitted that Eurolab's opposition to the granting of an interim interdict has little to do with the public interests and more with its desire to secure its advantage as the first producer of the generic product on the market, it is indisputable that if the sale of Enzutix were enjoined, the consequences for cancer patients using it would be serious and immediate. As mentioned, it is common cause that Xtandi is substantially more expensive than Enzutix and will be unaffordable for those patients who do not have medical aid.

[120] The patent is scheduled to expire within a few weeks. The primary harm anticipated for UC and Astellas should interim relief be denied, is financial. They maintain that this harm will be irreparable due to the challenges associated with quantifying losses, as previously outlined. While these challenges may exist, they have been substantially mitigated by the respondents' undertaking that each sale of Enzutix will be considered equivalent to a lost sale for UC and Astellas.

[121] It is important to acknowledge, as highlighted by this Court in *Cipla*, that (a) patent protection ordinarily results in the public being denied access to generic drugs for the duration of the patent term, and (b) given the commercial benefit associated with being first to market among generics, it is common practice for the patentee of a pharmaceutical

[29] Ibid para 52.

product to introduce an alternative competing product shortly before patent expiration, in anticipation of generic competition. [30]

[122] Counsel for UC correctly submitted that the protection of patents advances the public interest by fostering investment in the development of new pharmaceuticals. Pharmaceutical companies are incentivized to invest in research and the creation of improved medications only when they have confidence that the judiciary will uphold patent rights throughout their duration. As Nugent JA observed in *Cipla*, refusing an interdict solely to diminish a patentee's lawful monopoly would constitute an improper exercise of judicial discretion. [31]

[123] I, however, believe that in this case, there are compelling reasons to deny the interdict, namely: the immediate impact on cancer patients using Ezutix; the respondents' tender, which simplifies loss calculation for UC and Astellas, and the patent's imminent expiration in March 2026.

Summary and costs

[124] For the reasons stated above, all three applications fall to be dismissed. Regarding both Eurolab's groundless threat application and Dis-Chem's counterapplication, costs will be determined in accordance with the outcome. However, separate considerations apply to the costs relating to the interim interdict proceedings.

[124] As I explained above, the refusal of interim relief is based primarily on public interest considerations, not the respondents' case. The respondents' opposition was driven by their own financial interests, while UC and Astellas acted within their rights to protect the patent. UC and Astellas should, therefore, not be mulcted with costs. It is thus fair for the parties to bear their own costs in respect of the interim interdict proceedings. There is no reason why the respondents should not be ordered to pay all related costs, including those of two counsel where applicable, in the other two applications.

[30] Ibid para 53.
[31] Ibid para 56.

[125] In the result, the following order is made:

1 The appeal is upheld with costs, including the costs occasioned by the employment of two counsel.

2 The order of the Court of the Commissioner of Patents is set aside and replaced with the following order:

'(a) The application by first respondent, Eurolab (Pty) Ltd, brought under the provisions of s 70 of the Patents Act 57 of 1978, is dismissed with costs on Scale C, including the costs of two counsel where so employed, and the qualifying fees of the applicants' (the Regents of the University of California; Astellas Pharma Europe Ltd; Astellas Pharma Inc and Astellas Pharma (Pty) Ltd, respectively), expert witnesses.

(b) The counterapplication for revocation of patent no 2007/10870 instituted by the second to fourth respondents (Dis-Chem Oncology (Pty) Ltd; Dis-Chem Oncology Distibution (Pty) Ltd; and Dis-Chem Pharmacies (Pty) Ltd, respectively) is dismissed with costs on Scale C, including the costs of two counsel where so employed, and the qualifying fees of the applicants' expert witnesses.

(c) The application for interim relief instituted by the applicants is dismissed. Each party shall pay its own costs.'

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J E SMITH

JUDGE OF APPEAL

Molemela P

[126] I agree with the reasoning and conclusion of my brother, Justice Smith (the first judgment), except for the conclusion he reaches in para 43 of the judgment where he finds that 'UC is precluded from relying on the 2009 assignment to resist an attack on the validity of the patent based on s 61(1)(a) because the assignment did not exist at the time

of the patent application.' I respectfully disagree with the conclusion reached by my sister, Justice Baartman (the second judgment). I agree with the first judgment's finding that the orders granted by the Commissioner ought to be set aside. Furthermore, from my point of view, the Commissioner erred in granting Eurolab the order granted in respect of the application founded on groundless threats.[32] This is because, by the time the applications were heard, UC had already instituted action for damages against Eurolab. It goes without saying that once the damages claim was instituted, Eurolab could no longer be granted relief on the basis that UC had made groundless threats against it. It follows that it was no longer necessary for the Commissioner to consider granting the interdict sought, except for addressing himself to an appropriate costs order.

[127] It is correct that the disposed of the matter on the basis that the crux of the matter was whether UC, as the patentee, had been entitled to apply for the patent as provided in s 27 of the Act; specifically, whether UC was a 'person acquiring from [the inventor] the right to apply' for the patent. In finding that there was no such entitlement, the second judgment finds that in the Power of Attorney filed at the Registrar of Patents, Ms Silverman named the eight inventors but failed to file the 1986 Collaboration Agreement concluded between HHMI and UC, which purportedly evidenced the assignment of the rights of the HHMI inventors to UC.

[128] The second judgment posits that because the HHMI inventors were never in UC's employ, they could not conceivably have assigned the intellectual property rights pertaining to their inventions to UC in terms of their employment contracts. It is on that basis that the second judgment concludes that UC was not entitled to register the patent in the absence of a proper deed of assignment from the HHMI inventors, as UC had not declared any other mechanism through which it had obtained the rights of all the inventors. I disagree. In the succeeding paragraphs, I will illustrate that, although the 1986 Collaboration Agreement was not submitted to the South African Patents Office, the other

[32] The orders read as follows: '3.The application by Eurolab (Pty) Ltd brought under Case No:2023-108509 is granted to the extent that the treats of infringement proceedings made by The Regents of the University of California, Astellas Pharma Europe Ltd, Astellas Pharma Inc and Astellas Pharma (Pty) Ltd in relation to South African Patent No. 2024-039643 are found unjustifiable.
4.The Regents of The University of California, Astellas Pharma Europe Ltd, Astellas Pharma Inc and Astellas Pharma (Pty) Ltd are interdicted and restrained from a continuance of these threats.'

documents filed, when considered in their entirety, clearly establish a chain of title that entitled UC to file the PCT application and also register the patent at the South African Patents Office.

[129] It is noteworthy that the deponent to Eurolab's affidavit in the application concerning groundless threats did not contest the fact that Mr Sawyers, Mr Tran, and Mr Wongvipat were employed by HHMI when they made the inventions central to the dispute between the parties. In that affidavit, Eurolab admitted that a copy of the patent file from the South African patent office 'includes several documents relating to the assignment of rights from the inventors, including the Patents Agreement dated 1 January 1987. However, Eurolab asserted that none of those documents, read alone or together with documents later attached to correspondence, were 'sufficient to give UC the rights to the invention at either one of the filing date[s] of the PCT application or the lodging date of the patent at the South African patent office'. This assertion is not borne out by the documents attached to Eurolab's founding affidavit. It is to these documents that I now turn.

[130] In terms of a Patent Agreement concluded between HHMI and UC dated 1 January 1987, HHMI was required to assign to UC the rights to all patentable inventions that were conceived at UC's facilities by any HHMI employee pursuant to a programme financed by HHMI. The same agreement recorded that, subject to the sharing of patent costs and royalties, HHMI *shall* assign to UC all of its rights, title, and interest in HHMI patentable inventions.

[131] The key elements of a document titled 'Statement of Policy on Intellectual Property' outlined its primary objectives as follows:
'(a) The primary purpose of the Howard Hughes Medical Institute ("the Institute") is the promotion of human knowledge within the field of basic sciences and the effective application thereof for the benefit of mankind. To carry out these papers, the Institute has established this policy to promote disclosure of, and make available to the public on a nondiscriminatory basis, the results of Institute research, to define and protect the rights of institute personnel, to provide for an equitable distribution of the rewards and responsibilities attendant *upon inventions, discoveries, improvements and other*

intellectual property, and to provide that income of the Institute from such intellectual property be used for the purpose of promoting Institute research.
(b) This policy applies to *any invention,* discovery, improvements or other intellectual property*, whether or not patentable or copyrightable*, developed directly or indirectly as a result of a program of research financed by institute funds or by funds under the control of the institute (each a "subject property"). All salaried or hourly full-time or part-time Institute employees and the volunteers, including students, and all other persons who provide services to the Institute or use the Institute's facilities and equipment ("Institute personnel") shall be subject to this policy. The share of royalties of Institute personnel who develop a subject property as a result of their endeavors on behalf of the Institute ("inventors") shall be determined in accordance with this policy.' (Own emphasis.)
The same document further provides that any member of the committee established by the Chief Executive Officer of HHMI may sign documents and contracts on HHMI's behalf. It also makes provision for collaboration with affiliated institutions.

[132] Among the documents filed with the Registrar are three documents signed by the three HHMI inventors in 2003, titled 'Intellectual Property Statement of Agreement'. These documents outline a range of terms to which these inventors mutually consented. Among these terms are the following: (i) to abide by the HHMI Policy of Statement and any amendments thereto; (ii) to assign to HHMI 'all rights I may have or hereafter acquire in any and all subject property'; and (iv) to abide by the terms of any agreement entered into by HMMI with the government of the USA or another entity as a condition of receiving research materials, in connection with a research collaboration, or otherwise in connection with institute research.

[133] It is important to note that, in the Deed of Assignment entered into between Mr Sawyers and HHMI on 17 August 2005, Mr Sawyers recognised himself as both an inventor and an HHMI employee. It is equally crucial to note that, according to that document, he was not only assigning his rights to one specific invention to HHMI, but he was also doing so with respect to 'any invention, discovery, improvement, or other intellectual property, regardless of whether it is patentable or copyrightable'. He acknowledged that he was assigning his entire right title and interest not only in respect of the invention entitled 'Novel Androgen Receptor Inhibitors with Minimal Agonistic

Activities' issued from the United Patent and Trademark Office but also in relation to 'any and all patents issued therefrom; and all patents which are directed to the invention and which may be contained in continuation-in-part applications or in patents which issue therefrom'.

[134] Mr Sawyers also agreed to execute, upon request further documents that may be required for purposes of assigning his entire right, title and interest in the invention to HHMI *or others*, upon the direction of HHMI for purposes of applying for, obtaining, and enforcing patents, copyrights, or other rights in the United States and in any foreign country with respect to the invention. He also affirmed that he had not entered into any other agreement or assignment *that conflicts* with that Assignment. A similarly worded Deed of Assignment was signed by the inventors between 24 May 2006 and 12 June 2006 in relation to the Diarylhydantoin compounds. This assignment was in relation to P1, P2, P3, and RD162.

[135] Much was made about the fact that some of the assignment instruments were signed after the patent application date of 29 March 2006. This, however, fails to take into account that by virtue of their employment contracts, all employees of UC and HHMI had agreed to grant ownership rights of all conceived and to-be-conceived property to HHMI and UC as employers, and by the time the patent application was filed, such rights had already become vested in both HHMI and UC. The fact that other documents were subsequently signed by the same inventors does not detract from this, given that they had agreed to sign any documents their employers required. In my view, the collaboration between UC and HHMI and assignment of HHMI's rights to the inventions of its employees is implicit in the Assignment signed by Mr Sawyers on 17 August 2005.

[136] *Du Pont* and subsequent judgments that refer to it with approval[33] make it plain that it is not unusual for employers to include employment agreements with assignment clauses that unequivocally indicate an intention to grant the employer rights in inventions made by the employee during the period of employment. In the same vein, an assignment

[33] *Du Pont was confirmed in Firm Construction Co Ltd v PG Kusel* 1997 BIP 25 (CP), where it was held that an employment contract can be submitted as proof of ownership of the invention by the employer and lodged in the place of a formal assignment.

clause may unequivocally indicate an intention to transfer ownership of a future invention without the need for any subsequent agreement, with the effect that ownership transfers immediately upon the invention's creation. What is critical and decisive is the language that is used in the assignment clause.

[137] In this matter, the rationale for applying that approach is justified by the terms of the various agreements signed by the inventors, seen against the backdrop of the Statement of Policy as articulated in para 130 of this section of the judgment. The phrases 'hereby agree to assign and assign' constitute a present assignment clause intended to ensure that the transfer of ownership is immediate and effective. Similarly, the broad definition of intellectual property in phrases such as 'to assign to [HHMI] 'all rights I may have or hereafter acquire in *any and all* subject property', and to assign '*any* invention, discovery, improvement, or other intellectual property, whether or not patentable or copyrightable' as set out in the documents alluded to above, signal an intention to have an all-encompassing assignment of all rights title and interest to all inventions made by these employees in the course of their employment.

[138] Provisions requiring the inventor to sign additional documents to perfect the legal title in the future are phrases that are indicative of an intention to affect a valid transfer of ownership of the inventions made in the course of employment without requiring an employer to take further steps to obtain a valid assignment before applying for a patent. Therefore, the fact that the inventors agreed to sign further documents that were furnished to them must be considered against the backdrop of contractual arrangements that already permit such filings, and not as signalling an intention to correct what was legally impermissible. What is important to observe is that none of the documents subsequently signed by these inventors conflict with any of the contractual agreements to which they had committed themselves.

[139] As regards the 1986 Collaboration Agreement, sight must not be lost of the fact that neither Eurolab nor Dis-Chem disputed its authenticity. Eurolab contended that the agreement obligates HHMI to execute future assignments in favour of UC. At the same time, Dis-Chem posited that the agreement in question conferred a personal right on UC to acquire assignments from HHMI. Neither Eurolab nor Dis-Chem pleaded that the rights

to assignment as embodied in the 1986 Collaboration Agreement were conditional. The first judgment thus correctly concludes that the rights to assignment as embodied in the 1986 Collaboration Agreement were unconditional.

[140] As regards the assignment by HHMI to UC, the document ostensibly signed by HHMI on 31 August 2005, titled 'Appointment of Investigator as Agent', appoints Mr Sawyers to act as UC's agent for purposes of assigning to UC 'the rights [HHMI] has or may acquire in the Invention by reason of the research program conducted at UC'. In this regard, it is of significance that neither HHMI nor any of the inventors disputes the validity of the agreements concluded between the parties in 1986 and 1987. It is therefore opportunistic for Eurolab and Dis-Chem, which have not disputed the authenticity of any of these documents, to attack their legal force and effect on speculative grounds. In circumstances where one of the undisputed documents is a policy statement of HHMI, which stipulates that any member of the committee established by the Chief Executive Officer of HHMI may sign documents and contracts on behalf of HHMI and also allows collaboration with affiliated institutions, there is no basis for rejecting the validity of any of these agreements.

[141] It is not surprising that Eurolab did not join issue with Dis-Chem's challenge to Sawyers' authority in finalising the 2005 agreement. The assignment instrument clearly evinces a valid assignment. Furthermore, the agency document authorised Mr Sawyers to act as HHMI's agent in relation to the assignment of its rights, title, and interests in its inventions to UC. The authenticity of the document has not been disputed. However, Dis-Chem contends that this agency document cannot come to UC's aid because one cannot validate one's own agency. I disagree because the authenticity of the remaining documents has not been questioned.

[142] Notably, Mr Sawyers has deposed to an affidavit which aligns with the respondents' account of events. Moreover, the two other inventors who were employed by HHMI under similar contracts basically confirmed his version. Although the facts of cases involving the same patent in three different countries are not analogous to those of this matter, it is important to note that HHMI never challenged any of UC's claims during the 18 years the patent was registered. During this time, HHMI continued to receive royalties from the

patent, which, in my view, is a significant consideration. The Patent Agreement dated 1 January 1987; the assertions made by the three HHMI inventors in their affidavits; the undisputed assignment instrument executed by Mr Sawyers and HHMI, authorising Mr Sawyers to sign the assignments; the Statement of Policy on Intellectual Property endorsed by HHMI, which permits delegation of authority to sign agreements and documents to senior employees; the absence of demur from HHMI in ongoing litigation concerning these patents; and the continued receipt of royalties by HHMI, are all factors that, considered as a whole, reasonably support the conclusion that Mr Sawyers possessed the authority[34] to assign HHMI inventions in favour of UC.

[143] In any event, bearing in mind that both Eurolab and Dis-Chem bore the onus of establishing invalidity of the patent,[35] the inference Dis-Chem seeks to draw regarding Mr Sawyers' alleged lack of authority is not a reasonable one when the conspectus of the facts is considered. In my opinion, the evidence suggests that Mr Sawyers can be deemed competent to attest to the existence of the agency, define the scope of his authority, and confirm the contract executed on behalf of the principal.

[144] Since the patent under consideration falls in the category of PCT patents, there can be no reason why the documents furnished to the Registrar, along with the Patent Agreement dated 1987, cannot be regarded as adequately demonstrating UC's entitlement to apply for patents P1, P2, P3, and RD162. In my opinion, all the documents mentioned in the preceding paragraphs, considered together through the lens of the *Endumeni* interpretive exercise, reveal a clear intention (i) to automatically transfer ownership of inventions to HHMI and UC by their respective employees; and (ii) by HMMI to transfer its rights to UC in terms of the 1987 Patents Agreement. Considered as a whole, these agreements reveal a clear chain of title that entitled UC to apply for patent registration even in the absence of the 1986 Collaboration Agreement or the 2009 assignment. This aligns with the provisions of s 27(1) of the Act, which permit either the inventor or any other person acquiring the right from the inventor to apply for the patent.

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[34] Compare *Makate v Vodacom (Pty) Ltd* [2016] ZACC 13 para 165.

[35] In *Gentiruco AG v Firestone SA (Pty) Ltd* 1972 (1) SA 589 (A) at 629 E-F, it was held that the person attacking the validity of the patent bears the burden of proof. Also see *Roman Roller CC and another v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405 (A) at 412 F-G.

[145] For all the reasons stated above, I too conclude that the Commissioner erred in finding that UC's registration of the patent did not satisfy the requirements of s 27 of the Act.

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MB MOLEMELA
PRESIDENT OF THE APPEAL COURT

Baartman JA

[146] I have had the benefit of reading the first and second judgments. I concur with both judgments in respect of the issues for determination and conclusion in all but one issue. I respectfully differ in respect of the effect of s 61(1)(*a*) read with s 27 of the Patents Act on the facts in this matter. I deal with that issue below.

[147] The first appellant, the Regents of the University of California (UC), is the registered proprietor of South African patent No. 2007/10870 titled *Diarylhydantoin Compounds* and claims the compound enzalutamide ('RD162') used in the treatment of prostate cancer (the patent). The second to fourth appellants (Astellas) are the licensees under the patent. I shall refer to UC and Astellas collectively as the appellants. On 24 February 2025, the Court for the Commissioner of Patents for the Republic of South Africa, Pretoria, *per* Le Grange AJ, (the Commissioner) revoked the patent and granted ancillary relief. The appeal is with leave of the Commissioner of Patents.

[148] It was common cause that UC, in collaboration with the Howard Hughes Medical Institute (HHMI), invented the compound RD162'. Eight inventors were involved in the research, five of whom were UC employees (the UC inventors) and the remaining three were HHMI employees (the HHMI inventors). The patent, a national phase filing, was filed on 29 March 2006 under application number PCT/US2006/011417 (the PCT application).

The lodging date of the national phase patent application at the South African Patent Office was 13 December 2007, in terms of the Patents Act, 57 of 1978 (the Patents Act). It will expire on 29 March 2026. UC filed a declaration[36] claiming the earliest priority is US 60/680.835 dated 13 May 2005 (P1).

[149] Each UC inventor had signed a patent acknowledgement in favour of UC in their respective employment contracts. Similarly, in 2003, the HHMI inventors had assigned their rights in the invention to HHMI. In 1986, UC and HHMI entered into a Collaboration Agreement (the 1986 Collaboration Agreement). The admissibility of this agreement is in dispute; I deal with it below.

[150] On 23 April 2008, Cheryl Silverman (Ms Silverman), at the time UC's Patent Prosecution Manager, filed a declaration and power of attorney[37] with the South African Patent's Registrar claiming that 'the inventors of the abovementioned invention are the persons named above and the applicant has acquired the right to apply by virtue of an assignment from the inventors;'. Ms Silverman named the eight inventors and made no mention of the collaboration agreement or any transfer of rights from HHMI. In respect of the HHMI inventors, the declaration was false. UC declared no other mechanism in the prescribed declaration through which it had obtained the rights of all the inventors.

[151] In 2003, the first respondent, Eurolab (Pty) Ltd (Eurolab) obtained regulatory approval from the South African Health Products Regulatory Authority (SAHPRA) for Enzutrix, a generic of RD162' that fell within the scope of the patent. This concerned the appellants to the extent that they demanded Eurolab undertake neither to launch its product nor to give the rights to do so to a third party for the remaining life of the patent, failing which litigation would follow. In response, Eurolab denied that registration was a ground on which to threaten infringement proceedings[38] and alleged that the patent was, in any event, liable to be revoked. The parties were unable to resolve their differences. Therefore, on 19 October 2023, Eurolab launched proceedings (the groundless threats application) in terms of s 70[39] of the Patents Act, claiming the following relief:

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[36] In terms of regulation 22(1) of the Patent Regulations, 1978 (the Regulations).
[37] Section 30 of the Patents Act and regulations 8(1), 22(1) (c), 33 and 67B of the Regulations.
[38] Sections 45 and 69A of the Patents Act.
[39] Section 70 provides: '**Remedy for the groundless threats of infringement proceedings**

‘1. that the threats of infringement proceedings made by the respondents in relation to the South African Patent … are unjustifiable;
2. that the respondents are interdicted and restrained from the continuance of these threats…’

[152] In the groundless threats application, Eurolab alleged that the patent was liable to be revoked and indicated that it was applying for the revocation of the patent. Eurolab relied on the misrepresentations contained in the Silverman declaration for its claim that UC was not entitled, in terms of s 61(1)(*a*) read with s 27, to have applied for the patent when it did. Eurolab further alleged that UC had made material misrepresentations on the form P3 in the patent application, which also rendered the patent liable to be revoked in terms of s 61(1)*(g)* of the Patents Act.

[153] Astellas is the registered licensee of RD162’ and sells Xtandi, the active ingredient in RD162’, commercially known as enzalutamide’ and its generic Enzutrix. In 2024, in contravention of Astellas’ licence, the second to fourth respondents (collectively Dis-Chem) started distributing Enzutrix in South Africa. Disputes between Dis-Chem and Astellas arose which led to Astellas and UC launching interim interdict proceedings in which they sought to interdict Eurolab and Dis-Chem from infringing the patent (the interim interdict application). Dis-Chem responded by launching a counter-application for the revocation of the patent (the revocation application). Dis-Chem alleged that the patent was liable to be revoked for the reasons Eurolab had advanced and additionally attacked the novelty of the patent under s 61(1)(*c*) of the Patents Act.

[154] The three applications, the interim interdict, the groundless threats application, and the revocation application, served before the Commissioner simultaneously. The Commissioner held that in compliance with ss 61(1)(*a*) and 27 of the Patents Act, UC

(1) Where any person, by circular, advertisement or otherwise, threatens any other person with proceedings for infringement of a patent, a person aggrieved thereby may, whether the person making the threats is or is not entitled to or interested in a patent, or an application for a patent, institute proceedings against him and obtain a declaration to the effect that such threats are unjustified and an interdict against the continuance of such threats, and may recover such damages, if any, as he has sustained thereby, unless the person making the threats proves that that the acts in respect of which the proceedings are threatened, constitute or, if done, would constitute an infringement of the patent in respect of a claim in the specification which is not shown by the Plaintiff to be invalid: Provided that a circular, advertisement or communication addressed to any person , which comprises only a notification of the existence of a particular patent upon which the proprietor relies for the protecting of his interest shall not, by itself, be deemed to be a threat of proceedings for infringement.’

should have obtained from all the inventors the right to apply before it made the patent application. As the HHMI inventors had assigned their rights to HHMI and the latter had not ceded those rights to UC before it applied, the patent was liable to be revoked. Therefore, the Commissioner held that UC had not established the prima facie right contended for in the interim interdict application. The Commissioner considered that finding dispositive of the three applications and made the following order:

'1. The non-compliance by the parties with the provisions relating to forms and services are condoned.

2. The application by The Regent of the University of California, Astellas Pharma Europe Ltd, Astellas Pharma Inc and Astellas Pharma (Pty) Ltd brought under Case No: 2024-039643 is dismissed.

3. The application by Eurolab (Pty) Ltd brought under Case No:2023-108509 is granted to the extent that the treats of infringement proceedings made by The Regents of the University of California, Astellas Pharma Europe Ltd, Astellas Pharma Inc and Astellas Pharma (Pty) Ltd in relation to South African Patent No. 2024-039643 are found unjustifiable.

4. The Regents of The University of California, Astellas Pharma Europe Ltd, Astellas Pharma Inc and Astellas Pharma (Pty) Ltd are interdicted and restrained from a continuance of these threats.

5. The counter application by Dis-Chem Oncology (Pty) Ltd, Dis-Chem Oncology Distribution (Pty) Ltd and Dis-Chem Pharmacies (Pty) under Case No: 2024-039643 is granted to the extent that Patent No.2007/10870 is revoked in terms of section 61(1)(a) as read with section 27 of the Patents Act, No.57 of 1978.'

[155] The Commissioner did not deal with the other grounds of invalidity raised by Eurolab and Dis-Chem. At the hearing, in accordance with this Commissioner's ruling, all the issues in dispute were fully canvassed. While I agree with the majority judgment's finding regarding when the right to file must exist, I respectfully differ in respect of the effect of s 61(1)*(a)* read with s 27 of the Patents Act on the facts in this matter. I turn to that issue. Section 61(1)(*a*) provides as follows:

'(1) Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely-

(*a*) that the patentee is not a person entitled under section 27 to apply for the patent.'

Section 27(1) of the Patents Act provides as follows:

'(1) An application for a patent in respect of an invention may be made by the inventor or by any other person acquiring from him the right to apply or by both such inventor and such other person.'

[156] Sections 61(1)(*a*) and 27 must be read together. The approach to statutory interpretation is now well established. The courts have repeatedly stressed that commercial and legal documents must be interpreted contextually and purposively. In *Cool Ideas 1186 CC v Hubbard and Another*[40] the Constitutional Court held that:

'A fundamental tenet of statutory interpretation is that the words in a statute must be given their ordinary grammatical meaning, unless to do so would result in absurdity. There are three important interrelated riders, namely:

(*a*) that statutory provisions should always be interpreted purposively;[41]

(*b*) the relevant statutory provision must be properly contextualised[42]; and

(*c*) all statutes must be construed consistently with the Constitution, that is, where reasonably possible, legislative provisions ought to be interpreted to preserve their constitutional validity. This proviso to the general principle is closely related to the purposive approach referred to in (*a*).[43]'

[157] The interpretative exercise starts with the language of the sections. The appellants submitted that the reference to 'acquiring' is important as it indicates that a person may apply while in the process of acquiring the right from the inventor and that the time for consideration of the right to apply is the date when the application for revocation is made. The circumstances of this matter underscore the danger of accepting that proposition. To date, an unambiguous transfer of rights from HHMI to UC has not been filed with the registrar and the 20-year patent monopoly has a few weeks left before expiry.

[158] There is no ambiguity in the provisions of s 61(1)(*a*) read with s 27; it envisages an enquiry into the applicant's entitlement to have applied for registration of a patent as

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[40] *Cool Ideas 1186 CC v Hubbard and Another* [2014] ZACC 16; 2014 (4) SA 474 (CC);2014 (8) BCLR 869 (CC) para 28; *Natal Joint Municipality Pension Fund v Endumeni Municipality* [2012] ZASCA 13; [2012] 2 All SA 262 (SCA); 2012 (4) SA 593 (SCA) (*Endumeni*).

[41] *Dengetenge Holdings (Pty) Ltd v Southern Sphere Mining and Development Co Ltd and Others* 2014 (3) BCLR 265 (CC); [2013] ZACC 48 paras 84 – 86; and *Department of Land Affairs and Others v Goedgelegen Tropical Fruits (Pty) Ltd* 2007 (6) SA 199 (CC); 2007 (10) BCLR 1027; [2007] ZACC 12) para 5.

[42] *North East Finance (Pty) Ltd v Standard Bank of South Africa Ltd* 2013 (5) SA 1 (SCA); [2013] ZASCA 76 para 24; *KPMG Chartered Accountants (SA) v Securefin Ltd and Another* 2009 (4) SA 399 (SCA) ([2009] 2 All SA 523; [2009] ZASCA 7) para 39; and *Jaga v Dönges NO and Another; Bhana v Dönges NO and Another* 1950 (4) SA 653 (A) at 664E – H.

[43] *SATAWU and Another v Garvas and Others* 2013 (1) SA 83 (CC); 2012 (8) BCLR 840; [2012] ZACC 13) para 37.

at date of the application. Only after the application is granted is an applicant referred to as a patentee. Therefore, s 27 is concerned with the entitlement of an applicant before the patent is granted. This accords with the purpose of the Patents Act - protection of an inventor's right to exploit his or her invention. The patentee has a monopoly for the period of the patent's validity. This, as the facts in the matter show, can have far-reaching consequences for the public. In this instance, it is those suffering from prostate cancer who are denied access to a cheaper generic version of the patented compound.

[159] A register is kept to inform the public of the status of a patent and the restrictions it imposes on a particular industry. In *Ascendis Animal Health (Pty) Ltd v Merck Sharpe Dohme Corporations and Others*,[44] the Constitutional Court held:

'[100] …We must not lose sight of the fact that testing the validity of patents is in the public interest because patents create artificial monopolies. Currently, South Africa completely relies on private parties to regulate this artificial monopoly system because the government does not examine a patent's validity upon registration. Instead of deterring litigants, who are working both in a private capacity and for the public interest, there should be an inclination to encourage them to bring more revocation challenges, not to create extensions in common law that increase the costs and risks of doing so.' (Citations omitted.)

[160] It is in the public interest that inventors be encouraged to invest in research, knowing that their rights will be protected. However, a patent applicant engages in a specialised field and has the obligation to acquaint herself/himself/itself with the applicable legislative requirements before venturing into the field.[45] It requires the applicant to act with diligence to protect its invention. The responsibility for the accuracy of a declaration in an application for a patent rests fairly and squarely upon the applicant.[46] South Africa has mundane requirements for the registration of a patent. The system is dependent on the bona fides of applicants. UC engages in patent applications internationally and is experienced in the field. Ms Silverman is not an administrative clerk whose errors can be excused as such; instead, she was Patent Prosecution Manager

[44] *Ascendis Animal Health (Pty) Ltd v Merck Sharpe Dohme Corporation and Others* [2019] ZACC 41; 2020 (1) SA 327 (CC); 2020 (1) BCLR 1 (CC); 2019 BIP 34 (CC) para 100.
[45] In *Biogen v Celltrion* ECLI:NL:GHDHA :2019:1962 para 4.7, a matter in the Court of Appeal of The Hague the following was stated: '…the conditions for granting and revoking patent for a particular country are determined by the law of that country- the *lex loci protectionis*.'
[46] *Bendz Ltd and Another v South African Lead Works Ltd* 1963 BP 409 (A);1963 (3) SA 797 (A).

and could reasonably be expected to have known about the collaboration agreement between UC and HHMI. It is inconceivable that Ms Silverman did not know that the HHMI inventors had assigned their rights to their employer.

[161] As indicated above, the lodging date of the national phase patent application at the South African Patent Office was 13 December 2007. The application date for purposes of s 27 was 29 March 2006.[47] At that time, UC had obtained from the UC inventors their rights in the patent but not from the HHMI inventors. In 2006, the rights of the HHMI inventors vested in their employer. As indicated above, the Silverman declaration did not mention HHMI nor the collaboration agreement. That does not mean that UC was not vested with the rights to make the application, even though it does not appear from the documents filed in the register as the court in *Du Pont* correctly found.

[162] In *Du Pont*, the court dealt with an application for rectification under the Patents Act, 57 of 1952. It was alleged that the patent was liable to be revoked because the name of one inventor, Mr Gay, had been omitted from the application. The court held:

'When the relevant facts are considered, it seems clear that there is no question of a misrepresentation, let alone a material misrepresentation in the present case. *The applicant was at all relevant times the holder of all the rights, including those of Gay, to the invention. It could not, therefore, by omitting Gay's name as an inventor, obtain anything to which it was not entitled.*

…

The patent in suit is a document lodged in pursuance of an application for a patent and the omission is an error in such document for the amendment or rectification of which no provision is made elsewhere in the Act. The fact that the patent has expired, is irrelevant. It remains filed with the Registrar and the public is entitled to have access to it at any time, for example for purposes of establishing the state of the art or a possible anticipation of a later patent. The delay in bring this application is also irrelevant. There is no indication of bad faith or blameworthiness on the part of the applicant, and there can certainly not be any prejudice to anyone if the rectification should be effected. On the contrary, it will benefit the public and the art should the register be corrected in order to reflect the proper state of affairs. There is hence no valid objection to …rectification….'[48] (Own emphasis.)

[47] The date of filing of the international application number PCT/US2006/011417.
[48] Ibid at 289A-290C.

[163] The facts in this matter differ from those in *Du Pont*. Mr Gay had in his employment contract with the applicant ceded his rights in the invention to his employer. Therefore, the UC inventors are in the position of Mr Gay and UC always held all their rights in the invention. Not so with the HHMI inventors. UC had an enforceable contractual right against HHMI to transfer to it the rights of the HHMI inventors as per the collaboration agreement. Until HHMI transferred the rights of its inventors, HHMI was the holder thereof, not UC.

[164] In *Du Pont,* the court granted rectification on application. The court considered that 'there was no bad faith or blameworthiness on the part of the applicant, no prejudice to anyone, and that it was in the public interest that the register be correct.' I accept that errors in the register can be corrected. Section 50[49] deals with the correction of clerical errors. Ms Silverman's false declaration cannot be ascribed to clerical error as she was the patent prosecution manager when she made the declaration. Evidently, the section is not applicable.

[165] In the groundless threats application, UC relied on several documents it claimed had corrected its title in the register. I deal briefly with the futile 2017 attempt to amend UC's 'chain of title'. On 13 February 2017, UC applied in terms of regulation 39[50] of the Regulations to amend its title as follows:

'In terms of section 50(1)*(a)* of the Act and regulation 11 of the Patent Regulations, the applicant hereby requests the following:

That the application be corrected in that the assignment on file be replaced with the attached assignments showing the following chain of title: The applicant acquired the right to apply for a patent by virtue of an assignment from the inventors …[the UC inventors] to the applicant and by virtue of an assignment from the inventors SAWYERS, Charles L, TRAN, Chris and WONGVIPAT,

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[49] Section 50(1) provides: 'The registrar or the commission may authorise-
(a) The correction of any clerical error or error in translation in any patent, application for a patent or document lodged in pursuance of such an application, or in the register;
(b) The amendment otherwise of any document for the amending of which no express provision is made in the Act.'

[50] Regulation 39 provides: '**Requests and application to registrar**
Unless otherwise provided, any request or application to the registrar shall be made on form P4 in duplicate quoting the section or the Act or the regulation or both under which relief is sought and shall set out the relief claimed. The duplicate of the form shall be returned to the applicant or his agent.'

John Howard Hughes Medical Institute, which subsequently assigned to the applicant.' (Own emphasis.)

[166] UC relied on the 31 August 2005 authorisation HHMI gave to Mr L Charles Swayers (Mr Swayers), one of the HHMI inventors, to assert his authority to have assigned to it the right to have applied for the patent. The authorisation was signed by HHMI's Vice President and Chief Scientific Officer and provides in relevant part as follows (the 2005 authorisation):

'APPOINTMENT OF INVESTIGATOR AS AGENT

Appointment by [HHMI] (the "Institute") of Charles L. Swayers, MD, an employee of the Institute, as its agent for purpose of assigning certain rights to [UC].

WHEREAS, the Institute and [UC] collaborate in the active conduct of medical research pursuant to an Agreement between them dated as of November 1, 1986 (the "Agreement").

…

WHEREAS, research conducted pursuant to the Agreement by [Mr Swayers] while employed by the Institute at [UC] has resulted in the invention of a certain Subject Property entitled "Novel Androgen Receptor Inhibitors with Minimal Agonistic Activities," which is the subject of a patent application entitled "Novel Androgen Receptor Inhibitors with Minimal Agonistic Activities" filed in the U.S. Patent and Trademark Office on May 11, 2005, and the Invention is a Subject Property; and

WHEREAS, [HHMI] wishes [Mr Swayers] to act as its agent for the purpose of assigning to [UC] the rights [HHMI] has in the Invention by reason of the research program conducted at [UC]

NOW THEREFORE, [HHMI] hereby appoints [Mr Swayers] as its agent for the purpose of assigning the rights [HHMI] has or may acquire in the Invention by reason of the research program conducted at [UC] to [UC] with and subject to the conditions of the Agreement'

[167] Eurolab alleged that the 2005 authorisation was limited to the first priority document, which did not include the invention that forms the subject of the three applications under consideration. It made that allegation in the founding affidavit in the groundless threats application, paragraphs 5.30 - 5.30.2 as follows:

'5.30 The sixth document is titled "Appointment of Investigator as Agent" …The document was signed on 31 August 2005…

5.30.1 … The Swayers Agent Appointment thus appears to relate to P1.

5.30.2 The Swayers Agent Appointment was not sufficient to assign to UC the right to apply for the patent prior to the date of filing of the PCT application, because it is not an assignment, but simply appoints Swayers as HHMI's agent to effect an assignment or assignments to UC.'

[168] In answer to the above, UC's Chief Intellectual Property Office, Ms Charanjit Arora said: 'I admit these allegations'. Therefore, the Commissioner of Patents's finding that Mr Swayers's authority was limited to P1 and 'nowhere refers to any other or future inventions…' is unassailable. The appellants cannot in these proceedings rely on Mr Swayers's 2005 agency appointment.

[169] Nevertheless, in these proceedings, Mr Swayers attested to an affidavit and said that: 'On 9 November 2009, acting for myself and in my capacity as HHMI's agent, I formalised the assignment of HHMI's rights in the invention(s) (including all priority documents and the PCT application) to UC.' He annexed a document entitled 'ASSIGNMENT' in which he claimed to be acting 'for myself and as agent for [HHMI]…' But at the time, Mr Swayers had no entitlement to the invention as he had previously assigned his rights to HHMI. At the hearing, counsel submitted that the part of the 'ASSIGNMENT' where Mr Swayers alleged that he was acting on his own behalf can be ignored. That is contrary to the principles of interpretation referred to above. Counsel, on behalf of Eurolab, submitted that the Commissioner of Patents was correct in holding that Mr Swayers could not testify to his own authority.[51] In the circumstances of this matter, Mr Swayers's agency is problematic as UC had accepted that his 2005 authority was limited to P1 and Mr Swayers had relied on that authority for the 2009 Assignment. The above was filed in the 2017 attempt to correct the 'chain of title'. I am persuaded, for the reasons stated above, that the 2017 attempt to correct the 'chain of title' was unsuccessful.

[170] UC now proposes that its rights to the invention are derived from the 1986 Collaboration Agreement in terms whereof it owned HHMI's rights. The shoe is pinching. As indicated above, the collaboration agreement is not filed in the register; Eurolab and

[51] *MEC for Safety and Security, Eastern Cape v Mtokwana* [2010] ZASCA 88; 2010 (4) SA 628 (SCA); [2010] 4 All SA 583 (SCA) para 20 reads: '…In addition, the court below erred in inferring the agency of the attorney from his own acts. See…*Volkskas Bank Bpk v Bonitas Medical Aid Fund* 1993 (3) SA 779 (A) at 789I-J and the cases there cited.'

Dis-Chem, relying on s 72(3), submitted that UC is barred from relying on the agreement. Section 72(3) provides as follows:

'Except for the purpose of 52[52], a document or instrument in respect of which no entry has been made in the register in terms of section 10, shall not be permitted in evidence in any proceedings of proof of the title to a patent or application for a patent or to any interest therein unless the commissioner or a court, on good cause shown, otherwise directs.'

[171] In my view, a court has discretion to have regard to a document not filed in the register as the court did in *Du Pont*. I also make common cause with the factors that court took into consideration, although that is list is not exhaustive. However, I respectfully disagree with the court's finding that the delay in bringing the application for rectification is irrelevant. The length and reason for the delay are factors to be considered, among others.

[172] It is necessary to consider whether the collaboration agreement clothed UC with the right to apply for the patent on behalf of HHMI. If it did, depending on the circumstance, that might outweigh factors that militate against its inclusion at this late stage. The collaboration agreement, in relevant part, provides as follows:

'II. Assignment of Rights to University – Conditions

A. HHMI agrees that it will require all HHMI Personnel at HHMI at the HHMI UC Facilities to execute a written agreement pursuant to which all such HHMI Personnel at the HHMI UC Facilities to execute a written agreement pursuant to which all such HHMI Personnel shall agree therein to assign to HHMI and to execute any document requested by HHMI regarding their rights, title, and interests in or relating to any Patentable Invention conceived or developed, alone or together with others, as a result of their employment by HHMI, or during the course of use of any funds, …HHMI will retain and make available copies of all such agreements to the University upon the University's request.

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[52] Section 52 provides: 'Rectification of the Register
The registrar may order the register to be rectified by making, amendment or deletion of any entry therein, and such order may be made either on request in the prescribed manner or without such request: Provided that where the registrar intends to make an order otherwise than upon a request, he shall give notice of his intention to do so to the patentee or the applicant for the patent, as the case may be, and to any other person who appears to him to be concerned, and shall give such patentee or applicant or other person an opportunity of being heard before making the order.'

B. Except as provided in paragraph F of this Article II, HHMI shall assign to the University all of its rights, title and interest in HHMI Patentable Inventions, and HHMI further agrees that the University's policies and procedures, including the execution of Patent Agreement procedures, including the execution of the Patent Agreement pursuant to the University's Patent Policy, pertaining to the management and disposition of such Patentable Inventions shall apply thereto subject to the following conditions:

…

(vi) Except as otherwise required by law, or prevented by prior agreement between the University and a third party, if the University declines or fails, after reasonable request and notice by HHMI, to file for patent protection and prosecute diligently such application with respect to any HHMI Patentable Invention for which patent protection can be obtained, the University shall, upon request, assign back to HHMI all rights, title and interest assigned to the University pursuant to this Agreement, and all rights with respect to any patent issued thereon shall not be within the scope of this Agreement.…'

[173] When applying the applicable principles of interpretation, referred to above, it is apparent that the agreement obliges HHMI to obtain the rights to future inventions from its employees involved in research relevant to the collaboration agreement. UC could request proof of the assignment of rights from the inventors to HHMI. Thereafter, HHMI had an obligation, 'shall', to transfer its rights to UC on certain conditions. As is apparent from the relevant section of the collaboration agreement quoted above, UC is obliged to protect HHMI's patent rights.

[174] In terms of the 1986 Collaboration Agreement, UC has enforceable contractual rights against HHMI. The latter, if called upon, would be obliged to transfer its right in the patent to UC. That interpretation is also consistent with the way HHMI had, in 2005, transferred its rights in P1 to UC. As indicated above, HHMI transferred only its rights in P1. Similarly, HHMI can call upon UC to institute a process to defend any threat or breach of its patent rights. The interim interdict application is an example of UC complying with that obligation. The obligations in terms of the collaboration agreement do not establish a right to apply for the patent without any action on the part of HHMI. The 2005 transfer is consistent with the interpretation of the collaboration agreement contended for above.

[175] Applying the *Du Pont* criteria to the facts in this matter, the following is apparent. In *Du Pont*, the court found, correctly, that the applicant was vested with all the rights in the patent and the correction would state the correct legal position. That is not the case in the present matter; UC did not have the right as per its declaration. There is no apparent bad faith in the delay; instead, the facts indicate incredible disregard for the basic requirements of the law, which I find deplorable.

[176] The appellants' counsel, submitted that the issue is between UC and HHMI. As the latter has not raised any concerns, its consent should be inferred. Unfortunately, the information in the register is for the public benefit, and those interested in that industry are entitled to rely on the information contained in the register. As the Constitutional Court[53] emphasised, we should encourage challenges to patent monopoly because South Africa does not examine patent validity on registration. The opportunity for abuse is obvious and, in certain circumstances, could have dire consequences for the public.

[177] I accept that Eurolab and Dis-Chem are pursuing commercial interests and anticipate gaining from the advantage of being the first generic in the market. They are entitled to do so; they sought legal advice before the alleged patent infringement. The advantage cannot be understated. UC is the author of its own misfortune. As indicated above, the only mechanism recorded in the prescribed declaration was that UC had acquired its entitlement to make the application from the eight inventors. The submission from the appellants that 'the right to apply' should be determined with reference to those who had a contractual or other legally enforceable right at the time of making the application, has no merit as it would defeat the purpose of ss 60(1)(*a*) and 27, as discussed above. Section 27 envisages the applicant being the holder of rights at the date of application.

[178] Members of the public are entitled to rely on the information filed in the register. More importantly, patients have been on the impugned generic for several months. The submission that those patients can change to the original product is a callous disregard for the medical and financial implications for those patients who have not been dealt with

[53] Op cit fn 11.

on these papers. The patent has only a few weeks left, and disrupting patient treatment for that period with no evidence as to the effect of such interruption on the treatment is not desirable. In the circumstances of this matter, the public interest militates against granting rectification. In any event, the collaboration agreement does not correct UC's title. In these circumstances, allowing the agreement would not change the legal position, as it would only confirm the contractual relationship between UC and HHMI.

[179] If I commanded the majority, I would have dismissed the appeal with costs such to include the costs of two counsel where so employed.

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E BAARTMAN

JUDGE OF APPEAL

Appearances:

For the appellants:	G Marriott and A Molver
Instructed by:	Adams & Adams Attorneys, Pretoria
	Honey & Partners Inc, Bloemfontein
For the first respondent:	A Franklin SC and CC Bester
Instructed by:	Von Seidels c/o Smit & Van Wyk Inc, Pretoria
	Webbers Attorneys, Bloemfontein
For the second to fourth respondents:	RM Robinson SC and FW Landman
Instructed by:	Margo Attorneys Inc, Johannesburg
	Lovius Block Inc, Bloemfontein.